EXHIBIT T

DEPARTMENT OF HEALTH

SUBJECT: Rules for Control of Sources of Ionizing Radiation, 20 CAR pt. 3

DESCRIPTION: The proposed amendments are to comply with Acts 2025, No. 854 regarding diagnostic mammography and to comply with standards set by the U.S. Nuclear Regulatory Commission and required by federal law.

PUBLIC COMMENT: No public hearing was held on this rule. The public comment period expired on February 11, 2026. The agency provided a public comment summary which, due to its length, is attached separately.

The proposed effective date is pending legislative review and approval.

FINANCIAL IMPACT: The agency indicated that this rule has no financial impact.

LEGAL AUTHORIZATION: The State Board of Health is the designated State Radiation Control Agency for Arkansas and has the authority to promulgate rules "which may provide for licensing or registration relating to control, storage, or disposal of sources of ionizing radiation with due regard for compatibility with the regulatory programs of the United States Government." Ark. Code Ann. § 20-21-207(a)(3); *see also* Ark. Code Ann. § 20-21-206(a). The Board also has authority to promulgate rules establishing fees associated with licensing and registration of sources of ionizing radiation. Ark. Code Ann. § 20-21-217(c).

This rule implements Act 854 of 2025. The Act, sponsored by Representative Matthew Shepherd, increased accessibility while ensuring quality for certain facilities performing mammography services and amended the law concerning the quality standards for accreditation of facilities for mammography. Special language in Section 2(a) of the Act required the Department of Health to "modify all rules relating to performing diagnostic mammography services and the accreditation of facilities in which diagnostic mammography may be conducted to allow interpreting physicians to be immediately available via telecommunication."

PUBLIC COMMENT REPORT

Proposed Rules for Control of Sources of Ionizing Radiation, 20 CAR Pt. 3

PUBLIC COMMENTS:

Public comment period expired February 10, 2026

Alan B. Cohen M.S., DABR
Received February 4, 2026

In addition to the specific comments below, I also suggest that references be made to these IEC documents as the AR regulations do not directly address newer technology such as CBCT, on-line & real-time image guided radiotherapy, protons (Light Ions in IEC language) and treatment planning systems which determine how the radiation will be delivered.

> *IEC 60601-2-64: Medical electrical equipment: Particular requirements for the basic safety and essential performance of light ion beam me equipment*
>
> *Medical electrical equipment –*
>
> *Part 2-68: Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment*
>
> *IEC 62083: Requirements for the safety of radiotherapy treatment planning systems*
>
> *TR 62926: Guidelines for safe integration and operation of adaptive external-beam radiotherapy systems for real-time adaptive radiotherapy*
>
> *63322: Security of ME equipment containing high-activity sealed radioactive sources*

In particular, there appears to be a disconnect in radiation therapy centers between treatment planning systems being an FDA controlled medical device which requires documentation and testing for any device changes vs being a windows computer system which should be kept up to date like the office computers.

Please let me know if you need any follow-up information.

Section	*Comment*
RH-10 Definitions	*An information note would be valuable given that radioactive sources have been moved out of this section. It would make the changes to some of the definitions make more sense.* ***Installation*** *– the new definition excludes sealed sources as they are not considered machines. For example, Ir prostate seed implants.* ***Mobile radiation machine*** *– 1) I'm not sure what the C is for right after machine. 2)This definition would not include a mobile Tomotherapy unit as some shielding is assembled after moving. Would it be handled elsewhere since its also not technically a "permanent" structure?* ***Possessing a radiation machine*** *– This new definition now excludes standalone radioactive sources such as Cs & Ir.* ***Radiation*** *– suggest changing "capable of producing ions" to "capable of producing ionization in matter".* ***Radiation machine*** *– technically, a linear accelerator is a particle accelerator as it accelerates electrons. If you wish to exclude Light Ion machines as defined by the IEC then this should be rewritten. If that is the case, then a reference to where those devices would be covered should be included.* ***Storage*** *– What constitutes an "extended period of time"?*
RH-20	*It is not clear if this applies to a person in Arkansas, a radiation machine in Arkansas, or only if both are in Arkansas.*
RH-21 b.	*Operation of the machine is done during acceptance testing and commissioning as well as the radiation survey. Maybe change "Operation" to "Clinical Operation"*
RH-24	*Change to: A separate registration form shall be submitted for each installation even if submitted by the same person.*
RH-35 2.	*Does this also apply to x-ray tubes used in linac CBCT devices? If so, I suggest removing "diagnostic" and just say "X-ray systems"*
RH-1100	***Radiation machine*** *– the wording seems awkward since "but excluding particle accelerators" is missing from this definition compared to the one in RH-10. Suggest: Any device emitting or capable of producing radiation, excluding devices which only produce radiation by the use of radioactive material as the only source of radiation, and devices exempted by these Rules.*
RH-1102 c-e.	*Why are these special units? I suggest removing the word "special".*
RH-1309 c.	*Where is this label supposed to go? It only clear if it is a radiation machine that uses a radioactive source. Unless I missed it, a "radiation machine" is defined here as also including linacs so does the label go on the door entrance to the vault, control console, head of machine the patient sees, etc.?*
RH-5403 f.	*Please define what systems on the linac must be tied into the scram button. Some of the newer accelerators only kill the power to the magnetron/klystron and motion motors. The computer systems still maintain power.*
RH-10100	***Direct supervision*** *– What is "immediately available" Is it via phone or in person? Is it in the department where treatment is being delivered or on the other side of the hospital campus?* ***Field size, Gantry, IMRT, Isocenter, Moving beam radiation therapy*** *– See definitions in IEC 60601-2-1 ed. 4*

	Radiation therapy system *– The definition is too narrow. Expand to include electrons, protons, light ions, neutrons.* ***Simulator*** *– "x-ray system" is too narrow a definition. Change to "imaging system" (examples: Unity, ViewRay Reflexion)* ***Therapeutic radiation machine*** *– include light ion (protons, neutrons, carbon, etc.)* ***Virtual simulator*** *– replace "A computed tomography (CT)" with "An imaging" to include MRI & PET* *Possibly need "Virtual Wedge" definition as well as there should be requirements on it.*
RH-10302 b. 4	*This clause indicates that the preceding 3 clauses do not need to be measured on-site. i.e. radiation leakage can be done as a type test and not a site test.*
RH-10302	*This clause should be updated with the reworded requirements in IEC 60601-2-1 ed. 4. The new wording takes into account non-isocentric machines, filter free machines, and machines that do not have a standard 10x10 field. In addition, it references new technology and interconnectivity with other equipment now found on these machines such as CBCT.*
RH-10307.l	*I didn't see similar requirements for teletherapy planning systems. In addition, there are no requirements for what testing needs to be done after equipment/operating system changes.*

AGENCY RESPONSE:

Suggested- to reference IEC documents

- This editorial suggestion is noted for review prior to future "Rule" amendments. State agencies may not have ready availability to many IEC documents. Accordingly, incorporation by reference of such documents raises legal concerns of proper notice to licensees under the ARAPA as well as unlawful delegation which will require an in-depth review and analysis.

RH-10 Definitions;

- Decommission was removed as it was already defined in RH-200 Licensing of Radioactive Materials Definitions.
- Other definition changes from are from current RH-200, RH-1800.c. definitions and CRCPD SSR Part F, RH-5100, RH-7002.

RH-20

- Applies to equipment registered in Arkansas.

RH-21.b

- Editorial suggestion is noted for review prior to future "Rule" amendments.

RH-24

- No change from previous "Rule" version. However, the editorial suggestion is noted for review prior to future "Rule" amendments.

RH-35.2

- This applies to all Radiation Machines.

RH-1100

- Editorial suggestion is noted for review prior to future “Rule” amendments.

RH-1102.c-e.

- No change from previous “Rule” version. However, the editorial suggestion is noted for review prior to future “Rule” amendments.

- Editorial suggestion is noted for review prior to future “Rule” amendments.

RH-1309.c

- All labels should go on the console if possible.

RH-5403.f

- No change from previous “Rule” version. However, the editorial suggestion is noted for review prior to future “Rule” amendments.

RH-10100

- Direct Supervision
    - **Direct supervision** - A qualified practitioner must exercise general supervision and be ***present in the facility and immediately available*** to furnish assistance and direction throughout the performance of the procedure or service. Direct supervision ***does not mean that the qualified practitioner must be present in the room*** when the procedure or service is being performed.
- Field size, Gantry, IMRT, Isocenter, Moving beam radiation therapy
    - No change from previous “Rule” version. However, the editorial suggestion is noted for review prior to future “Rule” amendments.
- Radiation therapy system
    - No change from previous “Rule” version. However, the editorial suggestion is noted for review prior to future “Rule” amendments.
- Simulator
    - No change from previous “Rule” version. However, the editorial suggestion is noted for review prior to future “Rule” amendments.
- Therapeutic radiation machine
    - No change from previous “Rule” version. However, the editorial suggestion is noted for review prior to future “Rule” amendments
    - .
- Virtual simulator
    - No change from previous “Rule” version. However, the editorial suggestion is noted for review prior to future “Rule” amendments

RH-10302.b.4

- No change from previous “Rule” version. However, the editorial suggestion is noted for review prior to future “Rule” amendments.

RH-10302

- Editorial suggestion is noted for review prior to future "Rule" amendments.

RH-10307.1

- Editorial suggestion is noted for review prior to future "Rule" amendments

Adam C. Springer, DABR
February 10, 2026

Comments Regarding: ***Proposed revisions to the Arkansas State Board of Health Rules for Control of Sources of Ionizing Radiation, 20 CAR Pt. 3****-July 2025 package.*

- *RH-8801.* ***Reports and Notifications of a Dose to an Embryo/Fetus or a Nursing Child.*** *a. A licensee shall report any dose to an embryo/fetus that is greater than five (5) millisievert (500 mrem) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.*
    - *This limit is 10 times lower than the reportable limit in 10 CFR 35.3057.(b)(1) and the Council on Radiation Control Program Directors (CRCPD) Suggested State Rules (SSR) Section G.3047 – Report and Notification of a Dose to an Embryo/Fetus or Nursing Child. The proposed RH-8801.a. is identical to both of those rules with the exception of the limit, which is 50 mSv (5 rem) in the referenced rules.*
    - *RH-8801.d.1.G. further requires notifying the pregnant individual. Many administrations of radiopharmaceuticals will exceed 5 mSv to the fetus, thus requiring notification of the mother. Notifying a pregnant individual that the dose received by her fetus requires notification may cause her stress, which can significantly affect the developing fetus or embryo (Coussons-Read. Obstet Med. 2013 May 3;6(2):52-57.).*
    - *In contrast, birth defects are not a risk below a dose of 100 mSv (10 rem), according to The National Council on Radiation Protection and Measurements - Report 174 (2015). The NCRP report also states that the risk of cancer from this dose of radiation is far less than the natural risk of developing cancer in the absence of radiation exposures.*

- *The significant risks of causing maternal stress during pregnancy greatly outweigh the theoretical risk of cancer from fetal doses below 100 mSv.*
- *Please consider increasing the reportable limit for doses to an embryo or fetus to 50 mSv (5 rem) to align with 10 CFR 35.3057(b)(1) and the CRCPD's SSR Section G.3047 and to minimize unintentional harm to developing embryos and fetuses.*

- *RH-9200.c. The Qualified Expert, shall complete initial and routine compliance evaluations following nationally recognized procedures or those recognized by the Department. These evaluations shall include a review of the required quality control (QC) tests.*
- *RH-9201.d. Facilities using computed radiography (CR) or direct digital radiography (DRR) paragraphs 1. – 4.*
  - *These rules, while valuable, will be completely new to many facilities. While some technologists are more than capable of determining acceptable ranges for exposure values, most would rely on their Qualified Expert, who is required for compliance with paragraph 2. Most, if not all, facilities in Arkansas utilize consultants for their QE, who may only be present at each site once per year. Other facilities are not yet using a QE and would need to engage one. These steps will delay implementation of these rules by at least a year for facilities that already have a QE, and most likely much longer for those who do not.*
  - *Please indicate the Boards' expectation for compliance with RH-9201.d, i.e. whether citations will be issued for noncompliance during the next inspection, or only after a grace period (e.g. minimum of one year from the effective date or after the next inspection) to allow facilities to engage a QE and implement the required items.*
- *RH-9202.* ***Reports, Notifications, and Records.*** *a.2. Other than events that result from intervention by a patient or human research subject, a registrant shall report any event in which the administration of radiation from diagnostic or interventional radiography results in: A. Unintended skin dose to the same area in a single procedure greater than 200 rads (2 Gy); and 3. The registrant shall notify the Department by telephone no later than the next business day after the discovery of a*

misadministration.

- *Please clarify whether this reportable limit applies to fluoroscopically guided interventional procedures as it is not uncommon for such procedures to exceed 2 Gy air kerma.*

- *RH-9202.a.5. The registrant shall submit to the Department a written report, prepared by a Qualified Expert, within fifteen (15) calendar days after the discovery of a misadministration…*
  - *Much of the information in the report required by this rule is not within the scope of a Qualified Expert's expertise. The QE may provide a peak skin dose estimate and speak to technical factors that may have contributed to the dose (dose level, source-to-skin distance and source-to-image distance, etc.). However, stating why the event occurred (5.D.); The effect, if any, on the individual who received the administration (5.E.); what actions, if any, that have been taken, or are planned to prevent recurrence (5.F.); certification that the registrant notified the individual (5.H.) and what information was provided to the individual (5.H.) should be provided by a physician or administrator.*
  - *Please consider rewording this paragraph. We suggest moving the QE's skin dose estimate to the list of items required in the report.*

- *RH-9300.l.2. All persons operating, or supervising the operation of, fluoroscopy systems during fluoroscopically-guided interventional (FGI) procedures shall have completed a minimum of eight (8) hours of training approved by the Department. The topics shall include:*
  - *Many operators of fluoroscopy systems during FGI procedures receive the required training during residencies and fellowships. Please indicate whether such training will satisfy the requirement.*
  - *Certain board certifications require many more hours of such training. Please consider naming approved boards (e.g. American Board of Radiology) whose diplomates are allowed to use their certification as evidence that they meet the requirements of this new rule.*

- *This rule, as well as subsequent rules, appears to require annual testing of all X-ray systems.*

- *RH-9302.n.* ***Equipment performance evaluations****. 1. Fluoroscopic equipment performance evaluations shall be performed by a Qualified Expert within thirty (30) calendar days of installation and of any maintenance of the system that may affect the exposure rate. An evaluation by, or under the personal supervision of, a Qualified Expert shall also be performed at intervals not to exceed twelve (12) months from the date of the prior evaluation.*
  - *In the current rules Effective September 14, 2024, RH-1603.ij.1.A. requires evaluations by a qualified expert to be performed annually. As "annual" is not defined in the rules, we have asked for guidance from the Department. It is our understanding that the Department allows up to 14 months between required annual surveys. That timeline is consistent with the ACR's Digital Mammography Quality Control Manual, which explicitly allows an occasional period of up to 14 months between annual surveys. This manual was approved by the FDA. The 14-month timeline is also consistent with the ACR's QC manuals for all other imaging modalities.*
  - *Most, if not all, facilities in Arkansas utilize consulting QE's, most of whom travel from out of state, to perform the required surveys. Coordinating surveys on or before the anniversary date of the previous annual survey can prove difficult under normal circumstances. Unforeseen circumstances, such as the recent Winter storm, can prevent completion of planned trips, causing significant delays for numerous facilities when their busy consultant cannot return to remote facilities easily, leaving facilities out of compliance.*
  - *We request allowing up to 14 months between annual surveys.*
- *RH-9310.* ***Radiographic Equipment.*** *a. Digital radiographic systems shall be evaluated by a Qualified Expert within thirty (30) calendar days of clinical use and by or under the direct supervision of a Qualified Expert at intervals not to exceed twelve (12) months unless otherwise determined by the Department.*
  - *This requirement does not appear in the current rules and will significantly increase the number of facilities requiring a QE. The consulting QE's in all of the surrounding states are already working at near-maximum capacity and*

are finding it difficult to recruit additional physicists. Facilities will have trouble finding QE's to perform the additional required surveys annually.

- *Please consider whether this rule is necessary. When properly installed and maintained, as required by RH-9201.a.6., these systems do not present a significant hazard to patients or staff unless misused. If the Board feels that QE involvement is essential for radiographic equipment, then an acceptance test would allow assurance of proper installation, and the Department of Health can to verify performance via testing and review of maintenance records during inspections.*

AGENCY RESPONSE:

RH-8801

- No change from previous "Rule" version. However, the editorial suggestion is noted for review prior to future "Rule" amendments as it relates to pregnant and nursing women.

RH-9200.c

- Yes, all diagnostic x-ray.
- Editorial suggestion is noted for review prior to future "Rule" amendments.
- The Department expectation is that all annual QA/QC be performed per manufactures guidelines or annually if not indicated.

RH-9201.d

- In this case the vendor installing the equipment is considered the qualified expert.
- The equipment QA/QC program should be provided by a qualified expert, i.e. system manufacturer, system installer, or other nationally recognized organization.
- The Department currently uses a 14-month window for these reports which strikes a good balance between compliance and reasonable administrative expectations.

RH-9202

- Revised from RH-8800 previous "Rule"
- This Rule does apply to fluoroscopically guided interventional procedures.
- Editorial suggestion is noted for review prior to future "Rule" amendments.

RH-9202.a.5

- From RH-8800.d previous "Rule" However, the editorial suggestion is noted for review prior to future "Rule" amendments.

RH-9305.l.2

- Editorial suggestion noted for review prior to future "Rule" amendments.

- Yes, training from fellowships, and programs required by American Board of Radiology for certification will be recognized. The training documentation should be kept by the facility in a file designated for each user and available upon request by the Department.

RH-9305.n

- The Department currently uses a 14-month window for these reports which strikes a good balance between compliance and reasonable administrative expectations
- Editorial suggestion is noted for review prior to future "Rule" amendments.

RH-9310

- Editorial suggestion is noted for review prior to future "Rule" amendments.

Bobby Mathews, MS, DABR

February 10, 2026

Thank you for the opportunity to review the proposed Radiation Control rules and the Radiologic Technology Licensure updates. The incorporation of CRCPD State Suggested Regulation (SSR) language aligns well with established national model regulations, and I did not identify concerns related to clinical authorization within the Radiation Control rules, where "Authorized Medical Physicist" terminology remains clear.

One area that may benefit from clarification is the combined "radiation health physicist or medical physicist" language in the RTL rules, which could introduce unintended ambiguity regarding professional roles. While I understand the intent of this wording, additional clarification may help avoid potential misinterpretation.

Thank you for the time and effort invested in maintaining and updating these regulations.

AGENCY RESPONSE:

• This Editorial suggestion was sent to the Radiologic Technology Licensure Program for comments on its Rules where it was answered. To the extent this comment references the Rules for Control of Sources of Ionizing Radiation, 20 CAR Pt. 3, the commentor does not indicate any concerns with the same.

Kayla Avery, BS, CNMT
February 10, 2026

Rule #	***Rule***	***Comment***
RH-35.a.1.B	*Vendor shall notify the Department of customer's registration #*	*I understand the reasoning behind this, but the vendor is not going to know the registration #, nor is there a field for this on the FDA 2579 form.*

RH-35.a.1.C	*Notify Department of manufacturer, model number, and control panel serial number*	*Change to say control manufacturer, model number and serial number because the control manufacturer and model number might also be different from that of the tube head.*
RH-59.a.3	*Submit shielding plans for all fluoro and CT for approval*	*What about for c-arms used in multiple rooms? Calculations are usually not performed for c-arms used in multiple rooms.*
RH-1302.a.4	*Requires dosimeters for individuals entering high/very high radiation areas*	*No changes to this reg but a comment - Should this still be required for areas that have interlock controls? For example, we provide dosimeters to radiation therapists, whose reports always show minimal. There are interlocks that prevent them from entering the high radiation area when beam is on, so there is really no point in badging them. If there happens to be an equipment malfunction where the beam is still on (highly unlikely), there are also area monitors to warn the therapist. If the therapist must enter the vault in the event of an emergency and the beam is still on, dose calculations could be performed.*
RH-5407.a	*Area monitors set to activate at 100 mrem/hr*	*No changes to this reg but a question – I have interpreted this as setting the alarm at 100 mrem/hr, which will constantly go off in radiation therapy. Many facilities that I inspected in the past would silence the alarms because they would go off during each treatment because the radiation level always exceeded 100 mrem/hr in the treatment room. The radiation level will depend on where the detector is mounted in the treatment room, so I recommend not specifying the action level, but rather leave this up to each licensee.*
RH-5407.d.1	*Operational check for portable meters*	*Most facilities are not going to have a check source if they do not have RAM.*
RH-5407.f	*Annual vault surveys*	*Understand the requirement for surveys after changes but not annually if there are no changes. The concrete walls are not going to change and physicists are going to know if equipment malfunctions because there are so many safety checks performed on accelerators. Lynn Davis had requested that this not be put in as a regulation several years ago, but it was put in anyway.*
RH-8315.b.1.B	*Requiring RSO to have 1 year of full-time experience under a RSO*	*Some NUREGs do not say the 1 year experience is required. Tracy and I ran into this with the Radiopharmacy licensing guidance (Vol. 13).*

		Might want to look into this more since you all are mainly using the NUREGs.
RH-8801.a	*Reporting of dose to embryo/fetus or nursing child*	*Does not match NRC. ADH reg says 500 mrem (5mSv) but NRC says 5,000 mrem (50 mSv) in 35.3047. David was going to change this in the next reg revision.*
RH-9302.b	*Reporting of dose to embryo/fetus or nursing child*	*See above – does not match NRC*
RH-9305.l	*Fluoro operator training*	*Does a physician's residency count towards this training?*
RH-9305.l.3	*Fluoro operator training provided by QE or physician*	*If training 4/8 hour is not conducted by a QE, does the training material need to be submitted to ADH for approval? We have an online fluoroscopy training.* *Hands on training for our residents is performed by a rad tech or RA.*
RH-9305.m.7	*Written policy regarding patient dose management in fluoro*	*Does this replace the current RH-1603.h.1. regarding the 300 rad to allow registrants to develop their own SRDL? If so, this could be easily confused with the new RH-9202.a.2.A. which references 200 rads.*
RH-9305.o	*FGI Committee*	*Does membership have to include a physician from each group (one from IR, one from Cath lab, one from vascular, etc.)?*
RH-9305.o.2.E	*Annual report to RPC*	*Annual report of what… all the cases that exceeded the set SRDL?*
RH-9312.a.3	*DEXA manufacturer's specifications for periodic surveys*	*Says follow manufacturer's specifications for periodic surveys. What is considered a survey? PMs? Sometimes this is not specified in the owners manual and we found many people not doing any surveys/PMs. They never got checked but was not enforceable.*
RH-9320	*Dental cone beam*	*Could not find RH-9315.f.3 that is referenced in first paragraph.*
RH-9320.f.2	*Training for hand-held dental units*	*Says to complete training as specified by the manufacturer or approved by the Department… do registrants have to submit training to ADH for approval?*
RH-10200.h	*Visiting AU*	*Can we please add visiting QMPs? We have a lot of locum QMPs and it takes longer to add them to the licenses than they are here.*
RH-12200.l	*Testing of safety devices*	*Some manufacturers recommend semi-annually while others say annually. Please consider changing this to annually so they can be*

		performed at the same time as the annual radiation survey.
	Rad Techs operating fluoro	*The Health Facility Services rules, Section 20 A.6. states that radiologic technologists shall not independently perform fluoroscopic procedures. It would be helpful to have this in the Radiation Control rules as well because rad techs should not operate a fluoro unit without a physician.*

AGENCY RESPONSE:

RH-35.a.1.B

- Editorial suggestion is noted for review prior to future "Rule" amendments.

RH-35.a.1.C

- Editorial suggestion is noted for review prior to future "Rule" amendments.

RH-59.a.3

- This rule applies to stationary equipment; portable equipment only used in one room is considered stationary and would need to submit a shielding plan for review. For example a C-Arm located at a pain clinic.

RH-1302.a.4

- Editorial suggestion is noted for review prior to future "Rule" amendments.

RH-5407.a

- Editorial suggestion is noted for review prior to future "Rule" amendments.

RH-5407.d.1

- Facilities will need to be able to ensure portable monitoring equipment is operational.

RH-5407.f

- Editorial suggestion is noted for review prior to future "Rule" amendments.

RH-8315.b.1.B

- Editorial suggestion is noted for review prior to future "Rule" amendments.

RH-8801.a

- No change from previous "Rule" version. However, the editorial suggestion is noted for review prior to future "Rule" amendments.

RH-9202.b

- Editorial suggestion is noted for review prior to future "Rule" amendments.

RH-9305.l

- Yes, residency will count towards training.

RH-9305.l.3

- The training documentation should be kept by the facility in a file designated for each user and available upon request by the Department.RH-9305.m.7.
- Editorial suggestion is noted for review prior to future "Rule" amendments.

RH-9305.m.7

- Editorial suggestion is noted for review prior to future “Rule” amendments.

RH-9305.o

- It is up to the registrant to set policy/ procedures they believe applicable to their facility.

RH-9305.o.2.E

- Yes, in cases that exceed the substantial radiation dose level (SRDL).

RH-9312.a.3

- Editorial suggestion is noted for review prior to future “Rule” amendments.

RH-9320

- Reference should be 9320.f.3 instead of 9315, the Department will change this reference before publishing.

RH-9320.f.2

- The training documentation should be kept by the facility in a file designated for each user and available upon request by the Department.RH-9305.m.7.

RH-10200.h

- Editorial suggestion is noted for review prior to future “Rule” amendments.

RH-12200.l

- Editorial suggestion is noted for review prior to future “Rule” amendments.

No Rule Reference

- Rad Techs operating fluoro, Not applicable to Rules for Control of Sources of Ionizing Radiation, 20 CAR Pt. 3. There is no statutory authority to make such a change. Radiological Technology Licensure matters which are exclusively governed under another Arkansas Code Section.

AGENCY RECOMMENDATION:
Proceed to adoption.

QUESTIONNAIRE FOR FILING PROPOSED RULES WITH THE ARKANSAS LEGISLATIVE COUNCIL

DEPARTMENT Arkansas Department of Health
BOARD/COMMISSION Division for Health Protection, Radiation Control Section
BOARD/COMMISSION DIRECTOR Bernard Bevill, Section Chief
CONTACT PERSON S. Craig Smith, Attorney
ADDRESS 4815 West Markham Street, Slot 31, Little Rock, AR 72205
PHONE NO. (501) 534-6293 **EMAIL** Stephan.Smith@arkansas.gov
NAME OF PRESENTER(S) AT SUBCOMMITTEE MEETING
S. Craig Smith; Shane David
PRESENTER EMAIL(S) Stephan.Smith@arkansas.gov; Shane.David@arkansas.gov

INSTRUCTIONS

In order to file a proposed rule for legislative review and approval, please submit this Legislative Questionnaire and Financial Impact Statement, and attach (1) a summary of the rule, describing what the rule does, the rule changes being proposed, and the reason for those changes; (2) both a markup and clean copy of the rule; and (3) all documents required by the Questionnaire.

If the rule is being filed for permanent promulgation, please email these items to the attention of Rebecca Miller-Rice, miller-ricer@blr.arkansas.gov, for submission to the Administrative Rules Subcommittee.

If the rule is being filed for emergency promulgation, please email these items to the attention of Director Marty Garrity, garritym@blr.arkansas.gov, for submission to the Executive Subcommittee.

Please answer each question completely using layman terms.

****

1. What is the official title of this rule?
Rules for Control of Sources of Ionizing Radiation

2. What is the subject of the proposed rule? Administer the licensing program for use and control of ionizing ra

3. Is this rule being filed under the emergency provisions of the Arkansas Administrative Procedure Act? Yes ☐ No ☑

If yes, please attach the statement required by Ark. Code Ann. § 25-15-204(c)(1).

If yes, will this emergency rule be promulgated under the permanent provisions of the Arkansas Administrative Procedure Act? Yes ☐ No ☐

4. Is this rule being filed for permanent promulgation? Yes ☑ No ☐

If yes, was this rule previously reviewed and approved under the emergency provisions of the Arkansas Administrative Procedure Act? Yes ☐ No ☑

If yes, what was the effective date of the emergency rule? _____

On what date does the emergency rule expire?_____

5. Is this rule required to comply with a *federal* statute, rule, or regulation? Yes ☐ No ☑

If yes, please provide the federal statute, rule, and/or regulation citation.

6. Is this rule required to comply with a *state* statute or rule? Yes ☑ No ☐

If yes, please provide the state statute and/or rule citation.

Acts 2025, No. 854

7. Are two (2) rules being repealed in accord with Executive Order 23-02? Yes ☐ No ☑

If yes, please list the rules being repealed.
If no, please explain.

The proposed amendments are to comply with Acts 2025, No. 854 regarding diagnostic mammography and to comply with standards set by the U.S. Nuclear Regulatory Commission and required by federal law.

8. Is this a new rule? Yes ☐ No ☑

Does this repeal an existing rule? Yes ☐ No ☑
If yes, the proposed repeal should be designated by strikethrough. If it is being replaced with a new rule, please attach both the proposed rule to be repealed and the replacement rule.

Is this an amendment to an existing rule? Yes ☑ No ☐
If yes, all changes should be indicated by strikethrough and underline. In addition, please be sure to label the markup copy clearly as the markup.

9. What is the state law that grants the agency its rulemaking authority for the proposed rule, outside of the Arkansas Administrative Procedure Act? Please provide the specific Arkansas Code citation(s), including subsection(s).

Ark. Code Ann. §20-21-201, et seq.

10. Is the proposed rule the result of any recent legislation by the Arkansas General Assembly?
Yes ☑ No ☐

If yes, please provide the year of the act(s) and act number(s).

Acts 2025, No. 854

11. What is the reason for this proposed rule? Why is it necessary?

The proposed amendments are to comply with Acts 2025, No. 854 regarding diagnostic mammography and to comply with standards set by the U.S. Nuclear Regulatory Commission and required by federal law.

12. Please provide the web address by which the proposed rule can be accessed by the public as provided in Ark. Code Ann. § 25-19-108(b)(1).

https://www.healthy.arkansas.gov/proposed-amendment-to-existing-rules

13. Will a public hearing be held on this proposed rule? Yes ☐ No ☑

If yes, please complete the following:

Date: _____

Time: _____

Place: _____

Please be sure to advise Bureau Staff if this information changes for any reason.

14. On what date does the public comment period expire for the permanent promulgation of the rule? Please provide the specific date. 02/11/2026

15. What is the proposed effective date for this rule? 06/01/2026

16. Please attach (1) a copy of the notice required under Ark. Code Ann. § 25-15-204(a)(1) and (2) proof of the publication of that notice.

17. Please attach proof of filing the rule with the Secretary of State, as required by Ark. Code Ann. § 25-15-204(e)(1)(A).

18. Please give the names of persons, groups, or organizations that you anticipate will comment on these rules. Please also provide their position (for or against), if known.

19. Is the rule expected to be controversial? Yes ☐ No ☑

If yes, please explain.

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY.

DEPARTMENT Arkansas Department of Health
BOARD/COMMISSION Division for Health Protection, Radiation Control Section
PERSON COMPLETING THIS STATEMENT S. Craig Smith, Attorney
TELEPHONE NO. (501) 534-6293 **EMAIL** Stephan.Smith@arkansas.gov

To comply with Ark. Code Ann. § 25-15-204(e), please complete the Financial Impact Statement and email it with the questionnaire, summary, markup and clean copy of the rule, and other documents. Please attach additional pages, if necessary.

TITLE OF THIS RULE Rules for Control of Sources of Ionizing Radiation

1. Does this proposed, amended, or repealed rule have a financial impact?
   Yes ☐ No ☑

2. Is the rule based on the best reasonably obtainable scientific, technical, economic, or other evidence and information available concerning the need for, consequences of, and alternatives to the rule?
   Yes ☑ No ☐

3. In consideration of the alternatives to this rule, was this rule determined by the agency to be the least costly rule considered? Yes ☑ No ☐

   If no, please explain:

   (a) how the additional benefits of the more costly rule justify its additional cost;

   (b) the reason for adoption of the more costly rule;

   (c) whether the reason for adoption of the more costly rule is based on the interests of public health, safety, or welfare, and if so, how; and

   (d) whether the reason for adoption of the more costly rule is within the scope of the agency's statutory authority, and if so, how.

4. If the purpose of this rule is to implement a *federal* rule or regulation, please state the following:

   (a) What is the cost to implement the federal rule or regulation?

Current Fiscal Year		**Next Fiscal Year**	
General Revenue		General Revenue	
Federal Funds		Federal Funds	
Cash Funds		Cash Funds	
Special Revenue		Special Revenue	
Other (Identify)		Other (Identify)	
Total	$0.00	Total	$0.00

(b) What is the additional cost of the state rule?

Current Fiscal Year		**Next Fiscal Year**	
General Revenue		General Revenue	
Federal Funds		Federal Funds	
Cash Funds		Cash Funds	
Special Revenue		Special Revenue	
Other (Identify)		Other (Identify)	
Total	$0.00	Total	$0.00

5. What is the total estimated cost by fiscal year to any private individual, private entity, or private business subject to the proposed, amended, or repealed rule? Please identify those subject to the rule, and explain how they are affected.

Current Fiscal Year	**Next Fiscal Year**
$ 0.00	$ 0.00

6. What is the total estimated cost by fiscal year to a state, county, or municipal government to implement this rule? Is this the cost of the program or grant? Please explain how the government is affected.

Current Fiscal Year	**Next Fiscal Year**
$ 0.00	$ 0.00

7. With respect to the agency's answers to Questions #5 and #6 above, is there a new or increased cost or obligation of at least one hundred thousand dollars ($100,000) per year to a private individual, private entity, private business, state government, county government, municipal government, or to two (2) or more of those entities combined?

Yes ☐ No ☑

If yes, the agency is required by Ark. Code Ann. § 25-15-204(e)(4) to file written findings at the time of filing the financial impact statement. The written findings shall be filed simultaneously with the financial impact statement and shall include, without limitation, the following:

(1) a statement of the rule's basis and purpose;

(2) the problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute;

(3) a description of the factual evidence that:
(a) justifies the agency's need for the proposed rule; and
(b) describes how the benefits of the rule meet the relevant statutory objectives and justify the rule's costs;

(4) a list of less costly alternatives to the proposed rule and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;

(5) a list of alternatives to the proposed rule that were suggested as a result of public comment and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;

(6) a statement of whether existing rules have created or contributed to the problem the agency seeks to address with the proposed rule and, if existing rules have created or contributed to the problem, an explanation of why amendment or repeal of the rule creating or contributing to the problem is not a sufficient response; and

(7) an agency plan for review of the rule no less than every ten (10) years to determine whether, based upon the evidence, there remains a need for the rule including, without limitation, whether:
(a) the rule is achieving the statutory objectives;
(b) the benefits of the rule continue to justify its costs; and
(c) the rule can be amended or repealed to reduce costs while continuing to achieve the statutory objectives.

To: Members, Arkansas State Board of Health

From: Adelia Oldenbroek, Program Manager
Radiation Control
Division for Health Protection

Date: July 10, 2025

Subject: To request approval by the State Board of Health of the following proposed amendments to the Rules for Control of Sources of Ionizing Radiation.

Authority: Ark. Code Ann. §20-21-201, et seq.

Relevant Acts: Act 854 of 2025

DETAILED SUMMARY –

Page 1-1	RH-3 - from Conference of Radiation Control Program Directors (CRCPD) State Suggested Regulations (SSR) Part H
Page 1-3	RH-6 came from RH-105
Page 1-3	RH-7 came from RH-106
Page 1-3	RH-7.b changed working days to business days to be consistent throughout “Rules”
Page 1-3	RH-8 came from RH-107;
Page 1-3	RH-8 Deliberate Misconduct language from the Nuclear Regulatory Commission (NRC) § 50.5
Page 1-6	RH-10 definitions changes from current RH-200, RH-1800.c. definitions and CRCPD SSR Part F, RH-5100, RH-7002
Page 1-9	RH-21 new types of equipment defined in PART B from CRCPD SSR Part F
Page 1-10	RH-25 additions come from “Rules” RH-31, RH-409, and RH-1611

Page 1-15	RH-30 & RH-31 were moved to RH-3
Page 1-15	RH-34 clean up language to make it easier to read
Page 1-17	RH-34.f.8 was changed to bulleted format for easier reading
Page 1-21	RH-40.a was changed, to say exemptions shall be proposed and enacted through the "Administrative Procedure Act, Arkansas Code §25-15-201, et seq., as an amendment to this Section."
Page 1-21	RH-40.b came from RH-5600
Page 1-22	RH-40.c.1-5 the new language is from CRCPD SSR Part H
Page 1-23	RH-40.d-h comes from RH-5600
Page 1-23	RH-41 deleted
Page 1-26	RH-50 deleted, see RH-3
Page 1-26	RH-51 comes from RH-600
Page 1-26	RH-51.a. 1-5 required details the information listed
Page 1-28	RH-51.c. comes from SSR PART E.36
Page 1-28	RH-52 cleans up language for easier reading
Page 1-28	RH-53 deleted and incorporated into RH-52
Page 1-29	RH-55 deleted moved to Part E to Section 1
Page 1-30	RH-57 cleans up language for easier reading, listed required information; See RH-5214 and CRCPD SSR Part E. and Part H.
Page 1-32	RH-57.c, changed working days to business days to be consistent:
Page 1-32	RH-57.d.3. 180 days is defined in NRC Reciprocity
Page 1-32	RH-58 there were no changes to the fees, language changed for easier understanding
Page 1-33	RH-59 from National Council on Radiation Protection & Measurements (NCRP) Report No. 147
Page 1-33	RH-59.a.1.D Qualified Expert is defined in Part B, RH-10 Definitions

Page 1-35	RH-61 from Texas Radiation Rules §289.226(m)(11), describes conditions which loaner equipment is allowed
Page 1-36	RH-70 was changed from RH-60
Page 1-36	RH-70.a was changed from RH-60 and used language from RH-1602.a.7
Page 1-36	Numbering changes
Page 1-37, 38	Appendix A & Appendix B to Section 1comes from the National Council on Radiation Protection & Measurements (NCRP) Report no. 147
Page 1-40	Appendix C to Section 1 is from RH-1600.- RH-1611.and RH-1613.
Page 2-13	RH-200 some definitions were moved to RH-1800.c. definitions
Page 3-16	RH-1100 definition Protective apron is from RH-1601
Page 3-11	RH-1200.d. is from RH-1311
Page 3-11	RH-1200.g. Licensee and Registrant are defined in RH-1800.c definitions
Page 3-34	RH-1303 clarification of standard X-Ray symbol requires prescribed by Nuclear Regulatory Commission (NRC) https://www.nrc.gov/reading-rm/basic-ref/glossary/radiation-warning-symbol.html
Page 3-39	RH-1303.c.1 moved to RH-1303.b
Page 3-40	RH-1303.d.2 see RH-1303.b
Page 3-42	RH-1303.e.2. CRCPD SSR Part D.1602 and 1603
Page 3-52	RH-1303.i-k deleted, moved to RH-1309.b.-c
Page 3-57	RH-1308 deleted, moved to RH-1306
Page 3-96	Part G. RH-1600, RH-1611, and RH-1613 were moved to Section 10.
Page 3-97, 165, 166	RH-1601 images of all formulas in this section of definitions should be removed also, unable to strike out (Page 65 & 137)
Page 3-107	RH-1602.a.6 Gonadal shielding has been removed as discussed with the Board of Health during the April 2025 meeting; see position statements from : National Council on Radiation Protection and Measurements (NCRP); American Association of Physicists in Medicine (AAPM)

Page 3-140	RH-1607-1609 Moved to Section 11 Therapeutic Radiation Machines
Page 3-141	RH-1610 - Changed and moved to RH-9310.m. 21 CFR (Code of Federal Regulations) Part 900.12 (d)(iii) of the FDA's "Mammography Quality Standards Act." All systems designed for mammography shall comply with the Mammography Quality Standards Act of 1994, 42 USC 263b, as in effect on January 1, Page 2025
Page 3-148	RH-1610.c.7.A changed and moved RH-9310.m 2 -Pursuant to Act 854 of 2025
Page 3-160	RH-1612. - deleted. See Section 13.
Page 3-164	RH-1613 definitions- images of formulas to be removed unable to strike through
Page 3-173	RH-1800 – RH-1804, and Schedule B to Section 3, language changes made to directly reflect Nuclear Regulatory Commission (NRC) language regarding industrial radiographic operations.
Page 3-173	RH-1800.a. - Radiation Generating Devices (RGD's) defined RH-12100 Definitions
Page 3-174	RH-1800.b. - adds explanation of where to find information
Page 3-175	RH-1800.b.2.J. - NRC uses 180 days; CRCPD SSR Part E
Page 3-177	RH-1800.c - Definitions- Cabinet definitions moved to RH-12100 Part B. Definitions
Page 3-197	RH-1801.a.1corrected suite number
Page 3-231	RH-1803.g – was moved to RH-12200, Radiation Generating Device (RGD)
Page 3-241	Schedule B to Section 3- II.2.C - Registrant/Licensee defined in Part B, RH-10 Definitions
Page 3-289	RH-2900.- RH-2905. moved to Section 13
Page 3-290	RH-2901 Definitions moved to RH-12100, Part C
Page 3-290	RH-2900 – RH-2905 Moved to Part C
Page 6-3	RH-5006 clean up language, see Part G

Page 6-3	RH-5006.b. changed working days to business days to be consistent throughout Rules
Page 6-3	RH- 5007 - Deliberate Misconduct language is from NRC § 50.5
Page 9-148	RH-8800 is from NRC Subpart M—Reports § 35.3045 Report and notification of a medical event.
Page 10-1	Section 10 moved from Part G. RH-1600-RH1699
Page 10-40	RH-9305 CRCPD SSR Part 5 to comply with 21 CFR 1020.32
Page 10-45	RH-9305.e. - From RH-1603.a.4.C; CRCPD SSR Part 5 to comply with 21 CFR 1020.32
Page 10-69	RH-9310.m.1.- Refer to 21 CFR Part 900.12 (d)(iii) of the FDA's "Mammography Quality Standards Act." as Federal regulation require/define mammography compliance. All systems designed for mammography shall comply with the Mammography Quality Standards Act of 1994, 42 USC 263b, as in effect on January 1, 2025
Page 10-69	RH-9310.m.2 -Pursuant to Act 854 of 2025
Page 10-87	RH-9600 moved from Part I, RH-2110
Page 11-4	RH-10100 moved from RH-200
Page 11-21	RH-10200.e. updated language RTL is no longer sending certificates, only a license card
Page II	Section 13 from RH-2900-2999 (Page 201-208)
Page II	RH-12400 from RH-5600

NOTICE OF PUBLIC COMMENT PERIOD

The Arkansas Department of Health (ADH) is accepting public comments on the proposed Rules for Control of Sources of Ionizing Radiation, 20 CAR Pt. 3 from January 11, 2026 to February 10, 2026. The comment period is provided to allow interested parties and the public to provide any comments. The proposed rule revision with a summary of changes can be viewed online at https://www.healthy.arkansas.gov/proposed-amendment-to-existing-rules or you may request a copy from our office at 501-661-2301.

Comments on the proposed changes can also be mailed to Arkansas Department of Health, Comments/Slot #30, 4815 West Markham, Little Rock Arkansas, 72205, or emailed to adelia.oldenbroek@arkansas.gov.

ARKANSAS STATE BOARD OF HEALTH

RULES FOR CONTROL OF SOURCES OF IONIZING RADIATION

Promulgated Under the Authority of Act 96 of 1913
and
Act 8 of the Second Extraordinary Session of 1961, As Amended

This Revision Effective ~~September 14, 2024~~ _____, 2025

By the Arkansas State Board of Health

Arkansas Department of Health
Radiation Control Programs
Little Rock, Arkansas

Renee Mallory, RN, BSN
Secretary of Health

Jennifer Dillaha, MD
Director of the Department of Health

TABLE OF CONTENTS

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~~SECTION 1. REGISTRATION OF SOURCES OF RADIATION (Cont'd)~~

SECTION 2. LICENSING OF RADIOACTIVE MATERIALS

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SECTION 3. STANDARDS FOR PROTECTION AGAINST RADIATION

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~~**SECTION 3. STANDARDS FOR PROTECTION AGAINST RADIATION (Cont'd)**~~

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~~**SECTION 3. STANDARDS FOR PROTECTION AGAINST RADIATION** (Cont'd)~~

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~~SECTION 9. USE OF RADIONUCLIDES IN THE HEALING ARTS (Cont'd)~~

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SECTION 12. PHYSICAL PROTECTION OF CATEGORY 1 AND 2 QUANTITIES OF RADIOACTIVE MATERIAL

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SECTION 1.
REGISTRATION OF RADIATION MACHINE FACILITIES AND VENDOR SERVICES

PART A.
GENERAL

RH-1. **Authority**.

Act 96 of 1913, Act 8 of Second Extraordinary Special Session of 1961, as ~~A~~amended.

RH-2. **Effective Date**. January 1, 1963.

RH-3. ~~**Registration Requirement.**~~

~~**Every person possessing a reportable source of radiation shall register in accordance with the provisions of these Rules.**~~**Purpose and Scope.**

a. This Section provides for the registration of radiation machine facilities and for persons providing radiation machine vendor services. A person who receives, possesses, uses, owns, or acquires radiation machines prior to registering with the Department is also subject to the requirements of this Section.

b. In addition to the requirements of this Section, all registrants are subject to applicable provisions of "Standards for Protection Against Radiation" (Section 3), "Notices, Instructions, and Reports to Workers; Inspections" (Part N of Section 3), and "Rules of Practice" (Section 5) as well as any rules specific to the type of radiation machine use.

c. Registrants engaged in the non-therapeutic use of machine-produced radiation in the healing arts or veterinary medicine are also subject to the requirements in Section 10.

d. Morgues, educational facilities, and forensic medicine or investigations utilizing radiation machines for non-human use are also subject to the requirements in Section 10.

~~e.~~ Registrants using therapeutic radiation machines of less than 500 kV, electronic brachytherapy devices, or other use of electronically-produced radiation to deliver a therapeutic radiation dose are also subject to the requirements in Section 11. Radiation therapy simulation systems are also subject to applicable requirements in Sections 10 and 11.

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f. Registrants using radiation generating devices as defined in Section 13 are also subject to the requirements in Section 13.

g. Registrants engaged in industrial radiographic operations as defined in Part I of Section 3 are also subject to the requirements in Part I of Section 3.

RH-4. **Communications**.

Except where otherwise specified, ~~A~~all communications concerning these Rules ~~shall~~may be addressed to the Arkansas Department of Health, Radiation Control Section, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

RH-5. **Additional Requirements**.

In addition to the requirements of this Section, all registrants are subject to the applicable provisions of other Sections of these Rules.

~~RH-6. RH-9. Reserved.~~RH-6. **Interpretations**.

Except as specifically authorized by the Department in writing, no interpretations of the meaning of the rules in this Section by an officer or employee of the Department other than a written interpretation by the Department Director or designee will be recognized as binding upon the Department.

RH-7. **Completeness and Accuracy of Information**.

a. Information provided to the Department by an applicant for a registration or by a registrant or information required by statute or by the Department's rules, orders, or conditions to be maintained by the applicant or the registrant shall be complete and accurate in all material respects.

b. Each applicant or registrant shall notify the Department of information identified by the applicant or registrant as having for the regulated activity a significant implication for public health and safety or property. An applicant or registrant violates this paragraph only if the applicant or registrant fails to notify the Department of information that the applicant or registrant has identified as having a significant implication for public health and safety or property. Notification shall be provided to the Department within two (2) business days of identifying the information. This requirement is not applicable to information which is already required to be provided to the Department by other reporting or updating requirements.

RH-8. **Deliberate Misconduct**.

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a. Any registrant, applicant for a registration, employee of a registrant or of an applicant for a registration; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any registrant or of an applicant for a registration, who knowingly provides to any licensee, registrant, applicant, contractor or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's, registrant's, or applicant's activities subject to these Rules, shall not:

1. Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, registrant, or applicant to be in violation of any rule or order; or any term, condition, or limitation, of any license or registration issued by the Department; or

2. Deliberately submit to the Department, a licensee, a registrant, an applicant, or a licensee's, registrant's or applicant's, contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the Department.

b. A person who violates paragraph a.1. or a.2. of this section may be subject to enforcement action in accordance with the procedures in RH-80.

c. For purposes of paragraph a.1. of this section, deliberate misconduct by a person means an intentional act or omission that the person knows:

1. Would cause a licensee, registrant, or applicant to be in violation of any rule or order; or any term, condition, or limitation, of any license or registration issued by the Department; or

2. Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, registrant, applicant, contractor, or subcontractor.

RH-9. Reserved.

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PART B.
DEFINITIONS

RH-10. **Definitions**.

Act - Act 8 of Second Extraordinary Special Session of 1961, as amended.

~~**Decommission** - To remove (as a facility) safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of license.~~

Department - The Arkansas Department of Health.

Government agency - Any executive department, commission, independent establishment, corporation, wholly or partly owned by the United States of America, which is an instrumentality of the United States, or any board, bureau, division, service, office, officer, authority, administration, or other establishment in the executive branch of the Government.

Hand-held radiation machine – A radiation machine that is designed to be hand-held during operation. "Hand-held radiation machine" is equivalent to "hand-held x-ray equipment" in RH-9100 and to "hand-held x-ray system" in RH-12100.

Inspection - An official examination or observation including but not limited to, tests, surveys and monitoring to determine compliance with rules, orders, requirements and conditions of the Department.

Installation - The location where one or more ~~reportable sources of~~ radiation machines are used, operated or stored.

Mobile radiation machine – A radiation machine that is mounted on a permanent base with wheels or casters for moving while completely assembled. "Mobile radiation machine" is equivalent to "mobile x-ray equipment" in RH-9100 and to "mobile equipment" in RH-12100.

Person -

1. Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency of this state, political subdivision of this state, any other state or political subdivision or agency thereof; and

2. Any legal successor, representative, agent, or agency of the foregoing, but not including United States Government agencies.

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Physician - A doctor of medicine or doctor of osteopathy licensed by the Arkansas State Medical Board to prescribe drugs in the practice of medicine.

Portable radiation machine - A radiation machine that is designed to be hand-carried. "Portable radiation machine" is equivalent to "portable x-ray equipment" in RH-9100 and to "portable equipment" in RH-12100.

Possessing a ~~source of~~ radiation machine - Using, operating, storing, manufacturing or otherwise having control of a source of radiation machine in the State of Arkansas.

Qualified Expert - An individual specifically approved by the Department as having the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection matters. Individuals shall be certified in an appropriate field, commensurate with his or her duties, either by the American Board of Radiology, the American Board of Health Physics, the American Board of Medical Physics, or the Canadian College of Physicists in Medicine, or individuals may have equivalent qualifications. An individual that meets the qualifications in RH-10200.d. for a Qualified Medical Physicist also meets the qualifications of a Qualified Expert.

Radiation - Ionizing radiation, i.e., gamma rays and x-rays, alpha and beta particles, high speed electrons and protons, neutrons and other ~~nuclear~~ particles capable of producing ions.~~; but not sound or~~ Radiation, as used in these Rules, does not include non-ionizing radiation, such as radio waves or visible, infrared or ultraviolet light.

Radiation machine - Any device emitting or capable of producing radiation, but excluding particle accelerators (for the purposes of this Section), ~~and~~ devices ~~which produce radiation only by the use of~~ with radioactive material as the only source of radiation, and devices exempted by Part E of this Section~~.~~

Radiation Safety Officer (RSO) - An individual responsible for the overall radiation protection program (RH-1004.), on behalf of the registrant.

~~(Cont'd)~~

Radioactive material - Any material, solid, liquid, or gas which emits radiation spontaneously, including any natural radioactive material such as radium.

Registrant - Any person who is ~~registering or who has~~ registered with the Department and who is legally obligated to register with the Department pursuant to these Rules and the Act.

~~**Reportable source of radiation** - Any source of radiation as specified under RH-20 of these Rules.~~

Source of radiation - Any radioactive material or device or equipment emitting or capable of producing ~~any~~ radiation.

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~~,~~**Storage** - Condition in which a radiation machine will not be used for an extended period of time until put back in service or transferred.

RH-11.- RH-19.__—Reserved.

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PART C.
REGISTRATION OF RADIATION MACHINES

RH-20.— ~~Reportable Sources of Radiation~~**Registration Requirement**.

~~The following constitute reportable sources of radiation: radiation machines, except when not installed in such manner as to be capable of producing radiation.~~

Each person possessing a radiation machine shall register the machine in accordance with the provisions of this Section.

RH-21. **Initial Registration**.

a. Each person ~~(registrant) having physical possession or control of a radiation machine capable of producing radiation in the state of Arkansas~~ shall apply to the Department for registration of ~~such~~ a radiation machine ~~with the Department~~ within thirty (30) calendar days of the date of acquisition.

b. Notwithstanding RH-21.a., each applicant for the following uses shall apply for and receive authorization from the Department prior to operation of the machine: healing arts screening; therapeutic radiation machine use pursuant to RH-10301. or RH-10307.; other use of electronically-produced radiation to deliver therapeutic radiation dose pursuant to RH-10308.; ~~and~~ use of radiation therapy simulation systems, hand-held radiation machines; mobile or portable radiation machines; radiation machines for industrial radiography pursuant to Part I of Section 3; and use of personnel security screening systems for public protection. Shielding and safety design requirements, in accordance with RH-59, must also be met prior to operation of machines subject to RH-59.

c. A Radiation Safety Officer, as defined in RH-10, shall be designated on each application form. The qualifications of this individual shall be submitted for Department approval with the application. Qualifications of the RSO must be commensurate with the scope and extent of radiation machine use.

d. Each application shall be signed by the applicant or registrant or other individual duly authorized to act for and on his behalf.

e. A prospective Authorized User physician responsible for directing the operation of therapeutic radiation machines subject to RH-10301. or RH-10307., or the use of electronically-produced radiation to deliver therapeutic radiation dose subject to RH-10308., as applicable, shall be designated on each application.

f. An application for registration will be approved if the Department determines that an application meets the requirements of the Act and these

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Rules. The registration authorizes the proposed activity in such form and containing such conditions and limitations as the Department deems appropriate or necessary to effectuate the purposes of the Act.

RH-22. **Renewal of Registration**.

Every person possessing a registered source of radiation shall renew such registration with the Department during December of each year for the following year, as long as the activity requiring such registration continues and at such other times as the Department shall deem necessary.

RH-23. **Radiation Machine Registration Forms**.

Initial registration and subsequent notifications to the Department shall be made on forms RC FORM 200 and RC FORM 201, as applicable, and shall contain all appropriate information required by the forms. The Department may request additional information as part of the registration process.

RH-24. **Separate Installations**.

Every person who registers shall complete a separate registration form for each installation.

RH-25. **Terms and Conditions of Registrations.**

a. Each registration issued pursuant to this Section shall be subject to all the provisions of the Act, now or hereafter in effect, and to all rules and orders of the Department.

b. No registration issued under this Section shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any registration to any person unless the Department shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing.

c. Each person registered by the Department pursuant to this Section shall confine use and possession of the radiation machine registered to the locations and purposes authorized in the registration.

d. The Department may incorporate in the registration at the time of issuance, or thereafter by appropriate rule or order, such additional requirements and conditions with respect to the registrant's possession,

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use, and transfer of radiation machines subject to this Section as it deems appropriate or necessary in order to:

1. Protect health or to minimize danger to life or property;

~~RH-25.d. (Cont'd)~~

2. Require such reports and the keeping of such records as may be necessary or appropriate to effectuate the purposes of the Act; and

3. Prevent loss or theft of radiation machines subject to this Section.

e. The Department may request, and the registrant shall provide, additional information after the registration has been issued to enable the Department to determine whether the registration should be modified in accordance with RH-29.

f. No registrant shall engage any person for services described in Part D of this Section until the person provides to the registrant evidence of registration with the Department.

g. **Bankruptcy notification**.

1. Each registrant shall notify the Department, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title II (Bankruptcy) of the United States Code by or against:

A. The registrant;

B. An entity (as that term is defined in 11 U.S.C. 101(15)) controlling the registrant or listing the registration or registrant as property of the estate; or

C. An affiliate (as that term is defined in 11 U.S.C. 101 (2)) of the registrant.

2. This notification shall indicate:

A. The bankruptcy court in which the petition for bankruptcy was filed;

B. The case name and number; and

C. The date of the filing of the petition.

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h. **Medical research and investigational devices.**

1. Any research using radiation machines on humans shall be approved by an Institutional Review Board (IRB) as required by Title 45, Code of Federal Regulations (CFR), Part 46 and Title 21, CFR, Part 56. The IRB shall include at least one physician to direct any use of radiation in accordance with Section 10.

2. Facilities with radiation machines with investigational device exemptions that are involved in clinical studies shall comply with primary regulations that govern the conduct of clinical studies and that apply to the manufacturers, sponsors, clinical investigators, Institutional Review Boards, and the medical device. These regulations include:

A. 21 CFR, Part 812 – Investigational Device Exemptions;

B. 21 CFR, Part 50 – Protection of Human Subjects;

C. 21 CFR, Part 56 – Institutional Review Boards;

D. 21 CFR, Part 54 – Financial Disclosure by Clinical Investigators; and

E. 21 CFR, Part 820, Subpart C – Design Controls of the Quality System Regulation.

RH-26. **Report of Changes**.

The registrant shall notify the Department in writing of any changes that would render the information contained in the application for registration no longer accurate, including, but not limited to, the following changes: name or mailing address of the registrant; location of the installation or an additional use location; designation of the Radiation Safety Officer; the receipt, sale, or disposal of any radiation machine; and placement or removal of a radiation machine into or out of storage. Notification of the Department is required within ten (10) calendar days of a change, unless the change involves a machine use listed in RH-21.b. Changes regarding RH-21.b. uses must be reported in writing to the Department prior to the change being made.

RH-27. **Report of Discontinuance**.

a. Every registrant who permanently discontinues the use of all his radiation machines at an installation shall notify the Department in writing within ten (10) calendar days of such action. The notice shall be signed by the registrant or other individual duly authorized to act for and on his behalf.

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b. The registrant shall pay any outstanding fees in accordance with RH-58.

RH-28. **Report of Termination.**

a. Every registrant who permanently disposes or transfers all his radiation machines at an installation shall, within ten (10) calendar days of such action:

1. Notify the Department in writing, signed by the registrant or other individual duly authorized to act for and on his behalf; and

2. Submit to the Department a record of the disposal of the radiation machines, if applicable; and if transferred, to whom they were transferred.

b. The registrant shall pay any outstanding fees in accordance with RH-58.

RH-29. **Modification, Suspension, and Revocation of Part C Registrations.**

a. The terms and conditions of registrations issued pursuant to Part C of this Section shall be subject to revision or modification. -A registration may be suspended or revoked by reason of amendments to the Act or by reason of rules or orders issued by the Department.

b. Any registration may be revoked, suspended, or modified, in whole or in part, for any of the following:

1. Any material false statement in the application or any statement of fact required under provisions of the Act or of these Rules;

2. Conditions revealed by such application or statement of fact or any report, record, or inspection or other means that would warrant the Department to refuse to grant a registration on an original application;

3. Violation of, or failure to observe any of, the terms and conditions of the Act, or the registration, or of any rule or order of the Department; or

4. Existing conditions that constitute a substantial threat to public health or safety or the environment.

c. Except in cases of willful violation or those in which the public health, interest, or safety requires otherwise, no registration shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the registrant in writing, and the registrant shall have been accorded opportunity to demonstrate or achieve compliance with all lawful requirements.

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d. Each registration revoked by the Department expires with the Department's final determination to revoke the registration, or on the expiration date stated in the determination, or as otherwise provided by Department Order.

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PART D.
REGISTRATION OF VENDOR SERVICES

RH-30. ~~**Purpose and Scope.**~~ **Deleted**

~~This Part provides for the registration of persons providing radiation machine installation, servicing and/or vendor services to licensees or registrants.~~

RH-31. ~~**Installers of Radiation Machines.**~~

~~Each individual who is engaged in the business of installing or offering to install radiation machines, or is engaged in the business of furnishing or offering to furnish radiation machine servicing or services in this state to a Department registrant, shall apply for registration of such services with the Department on July 1, 1983 or thereafter, prior to furnishing or offering to furnish any such services.~~

Registration Requirement.

Persons providing services as described in RH-34 to licensees or registrants in this State shall be registered with the Department in accordance with this Part.

RH-32. **Vendor Services Registration Forms**.

Registration and changes to a registration shall be made on forms RC FORM 800 or RC FORM 801, as applicable, and shall contain all information required by the Department as indicated on the forms and accompanying instructions. The Department may request additional information as part of the registration process.

RH-33. **Training**.

Each person applying for registration under this Part shall specify the training and experience that qualify the individual to discharge the services for which the individual is applying for registration.

RH-34. **Services**.

a. Each registrant as described in this Part shall not provide ~~the~~ services until such persons provides evidence that ~~they~~ he or she ~~have~~ has ~~been~~ registered with the Department. ~~For the purpose of this Part, services may include but shall not be limited to:~~

b. No registrant shall perform services that have not been specifically approved for that individual by the Department.

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c. No person shall provide vendor services for a person who cannot produce evidence of a completed application for registration or a valid registration issued by the Department except for:

1. The initial installation of the first machine(s) for a new registration, not including machines identified in RH-21.b.

2. The demonstration and sale of a radiation machine by a registrant authorized to conduct such activities, not including machines identified in RH-21.b.

d. Each registrant shall notify the Department in writing before making any change that would render the information contained in his application for registration or the notice of registration no longer accurate.

e. Each registrant who decides to terminate all vendor service activities shall, within ten (10) calendar days of such action:

1. Notify the Department in writing, signed by the registrant or other individual duly authorized to act for and on his or her behalf; and

2. Pay any outstanding fees in accordance with RH-58.

f. Vendor services may include, unless otherwise specified in these Rules or in a condition found in a license or registration, but shall not be limited to:

~~a.~~1. Assembly, ~~I~~installation, ~~or~~ servicing, or repair of radiation machines or particle accelerators and associated ~~radiation machine~~ components.

~~b.~~2. Assembly, ~~I~~installation, ~~or~~ servicing, or repair of devices containing radioactive material.

3. Demonstration and sale of radiation machines that require the individual to operate or cause a radiation machine to be operated in order to demonstrate or sell.

4. Providing radiation machines to a facility for even limited time periods.

~~RH-34. (Cont'd)~~

~~c.~~5. ~~Consulting services including~~ Health physics consultations or surveys, ~~and evaluation~~including that of Naturally Occurring Radioactive Material (NORM) sites or material.

~~d.~~6. Calibration of radiation machines, particle accelerators, or radiation measurement instruments or devices.

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e.7. Leak tests collection and leak test analysis. Procedures must be submitted to this Department on how the test is performed and how the analysis is performed at the time of application.

f.8. Providing tTraining provided to licensee or registrant personnel or to Radiation Safety/or Radiation Protection Officers. Training outline must be submitted to the Department at the time of application. Training includes but is not limited to safe use and handling of:

1.A. Safe use and handling of x-ray equipmentradiation machines and particle accelerators.

2.B. Safe use and handling of radioactive material.

3.C. Safe use and handling of Naturally Occurring Radioactive Material (NORM).

4. Training provided to Radiation Safety/Protection Officer.

g.9. **Personnel Dosimetry Services.**Personnel dosimetry services.

1. Any individual offering or furnishing personnel dosimetry services to a Department licensee or registrant shall report each year to the Department all radiation exposure levels greater than limits set forth in RH-1200.a., within ten (10) days after the start of the next reporting period. This report shall include but is not limited to:

A. Name of exposed individual.

B. Name and address of the registrant or licensee employing the individual.

C. Amount of the exposure.

D. Monitoring year exposed.

2.A. Any individual offering or furnishing personnel dosimetry services shall not lower or amend radiation exposure reports except by authorization from the Department.

RH-34.g. (Cont'd)

3.B. Any individual offering or furnishing personnel dosimetry services shall comply with all additional requirements of

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quality assurance and control of personnel dosimetry, as deemed appropriate and necessary by the Department.

RH-35. **Requirements Specific to Vendor Activities~~Assembler and/or Transfer Requirement~~.**

a. ~~1.~~ Any person who sells, leases, transfers, lends, disposes, assembles or installs radiation machines in this ~~s~~State shall notify the Department of the following information within fifteen (15) calendar days of the activity that initiated the notification requirement:

~~1.~~A. The name and address of persons who have received these machines;

B. The registration number of persons who have received the machines, except in the case of initial installation of the first machine(s) for a new registration;

~~2.~~C. The type of radiation machine, the manufacturer, model number, and control panel serial number of each radiation machine ~~transferred~~; and

~~3.~~D. The date of ~~transfer of each radiation machine~~ the activity.

~~B~~2. In the case of diagnostic x-ray systems ~~which~~ that contain certified components, a copy of the assembler's report prepared in compliance with requirements of the Federal diagnostic x-ray standard (21 CFR 1020.30(d)) shall be submitted to the Department within fifteen (15) calendar days following completion of the assembly. ~~-~~Such report shall suffice in lieu of any other report by the assembler.

~~c~~b. No person shall make, sell, lease, transfer, lend, assemble, ~~or~~ install, or repair ~~-~~radiation machines or the ~~supplies~~ components used in connection with such machines unless such ~~supplies~~ components and equipment when properly placed in operation and used shall meet the requirements of these Rules.

RH-36. **Modification, Suspension, and Revocation of Part D Registrations**.

a. The terms and conditions of registrations issued pursuant to Part D of this Section shall be subject to revision or modification. ~~-~~ A registration may be suspended or revoked by reason of amendments to the Act, or by reason of rules or orders issued by the Department.

b. Any registration may be revoked, suspended, or modified, in whole or in part, for any of the following:

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1. Any material false statement in the application or any statement of fact required under provisions of the Act or of these Rules;

2. Conditions revealed by such application or statement of fact or any report, record, or inspection or other means that would warrant the Department to refuse to grant a registration on an original application;

3. Violation of, or failure to observe any of, the terms and conditions of the Act, or the registration, or of any rule or order of the Department; or

4. Existing conditions that constitute a substantial threat to public health or safety or the environment.

c. Except in cases of willful violation or those in which the public health, interest, or safety requires otherwise, no registration shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the registrant in writing, and the registrant shall have been accorded opportunity to demonstrate or achieve compliance with all lawful requirements.

d. Each registration revoked by the Department expires with the Department's final determination to revoke the registration, or on the expiration date stated in the determination, or as otherwise provided by Department Order.

RH-37.- RH-39. Reserved.

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PART E.
~~EXCLUSIONS FROM REGISTRATION~~EXEMPTIONS

RH-40. ~~**Excluded Material and Devices.**~~

~~The following materials and devices do not require registration:~~

~~a. Domestic television receivers, providing the dose rate at 5 cm from any outer surface of 10 cm^2 area is less than 0.5 mrem per hour.~~

~~b. Other electrical equipment that produces radiation incidental to its operation from other purposes, providing the dose rate to the whole body at the point of nearest approach to such equipment when any external shielding is removed does not exceed 0.5 rem per year. The production testing or factory servicing of such equipment shall not be exempt.~~

~~c. Radiation machines while in transit or storage incident thereto.~~

Exemptions.

a. The Department may consider additional exemptions under this Section upon application of any interested person or upon its own initiative. Any exemptions shall be proposed and enacted through the Administrative Procedure Act, Arkansas Code §25-15-201, et seq., as an amendment to this Section.

b. Any U.S. Department of Energy (DOE) contractor or subcontractor and any U.S. Nuclear Regulatory Commission (NRC) contractor or subcontractor of the following categories operating within this State is exempt from these Rules to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers or acquires sources of radiation:

1. Prime contractors performing work for the DOE at U.S. Government-owned or -controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;

2. Prime contractors of the DOE performing research in or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof;

3. Prime contractors of the DOE using or operating nuclear reactors or other nuclear devices in a U.S. Government-owned vehicle or vessel; and

4. Any other prime contractor or subcontractor of the DOE or of the NRC when the State and the NRC jointly determine:

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A. That the exemption of the prime contractor or subcontractor is authorized by law; and

B. That under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

c. The following machines and equipment are exempt from these Rules:

1. Domestic television receivers and video display terminals, provided the exposure rate at five (5) centimeters from any outer surface is less than 0.5 milliroentgens per hour.

2. Cold-cathode gas discharge tubes, provided the exposure rate at a distance of thirty (30) centimeters from any point on the external surface of the tube does not exceed 10 milliroentgens per hour.

3. Electron microscopes, provided the exposure rate at five (5) centimeters from any accessible surface is less than 0.5 milliroentgens per hour.

4. Other electrical equipment that produces radiation incidental to its operation for other purposes, provided the dose rate to the whole body at the point of nearest approach to such equipment when any external shielding not integral to the equipment is removed does not exceed 25 millirem (mrem) [0.25 millisievert (mSv)] per year. The production testing or factory servicing of such equipment shall not be exempt.

5. Equipment described in paragraph c. of this section shall not be exempt if it is used or handled in such a manner that any individual might receive a dose of radiation in excess of the limits specified in Section 3 of these Rules.

d. Radiation machines in transit or in storage incident to transit are exempt from these Rules. This exemption does not apply to the providers of radiation machines for mobile services.

e. Facilities that have placed all radiation machines in storage, including on-site storage, and have notified the Department in writing in accordance with RH-27., are exempt from these Rules. This exemption is void if any radiation machine is energized resulting in the production of radiation.

f. A radiation machine placed into storage, including on-site storage, where the Department has been notified in writing in accordance with RH-26., is exempt from these Rules. This exemption is void if the radiation machine is energized resulting in the production of radiation.

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g. A person that takes possession of a radiation machine as the result of foreclosure, bankruptcy, or other default of payment is exempt from registration for the purposes of selling, leasing, or transferring. If the machine is energized, it shall be under the supervision of a person registered in accordance with this Section and shall be energized only to demonstrate that the machine is operable for sale, lease, or transfer purposes. The Department shall be notified of possession in relation to this paragraph.

h. Facilities, including academic institutions and research and development facilities, registered for the use of radiation machines are exempt from the registration requirements in Part D of this Section, regarding vendor services, to the extent that their personnel perform radiation services only for the registrant by whom they are employed.

RH-41. Deleted~~**Excluded Possessors**~~.

~~Common and contract carriers are exempt from the requirement to register to the extent that they transport or store reportable sources of radiation in the regular course of their carriage for another or storage incident thereto.~~

RH-42.- RH-49. Reserved.

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PART F.
RECORDS, INSPECTIONS, ~~EXEMPTIONS, AND ADDITIONAL REQUIREMENTS~~TESTS

RH-50. ~~**Radiation Protection Standards**.~~ Deleted

~~Any person possessing a radiation machine that is a reportable source of radiation or who provides radiation machine installations and/or services shall be subject to the requirements of Section 3 of these Rules, "Standards for Protection Against Radiation."~~

RH-51. **Records ~~to be Maintained~~.**

a. **Receipt, transfer, and disposal.**

Each person who possesses a ~~reportable source of~~ radiation machine ~~shall keep~~ maintain records showing the receipt ~~(for any source received after January 1, 1963),~~ transfer or disposal of such ~~source of radiation~~machine. ~~Additional record requirements are specified elsewhere in these Rules.~~The records shall include the following information and shall be kept until termination of the registration:

1. Date of the receipt, transfer, or disposal;
2. Manufacturer's name;
3. Model and serial number from the control panel;
4. Name and address where the machine was received from, transferred to, or disposed of; and
5. Name of the individual making the record.

b. **Record retention periods**.

1. Each registrant shall retain each record that is required by the rules in this Section, Sections 10 and 11, and Section 13 of these Rules or by a condition in the registration for the period specified by the appropriate rule or condition in the registration. If a retention period is not otherwise specified by rule or a by condition in the registration, the record must be retained until the Department terminates each registration that authorizes the activity that is subject to the recordkeeping requirement.
2. If there is a conflict between the Department's rules in this Section, Sections 10 and 11, and Section 13 of these Rules, condition in the registration, or other written Department approval or authorization

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pertaining to the retention period for the same type of record, the retention period specified in the rules in this Section, Sections 10 and 11, and Section 13 of these Rules for such records shall apply unless the Department, pursuant to RH-40.a. has granted a specific exemption from the record retention requirements specified in the rules in this Section, Sections 10 and 11, and Section 13 of these Rules.

c. **Record maintenance.**

Each record required by this Section, Sections 10 and 11, and Section 13 of these Rules must be legible throughout the specified retention period. The record may be the original or a reproduced copy or microform if such reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by Department rules. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

RH-52. ~~**Access to Premises**~~**Inspections**.

~~The Department or its duly authorized representatives shall for reasonable cause have the power to enter at all reasonable times upon any private or public property for the purpose of determining whether or not there is compliance with or violation of the provisions of these rules, except that entry into areas under the jurisdiction of the federal government shall be effected only with the concurrence of the federal government or its duly designated representative.~~

a. Each licensee or registrant shall afford to the Department at all reasonable times opportunity to inspect sources of radiation and the premises and facilities wherein such sources of radiation are used or stored.

b. Each registrant shall make available to the Department for inspection, upon reasonable notice, records kept by the registrant pursuant to these Rules.

RH-53. ~~**Access to Records.**~~Deleted

~~Each registrant shall, upon reasonable notice, make available for inspection by the Department records kept by the registrant pertaining to his receipt, possession, use, transfer or disposal of sources of radiation.~~

RH-54. **Tests.**

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Upon instruction from the Department, each registrant shall perform or cause to have performed and shall permit the Department to perform, such reasonable tests as the Department deems appropriate or necessary ~~in the administration of the rule~~, including, but not limited to, tests of:

a. Sources of radiation~~.~~;

~~RH-54. (Cont'd)~~

b. Facilities wherein sources of radiation are used or stored~~.~~;

c. Radiation detection and monitoring instruments~~.~~; and

d. Other equipment and devices used in connection with utilization or storage of registered sources of radiation.

RH-55. ~~**Exemptions**~~Deleted~~.~~

~~a. The Department may, upon application therefore, or upon its own initiative, grant such exemptions or exceptions from the requirements of these Rules as it determines are authorized by law and will not result in undue hazard to public health and safety or property.~~

~~b. U.S. Department of Energy Contractors and U.S. Nuclear Regulatory Commission Contractors. Any U.S. Department of Energy contractor or subcontractor and any U.S. Nuclear Regulatory Commission contractor or subcontractor of the following categories operating within this state is exempt from these Rules to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers or acquires sources of radiation:~~

~~1. Prime contractors performing work for the U.S. Department of Energy at U.S. Government-owned or controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;~~

~~2. Any other prime contractor or subcontractor of the U.S. Department of Energy or of the U.S. Nuclear Regulatory Commission when the Department and the U.S. Nuclear Regulatory Commission jointly determine:~~

~~A. that the exemption of the prime contractor or subcontractor is authorized by law; and~~

~~B. that under the terms of the contract or sub-contract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.~~

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PART G.
ADDITIONAL REQUIREMENTS

RH-56. **Additional Requirements**.

The Department may, by rule or order, impose upon any registrant such requirements in addition to those established in these Rules as it deems appropriate or necessary to minimize danger to public health and safety or property.

RH-57. **Reciprocal Recognition of Out-of-State Radiation Machine Registrations**.

a. ~~The~~Whenever any radiation machine is brought into the ~~s~~State for any temporary use, the persons proposing to bring such a machine into the ~~s~~State shall ~~give written notice to the Department at least two (2) days before such a machine enters the state~~ apply for and receive a notice from the Department granting reciprocal recognition prior to beginning operations. ~~The notice~~ request for reciprocity shall include the following:

1. ~~t~~Type of radiation machine;

2. ~~the n~~Nature, duration and scope of use;

3. ~~and the e~~Exact location(s) where the radiation machine is to be used; ~~and state(s) in which this machine is registered.~~

4. Copy of the applicant's current license, registration or equivalent document;

5. Copy of the applicant's current operating and emergency procedures pertinent to the proposed use;

6. Name and Arkansas licensing board number of the licensed practitioner, working within his or her scope of practice, if the radiation machine is for human use;

7. Qualifications of individuals who will be operating machines for human use, satisfying the requirements in these Rules and the Rules Pertaining to Radiologic Technology Licensure;

8. Qualifications for each radiographer who will be working in Arkansas if the reciprocity request is for industrial radiography as defined in Part I of Section 3; and

9. Applicable fee as specified in RH-58.

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b. Upon a determination that the request for reciprocity meets the requirements of the Department, the Department may issue a notice granting reciprocal recognition authorizing the proposed use.

c. Once reciprocity is granted, the out-of-state registrant shall notify the Department in writing prior to each entry into the State. This notice shall be submitted at least three (3) business days before the radiation machine is to be used in the State. If for a specific case, the ~~two~~ three (~~2~~3) business day period would impose an undue hardship ~~on the person~~, the out-of-state registrant may, ~~upon application to~~ at the determination of the Department, obtain permission to proceed sooner ~~may be granted~~.

d. ~~In addition, t~~The out-of-state ~~person~~ registrant~~must~~ shall:

~~a~~1. Comply with all applicable rules of the Department~~;~~ and with all the terms and conditions of the out-of-state registration, except any such terms and conditions that may be inconsistent with applicable rules of the Department; and

~~b~~2. Supply the Department with such other information as the Department may reasonably request~~.~~; and

3. Only operate in the State for 180 or less calendar days per year.

e. Use in excess of 180 days per calendar year requires registration in accordance with Part C of this Section.

f. If the State from which the radiation machine is brought does not issue registrations or equivalent documents, registration shall be obtained from the Department in accordance with Part C of this Section.

g. The Department may withdraw, limit, or qualify its acceptance of any registration or equivalent document issued by another State upon determining that the action is necessary to prevent undue hazard to occupational or public health and safety.

h. Vendor services provided by a person from out-of-state shall not be granted reciprocity. Whenever vendor services are to be provided by a person from out-of-state, that person shall apply for and receive a registration from the Department before providing services. The application shall be submitted in accordance with Part D of this Section.

RH-58. ~~Registration~~ **Fees**.

In accordance with Arkansas Code Annotated §20-21-217, annual fees for registration shall be paid.~~-~~ Nonpayment of fees shall result in escalated enforcement action ~~and/or~~ or revocation of registration.

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In accordance with Arkansas Code Annotated §20-21-217, X-ray Registration Fees are as follows:

a. All x-ray units - $65.00 per tube, up to a maximum of $260.00.

b. Vendor services providing radiation equipment services or radiation safety services, or both - $65.00.

RH-59. ~~Reserved.~~ **Shielding and Safety Design Requirements for Non-Therapeutic Use of Machine-Produced Radiation in the Healing Arts.**

a. Shielding plan review.

1. Prior to equipment use, the floor plans, shielding specifications, and equipment arrangement of all new installations or modifications of existing installations utilizing radiation for non-therapeutic uses in the healing arts and veterinary medicine, except bone densitometry, podiatric, and dental, other than cone beam computed tomography, shall be completed by a Qualified Expert and shall be made available for review by the Department upon request. Modifications subject to this paragraph include, but are not limited to:

A. Replacing a radiation machine with one of a higher output;

B. Changing the orientation of the radiation machine or image receptor;

C. Changing the occupancy of areas adjacent to the radiation machine room; and

D. Changing the radiation machine workload or technique factors, deemed significant by a Qualified Expert.

2. Shielding plans shall, at a minimum, include information contained in Appendix A to Section 1.

3. Notwithstanding paragraph.a.1. of this section, the shielding plans for all new installations or modifications of existing installations utilizing fluoroscopy or computed tomography shall be submitted for Department review and approval prior to equipment use.

4. After installation of a radiation machine subject to paragraph a. of this section, the registrant shall maintain the following for inspection by the Department:

A. The maximum rated technique factors of each machine; and

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B. A scale drawing of the room in which a stationary radiation machine is located with such drawing indicating:

i. The use of areas adjacent to the room and an estimation of the extent of occupancy by an individual in such areas; and

ii. Results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions; or the type and thickness of materials, or lead equivalency, of each protective barrier.

5. Shielding plan approval shall not preclude the requirement of revisions to the plan should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in Part C of Section 3.

b. Safety design requirements for an operator's booth.

Prior to equipment use, each new radiation machine installation utilizing an operator's booth as part of the shielding plan, or modification of an existing installation where the changes involve a booth, shall be in compliance with the design requirements specified in Appendix B to Section 1. The registrant may apply for Department approval of alternate design criteria provided the same level of radiation protection will be achieved.

RH-60. Reserved.

RH-61. **Loaner Radiation Machines.**

For persons having a valid registration, a loaner radiation machine may be used for up to 60 days, without registering it with the Department, provided that:

a. The loaner is of a similar type to a machine currently on the registration;

b. The loaner is not for a machine use listed in RH-21.b., unless authorization is received from the Department prior to operation;

c. Requirements in these Rules for the specific use are met, including equipment performance evaluations, as applicable; and

d. Shielding and safety design requirements are met in accordance with RH-59.

RH-62. -RH- 69. Reserved.

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PART ~~G~~H.
PROHIBITED USES

RH-~~60~~70. ~~**Hand-Held Fluoroscopic Screens Prohibited**~~**Prohibitions**.

a. No person shall expose an individual to radiation for training, demonstration, or other non-healing arts purpose.

b No person shall use radiation machines or perform radiation machine services except as authorized in a registration issued by the Department in accordance with the rules in this Section.

c. The Department may prohibit use of radiation machines that pose a significant threat or endanger occupational or public health and safety, in accordance with Part I of this Section and Sections 3 and 5 of these Rules.

d.~~No~~ A hand-held fluoroscopic screen shall not be used unless it has clearance or approval through the U.S. Food and Drug Administration, Center for Devices and Radiological Health. Registration for non-prohibited hand-held radiation machines shall be in accordance with Part C of this Section.

~~RH-61. **X-ray Shoe-Fitting Equipment**.~~

~~No~~ A shoe-fitting device ~~or shoe-fitting machine which~~ that uses fluoroscopic, x-ray, or radiation principles shall not be ~~operated or maintained in this state~~used.

e.

RH-~~62~~71.- RH-~~69~~79. Reserved.

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PART ~~H~~I.
ENFORCEMENT

RH-~~70~~80. **Violations**.

a. Any person who violates any of the provisions of the Act or rules or orders in effect pursuant thereto of the Department shall, upon conviction thereof, be punished by a fine of not less than one hundred dollars ($100.00) nor more than two thousand dollars ($2,000.00), or by imprisonment for not more than six (6) months or be both fined and imprisoned.

b. Impounding.

Sources of radiation shall be subject to impounding pursuant to Section 5 of these Rules.

RH-~~71~~81.- RH-99. Reserved.

APPENDIX A TO SECTION 1

RADIATION SHIELDING INFORMATION REQUIRED FOR PLAN REVIEWS PURSUANT TO RH-59.

I. A shielding plan shall contain, at a minimum, the following information:

A. Basic facility information including the following: name, telephone number, and Department vendor registration number of the individual responsible for preparation of the shielding plan; name and telephone number of the facility supervisor; the street address of the radiation machine facility; and the room number of the radiation machine. The plan should also indicate whether this is a new structure or a modification to an existing structure.

B. The normal location of the x-ray tube, along with an indication of anode-cathode orientation to the cassette holders; the limits of the tube travel; the directions in which the tube is pointed; locations of any windows and doors or other openings; the location of the operator's booth or operator's position; the location of the exposure switch; and position of the viewing window, if any;

C. The structural composition and thickness or lead equivalence of all walls, doors, partitions, floor, and ceiling of the room(s) concerned;

D. The dimensions of the room(s) concerned;

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E. The identification of and occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present;

F. The make and model of the equipment, the maximum technique factors, and the energy waveform (single phase, three phase, etc.);

G. The type of examination(s) or treatment(s) which will be performed with the equipment;

H. The maximum anticipated number of patients per week; and

I. The anticipated workload of the x-ray system.

II. A report shall be completed showing all basic assumptions used in the development of the shielding specifications and verifying that the shielding and safety design is in compliance with dose limits specified in Section 3 of these Rules.

APPENDIX B TO SECTION 1

DESIGN REQUIREMENTS FOR AN OPERATOR'S BOOTH

I. Space Requirements:

A. The operator shall be allotted not less than 7.5 ft^2 (0.70 m^2) of unobstructed floor space in the booth;

B. The operator's booth may be any geometric configuration with no dimension of less than 2 feet (0.6 meters);

C. The allotted space shall exclude any encumbrance by the x-ray control panel, such as overhang, cables, or other similar encroachments;

D. The booth shall be located or constructed such that unattenuated direct scatter radiation originating on the examination table or at the wall-mounted image receptor will not reach the operator's position in the booth.

II. Structural Requirements:

A. The booth walls shall be permanently fixed barriers of at least 7 feet (2 meters) high;

B. When a door or movable panel is used as an integral part of the booth structure, it must have an interlock that will prevent an exposure when the door or panel is not closed;

C. Shielding shall be provided to meet the requirements of Section 3 of these Rules.

III. Radiation Exposure Control Placement:

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The radiation exposure control for the system shall be fixed within the booth and:

A. Shall be at least 40 inches (1 meter) from any point subject to direct scatter, leakage, or primary beam radiation;

B. Shall allow the operator to use the available viewing windows.

IV. Viewing System Requirements:

A. Each booth shall have at least one viewing device that will be placed such that the operator can view the patient during any exposure, view any occupant of the room, and view any entry into the room. If any door that allows access to the room cannot be seen from the booth, then outside that door there shall be an "x-ray on" warning sign that will be lighted anytime the rotor of the x-ray tube is activated. Alternatively, an interlock shall be present such that exposures are prevented unless the door is closed.

B. When the viewing system is a window, the following requirements also apply:

1. The window shall have a viewing area of at least 1 ft^2 (0.09 m^2);

2. Regardless of the size or shape of the window, at least 1 ft^2 (0.09 m^2) of the window area must be centered no less than 2 feet (0.6 meters) from the open edge of the booth and no less than 5 feet (1.5 meters) from the floor;

3. The material constituting the window shall have at least the same lead equivalence as that required in the booth's wall in which it is mounted.

C. When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the general requirements in Section IV.A. of this Appendix.

D. When the viewing system is by electronic means:

1. The camera shall be so located as to accomplish the general requirements in Section IV.A. of this Appendix; and

2. There shall be an alternate viewing system as a backup for electronic failure.

APPENDIX C TO SECTION 1

INFORMATION TO BE SUBMITTED BY PERSONS PROPOSING TO CONDUCT HEALING ARTS SCREENING

Persons requesting that the Department approve a healing arts screening program shall submit the following information:

I. Name and address of the applicant and, where applicable, the names and addresses of agents within this State;

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II. Diseases or conditions for which the x-ray examinations are to be used in diagnoses;

III. A detailed description of the x-ray examinations proposed in the screening program;

IV. An indication of the frequency of screening and the duration of the entire screening program.

V. Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information;

VI. An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used instead of the x-ray examinations;

VII. For mobile screening operations, locations where radiation machines are used and maintained.

VIII. For x-ray systems other than DXA bone densitometers, operating procedures to include:

A. An evaluation by a Qualified Expert of the x-ray system(s) to be used in the screening program. The evaluation by the Qualified Expert shall show that such system(s) do satisfy all requirements of these Rules. The evaluation shall include a measurement of patient exposures from the x-ray examinations to be performed;

B. A description of the diagnostic x-ray quality control program; and

C. A copy of the technique chart or CT protocols to be used;

IX. For DXA bone densitometers, operating procedures to include the manufacturer's evaluation of the system to be used in the screening program. The evaluation shall show that such a system satisfies all requirements of these Rules.

X. The qualifications of each individual who will be operating the x-ray system(s);

XI. The qualifications of the individual who will be supervising the operators of the x-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified;

XII. The name and address of the individual who will interpret the radiograph(s);

XIII. A description of the procedures to be used in advising the individuals screened of the results of the screening procedure and any further medical needs indicated;

XIV. A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the x-ray examinations.

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SECTION 2.
LICENSING OF RADIOACTIVE MATERIALS

(FOOTNOTES APPEAR AT THE END OF THIS SECTION)

PART A.
GENERAL

RH-100. **Authority**. Act 8 of Second Extraordinary Session of 1961, as amended.

RH-101. **Effective Date**.

The provisions of these Rules shall become operative on the effective date of an agreement executed by the State of Arkansas and the Federal Government under the provisions of Section 274 of the Atomic Energy Act of 1954, as amended (73 Stat. 689).

RH-102. **Purpose and Scope**.

a. Section 2, Part I of Section 3, Part J of Section 3, and Sections 7 through 9 provide for the licensing of radioactive material. Except for persons exempt as provided in Part C of Section 2 and RH-750., no person shall manufacture, produce, transfer, receive, acquire, own, possess, or use radioactive material except as authorized in a specific or general license issued in accordance with these Rules.[1/]

b. In addition to the requirements of this Section, all licensees, except as otherwise noted in these Rules, are subject to the requirements of Section 3 and Section 4 as well as any rules specific to the type of radioactive material or particle accelerator use. Licensees engaged in industrial radiographic operations are subject to the requirements in Part I of Section 3; licensees engaged in well logging and subsurface tracer studies are subject to the requirements in Part J of Section 3; licensees using Naturally Occurring Radioactive Material (NORM) are subject to the requirements in Section 7; licensees using irradiators are subject to the requirements in Section 8; and licensees using radionuclides in the healing arts are subject to the requirements in Section 9. Particle accelerators are licensed pursuant to Section 6, with use requirements found in Sections 6 and 11.

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RH-103. **Fees**.

In accordance with Act 596 of 2011, codified at Arkansas Code Annotated §20-21-217, annual fees for licensing shall be paid. Applicants shall be charged for a full calendar year regardless of the month the license is issued. Nonpayment of fees shall result in escalated enforcement action ~~and/or~~ or revocation of license.

a. The following Specific License Fees are based upon 15% of the U. S. Nuclear Regulatory Commission's Fiscal Year 2012 annual fees found in 10 CFR 171.16:

CATEGORY	CODE	FEE
Academic Broad Scope	01100, 01110, 01120	$2,115
Academic R&D	03620	$1,215
Accelerator Produced Radionuclides	03210	$2,280
Other Services	03225	$2,145
Eye Applicator (Sr-90)	02210	$1,260
Gamma Knife	02310	$2,625
Gas Chromatographs	03123	$720
High Dose Rate Remote Afterloader	02230	$1,260
Industrial Radiography	03310, 03320	$3,855
Instrument Calibration; Leak Testing	03221, 03222; 03220	$720
In-vitro Testing	02410	$720
Irradiators – Activity < 10,000 Curies	03511	$2,280
Irradiators – Activity ≥ 10,000 Curies	03521	$20,625
Irradiators – Self-shielded	03510, 03520	$1,305
Manufacturing & Distributing	03214	$1,770
Measuring Systems – Analytical Devices	03122	$720
Measuring Systems – Fixed Gauge	03120	$720
Measuring Systems – Portable Gauge	03121	$720
Medical Broad Scope	02110	$6,810
Medical Institution – No Written Directive Required	02121	$1,260
Medical Institution – Written Directive Required	02120	$1,260
Medical Private Practice – No Written Directive Required	02201	$1,260
Medical Private Practice – Written Directive Required	02200	$1260

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Medical Therapy – Emerging Technologies	02240	$1,260
Mobile Medical Services	02220, 02231	$1,260
Nuclear Pharmacy	02500	$2,430
Veterinary	02400	$720
Well Logging – Including Tracers	03110, 03111, 03112	$1,500
Decommissioning – All Radioactive Material	99999	$5,000

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b. The General License Registration Fees are as follows:

CATEGORY	FEE
Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere (including certain ECDs in gas chromatographs)	$720
Depleted uranium contained in industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device	$150
In vitro clinical or laboratory testing	$25
Naturally Occurring Radioactive Material (NORM)	$500

c. Other fees are as follows:

CATEGORY	FEE
Naturally Occurring Radioactive Material (NORM) Specific License	$2,500
Arkansas State Board of Health Rules for Control of Sources of Ionizing Radiation	$0 for first hard copy $30 for each additional hard copy
Amendment to existing license	$50 per amendment

d. Reciprocity fees are as follows:

CATEGORY	FEE
Consultant	$2,145
Decommissioning – All Radioactive Material	$5,000

Decommissioning – Naturally Occurring Radioactive Material (NORM) Only	$2,500
Industrial Radiography	$3,855
Mobile Medical Services	$1260
Nuclear Gauge, Gas Chromatograph, Lead Paint Analyzer, or other similar specifically licensed device	$720
Well Logging – Including Tracers	$1,500

RH-104. **Communications**.

Except where otherwise specified, all communications concerning these Rules may be addressed to the Arkansas Department of Health, Radiation Control Section, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

RH-105. **Interpretations**.

Except as specifically authorized by the Department in writing, no interpretations of the meaning of the rules in this Section by an officer or employee of the Department other than a written interpretation by the Department Director or designee will be recognized as binding upon the Department.

RH-106. **Completeness and Accuracy of Information.**

a. Information provided to the Department by an applicant for a license or by a licensee or information required by statute or by the Department's rules, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects.

b. Each applicant or licensee shall notify the Department of information identified by the applicant or licensee as having for the regulated activity a significant implication for public health and safety or property. An applicant or licensee violates this paragraph only if the applicant or licensee fails to notify the Department of information that the applicant or licensee has identified as having a significant implication for public health and safety or property. Notification shall be provided to the Department within two (2) working days of identifying the information. This requirement is not applicable to information which is already required to be provided to the Department by other reporting or updating requirements.

RH-107. **Deliberate Misconduct**.

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a. Any licensee, certificate of registration holder, applicant for a license or certificate of registration, employee of a licensee, certificate of registration holder or applicant; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or certificate of registration holder, or applicant for a license or certificate of registration, who knowingly provides to any licensee, applicant, certificate holder, contractor or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's, certificate holder's, or applicant's activities subject to this Section, may not:

1. Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee, certificate of registration holder, or applicant to be in violation of any rule or order; or any term, condition, or limitation of any license issued by the Department; or

2. Deliberately submit to the Department, a licensee, certificate of registration holder, an applicant, or a licensee's, certificate holder's or applicant's, contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the Department.

b. A person who violates paragraph a.1. or a.2. of this section may be subject to enforcement action in accordance with the procedures in RH-700.

c. For purposes of paragraph a.1. of this section, deliberate misconduct by a person means an intentional act or omission that the person knows:

1. Would cause a licensee, certificate of registration holder, or applicant to be in violation of any rule or order; or any term, condition, or limitation, of any license issued by the Department; or

2. Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, certificate of registration holder, applicant, contractor, or subcontractor.

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PART B.
DEFINITIONS

RH-200. **Definitions**.

Accelerator-produced material - Any material made radioactive by a particle accelerator.

Act - Act 8 of Second Extraordinary Session of 1961, as amended.

Active maintenance - Any significant remedial activity needed during the period of institutional control to maintain a reasonable assurance that the performance objectives in RH-407.c.2. and 3. are met. Such active maintenance includes ongoing activities such as the pumping and treatment of water from a disposal unit or one-time measures such as replacement of a disposal unit cover. Active maintenance does not include custodial activities such as repair of fencing, repair or replacement of monitoring equipment, revegetation, minor additions to soil cover, minor repair of disposal unit covers and general disposal site upkeep such as mowing grass.

Agreement State - Any state with which the Atomic Energy Commission or the U.S. Nuclear Regulatory Commission has entered into an effective agreement under subsection 274 b. of the Atomic Energy Act of 1954 (68 Stat. 919), including any amendments thereto. Non-agreement State means any other State.

Alert - Events may occur, are in progress, or have occurred that could lead to a release of radioactive material but that the release is not expected to require a response by offsite response organizations to protect persons offsite.

Becquerel (Bq) – One becquerel is equal to one disintegration per second (dps).

Buffer zone - A portion of the disposal site that is controlled by the licensee and that lies under the disposal units and between the disposal units and the boundary of the site.

Byproduct material -

1. Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

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2. The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. ~~-~~Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition;

3. A. Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

   B. Any material that:

      i. Has been made radioactive by use of a particle accelerator; and

      ii. Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

4. Any discrete source of naturally occurring radioactive material, other than source material, that:

   A. The U.S. Nuclear Regulatory Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

   B. Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

CFR - Code of Federal Regulations.

Chelating agent - Amine polycarboxylic acids (e.g., EDTA, DTPA), hydroxycarboxylic acids and polycarboxylic acids (e.g., citric acid, carbolic acid and glucinic acid).

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Commencement of construction - Any action defined as "construction" or any other activity at the site of a facility subject to the rules in this Section that has a reasonable nexus to radiological health and safety.

Consortium - An association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the

~~RH 200. (Cont'd)~~

operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a Federal facility or a medical facility.

Construction - The installation of foundations, or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to the rules in this Section that are related to radiological safety or security. The term "construction" does not include:

1. Changes for temporary use of the land for public recreational purposes;

2. Site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;

3. Preparation of the site for construction of the facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;

4. Erection of fences and other access control measures that are not related to the safe use of, or security of, radiological materials subject to this part;

5. Excavation;

6. Erection of support buildings (e.g., construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility;

7. Building of service facilities (e.g., paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines);

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8. Procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility; or

9. Taking any other action that has no reasonable nexus to radiological health and safety.

~~RH-200. (Cont'd)~~

Curie (Ci) – One curie is that amount of radioactive material which disintegrates at the rate of 37 billion atoms per second.

Custodial Agency - An agency of the government designated to act on behalf of the government owner of the disposal site.

Cyclotron – A particle accelerator in which the charged particles travel in an outward spiral or circular path. A cyclotron accelerates charged particles at energies usually in excess of 10 megaelectron volts and is commonly used for production of short half-life radionuclides for medical use.

Decommission - to remove a facility or site safely from service and reduce residual radioactivity to a level that permits:

1. Release of the property for unrestricted use and termination of the license; or

2. Release of the property under restricted conditions and termination of the license.

Department - Arkansas Department of Health.

Depleted uranium - The source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.

Discrete source – A radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

Disposal - The isolation of radioactive wastes from the biosphere inhabited by man and containing his food chains by emplacement in a land disposal facility.

Disposal site - That portion of a land disposal facility which is used for disposal of waste. It consists of disposal units and a buffer zone.

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Disposal unit - A discrete portion of the disposal site into which waste is placed for disposal. For near surface disposal, the unit is usually a trench.

Dose commitment – The total radiation dose to a part of the body that will result from retention in the body of radioactive material. For purposes of estimating the dose commitment, it is assumed that from the time of intake the period of exposure to retained material will not exceed 50 years.

~~RH-200. (Cont'd)~~

Effective Dose Equivalent - The sum of the products of the dose equivalent to the organ or tissue and the weighting factors applicable to each of the body organs or tissues that are irradiated. Weighting factors are: 0.25 for gonads, 0.15 for breast, 0.12 for red bone marrow, 0.12 for lungs, 0.03 for thyroid, 0.03 for bone surface, and 0.06 for each of the other five organs receiving the highest dose equivalent.

Engineered barrier - A man-made structure or device that is intended to improve the land disposal facility's ability to meet the performance objectives in RH-407.c.

Explosive material - Any chemical compound, mixture, or device which produces a substantial instantaneous release of gas and heat spontaneously or by contact with sparks or flame.

Government agency - Any executive department, commission, independent establishment, corporation, wholly or partly owned by the United States of America, which is an instrumentality of the United States, or any board, bureau, division, service, office, officer, authority, administration, or other establishment in the executive branch of the Government.

Hazardous waste - Those wastes designated as hazardous by Environmental Protection Agency regulations in 40 CFR Part 261.

Human use - The internal or external administration of radiation or radioactive materials to human beings.

Hydrogeologic unit - Any soil or rock unit or zone which by virtue of its porosity or permeability or lack thereof, has a distinct influence on the storage or movement of ground water.

Inadvertent intruder - A person who might occupy the disposal site after closure and engage in normal activities, such as agriculture, dwelling construction or other pursuits in which the person might be unknowingly exposed to radiation from the waste.

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Individual - Any human being.

Inspection - An official examination or observation including but not limited to, tests, surveys and monitoring to determine compliance with rules, orders, requirements and conditions of the Department.

Intruder barrier - A sufficient depth of cover over the waste that inhibits contact with waste and helps to ensure that radiation exposures to an inadvertent intruder

~~RH-200. (Cont'd)~~

will meet the performance objectives set forth in this Section or engineered structures that provide equivalent protection to the inadvertent intruder.

Land disposal facility - The land, buildings and equipment which are intended to be used for the disposal of the radioactive wastes into the subsurface of the land. For purposes of this Section, a geologic repository is not considered a land disposal facility.

License - Except where otherwise specified, a license issued pursuant to these Rules.

Licensed material - Source material, special nuclear material, or byproduct material received, possessed, used, transferred or disposed of under a general license provided by rule or a specific license issued by the Department.

Licensee - Any person who is licensed by the Department in accordance with these Rules and the Act.

Licensing State - Any state with regulations equivalent to the Suggested State Regulations for Control of Radiation relating to, and an effective program for, the regulatory control of Naturally-Occurring and Accelerator-Produced Radioactive Material (NARM).

Lot Tolerance Percent Defective – Expressed in percent defective, the poorest quality in an individual inspection lot that should be accepted.

Monitoring - Observing and making measurements to provide data to evaluate the performance and characteristics of the disposal site.

Near-surface disposal facility - A land disposal facility in which radioactive waste is disposed of in or within the upper 30 meters of the earth's surface.

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Particle accelerator - Any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 megaelectron volt. ~~-~~For purposes of this definition, ‘‘accelerator’’ is an equivalent term.

Person -

1. Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency of this state, political subdivision of this state, any other state or political subdivision or agency thereof; and

~~RH-200. (Cont'd)~~

2. Any legal successor, representative, agent, or agency of the foregoing, but not including United States Government agencies.

Pharmacist - An individual registered by this State to compound and dispense drugs, prescriptions and poisons.

Physician - A doctor of medicine or doctor of osteopathy licensed by the Arkansas State Medical Board to prescribe drugs in the practice of medicine.

Principal activities - Activities authorized by the license which are essential to achieving the purpose(s) for which the license was issued or amended. ~~-~~Storage during which no licensed material is accessed for use or disposal and activities incidental to decontamination or decommissioning are not principal activities.

Pyrophoric liquid - Any liquid that ignites spontaneously in dry or moist air at or below 130^0 F (54.5^0 C). ~~-~~A pyrophoric solid is any solid material, other than one classed as an explosive, which under normal conditions is liable to cause fires through friction, retained heat from manufacturing or processing or which can be ignited readily and when ignited, burns so vigorously and persistently as to create a serious transportation, handling or disposal hazard.~~-~~ Included are spontaneously combustible and water-reactive materials.

Radiation - Ionizing radiation, i.e., gamma rays and x-rays, alpha and beta particles, high speed electrons, neutrons and other nuclear particles; but not sound, radio waves, visible, infrared or ultraviolet light.

Radioactive material - Any material, solid, liquid or gas which emits radiation spontaneously, including any natural radioactive material such as radium.

~~**Radiographer** - Any individual who performs or who, in attendance at the site where sources of radiation are being used, personally supervises industrial radiographic operations and~~

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~~who is responsible to the licensee or registrant for assuring compliance with the requirements of these Rules and the conditions of registration or of a license.~~

~~**Radiographer's assistant** - Any individual who, under the personal supervision of a radiographer, uses sources of radiation, related handling tools or survey instruments in industrial radiography.~~

~~**Radiographic exposure device** - Any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure.~~

~~RH 200. (Cont'd)~~

Radiography - The examination of the macroscopic structure of materials by nondestructive methods utilizing sources of radiation.

Registrant - Any person who is registered with Department and is legally obligated to register with the Department pursuant to these Rules and the Act.

Registration - Registration with the Department in accordance with these Rules adopted by the Department.

Research and Development -

1. Theoretical analysis, exploration or experimentation; or

2. The extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, material and processes.

   Research and Development used in these Rules does not include the internal or external administration of radiation or radioactive material to human beings.

Sealed source - Radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

Sealed Source and Device Registry – The national registry that contains all the registration certificates, generated by both the U.S. Nuclear Regulatory Commission and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

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– **Site Area Emergency** - Events may occur, are in progress, or have occurred that could lead to a significant release of radioactive material and that could require a response by offsite response organizations to protect persons offsite.

Site closure and stabilization - Those actions that are taken upon completion of operations that prepare the disposal site for custodial care and assure that the disposal site will remain stable and will not need ongoing active maintenance.

Source material -

1. Uranium or thorium or any combination thereof in any physical or chemical form, or

~~RH 200. (Cont'd)~~

2. Ores which contain by weight one-twentieth of one percent (0.05%) or more of uranium, thorium or any combination thereof. –Source material does not include special nuclear material.

— **Source of radiation** - Any radioactive material, or device or equipment emitting or capable of producing radiation.

Special nuclear material -

1. Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the U.S. Nuclear Regulatory Commission, pursuant to the provisions of Section 51 of the Atomic Energy Act of 1954, as amended, determines to be special nuclear material, but does not include source material, or

2. Any material artificially enriched by any of the foregoing but does not include source material.

Special nuclear material in quantities not sufficient to form a critical mass - Uranium enriched in the isotope 235 in quantities not exceeding 350 grams of contained uranium-235; uranium-233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams or any combination of them in accordance with the following formula:

For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination shall not exceed "1" (i.e., unity). For example, the following quantities in combination would not exceed the limitation and are within the formula, as follows:

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$$\frac{175 \text{ (grams contained U-235)}}{350} + \frac{50 \text{ (grams U-233)}}{200} + \frac{50 \text{ (grams Pu)}}{200} = 1$$

Stability - Structural stability.

Surveillance - Observation of the disposal site for purposes of visual detection of need for maintenance, custodial care, evidence of intrusion and compliance with other license and regulatory requirements.

Unrefined and unprocessed ore - Ore in its natural form prior to any processing, such as grinding, roasting, beneficiating or refining. Processing does not include sieving or encapsulation of ore or preparation of samples for laboratory analysis.

~~RH-200. (Cont'd)~~

U.S. Department of Energy - The Department of Energy established by Public Law 95-91, August 4, 1977, 91 Stat. 565, 42 U.S.C. 7101 et seq., to the extent that the Department exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to Sections 104(b), (c) and (d) of the Energy Reorganization Act of 1974 (Public Law 93-438, October 11, 1974, 88 Stat. 1233 at 1237, effective January 19, 1975) and retransferred to the Secretary of Energy pursuant to Section 301(a) of the Department of Energy Organization Act (Public Law 95-91, August 4, 1977, 91 Stat. 565 at 577-578, 42 U.S.C. 7151, effective October 1, 1977.)

Waste - Those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in paragraphs 2., 3., and 4. of the definition of byproduct material set forth in this section.

Waste handling licensees - Persons licensed to receive and store radioactive wastes prior to disposal or ~~and/or~~ persons licensed to dispose of radioactive waste.

RH-201.- RH-299. –Reserved.

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PART C.
EXEMPTIONS

RH-300. **Unimportant Quantities of Source Material**.

a. Any person is exempt from this Section to the extent that such person receives, possesses, uses, owns, transfers, or delivers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than one-twentieth of one percent (0.05%) of the mixture, compound, solution, or alloy.

b. Any person is exempt from this Section to the extent that such person receives, possesses, uses, or transfers unrefined and unprocessed ore containing source material; provided that, except as authorized in a specific license, such person shall not refine or process such ore.

c. 1. Any person is exempt from this Section and Section 3 to the extent that such person receives, possesses, uses, or transfers:

A. Any quantities of thorium contained in:

i. Incandescent gas mantles;

ii. Vacuum tubes;

iii. Welding rods;

iv. Electric lamps for illuminating purposes, provided that each lamp does not contain more than fifty (50) milligrams of thorium;

v. Germicidal lamps, sunlamps, and lamps for outdoor or industrial lighting, provided that each lamp does not contain more than two (2) grams of thorium;

vi. Rare earth metals and compounds, mixtures, and products containing not more than 0.25 percent by weight thorium, uranium, or any combination of these; or

vii. Personnel neutron dosimeters, provided that each dosimeter does not contain more than fifty (50) milligrams of thorium;

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B. Source material contained in the following products:

i. Glazed ceramic tableware manufactured before August 27, 2013, provided that the glaze contains not more than twenty percent (20%) by weight source material;

ii. Piezoelectric ceramic containing not more than two percent (2%) by weight source material;

iii. Glassware containing not more than two percent (2%) by weight source material or, for glassware manufactured before August 27, 2013, 10 percent (10%) by weight source material; but not including commercially manufactured glass brick, pane glass, ceramic tile, or other glass or ceramic used in construction; or

iv. Glass enamel or glass enamel frit containing not more than ten percent (10%) by weight source material imported or ordered for importation into the United States, or initially distributed by manufacturers in the United States, before July 25, 1983;

C. Photographic film, negatives, and prints containing uranium or thorium;

D. Any finished product or part fabricated of, or containing tungsten or magnesium-thorium alloys, provided that the thorium content of the alloy does not exceed four percent (4%) by weight and that the exemption contained in RH-300.c.1.D. shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such product or part;

E. Uranium contained in counterweights installed in aircraft, rockets, projectiles, and missiles or stored or handled in connection with installation or removal of such counterweights, provided that:

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RH-300.c.1.E. ~~(Cont'd)~~

i. Each counterweight has been impressed with the following legend clearly legible through any plating or other covering: -"**DEPLETED URANIUM**";[2/]

ii. Each counterweight is durably and legibly labeled or marked with the identification of the manufacturer and the statement "**UNAUTHORIZED ALTERATIONS PROHIBITED**";[2/] and

iii The exemption contained in RH-300.c.1.E. shall not be deemed to authorize the chemical, physical, or metallurgical treatment or processing of any such counterweights other than repair or restoration of any plating or other covering;

F. Natural or depleted uranium metal used as shielding constituting part of any shipping container, provided that:

i. The shipping container is conspicuously and legibly impressed with the legend "**CAUTION - RADIOACTIVE SHIELDING - URANIUM**"; and

ii. The uranium metal is encased in mild steel or equally fire resistant metal of minimum wall thickness of one-eighth inch (3.2 mm);

G. Thorium or uranium contained in or on finished optical lenses and mirrors, provided that each lens or mirror does not contain more than ten percent (10%) by weight thorium or uranium or, for lenses manufactured before August 27, 2013, 30 percent (30%) by weight of thorium; and that the exemption contained in RH-300.c.1.G. does not authorize either:

i. The shaping, grinding, or polishing of such lens or mirror or manufacturing processes other than the assembly of such lens or mirror into optical systems and devices without any alteration of the lens or mirror; or

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ii. The receipt, possession, use, or transfer of uranium or thorium contained in contact lenses, or in spectacles, or in eyepieces in binoculars or other optical instruments;

~~RH-300.c.1. (Cont'd)~~

H. Thorium contained in any finished aircraft engine part containing nickel-thoria alloy, provided that:

i. The thorium is dispersed in the nickel-thoria alloy in the form of finely divided thoria (thorium dioxide); and

ii. The thorium content in the nickel-thoria alloy does not exceed four percent (4%) by weight.

2. The exemptions contained in RH-300.c.1. do not authorize the manufacture, of any of the products described.

3. No person may initially transfer for sale or distribution a product containing source material to persons exempt under RH-300.c.1., or equivalent regulations of the U.S. Nuclear Regulatory Commission or of an Agreement State, unless authorized by a license issued under 10 CFR 40.52 to initially transfer such products for sale or distribution.

A. Persons initially distributing source material in products covered by the exemptions in RH-300.c.1. before August 27, 2013, without specific authorization may continue such distribution for 1 year beyond this date. -Initial distribution may also be continued until the NRC takes final action on a pending application for license or license amendment to specifically authorize distribution submitted no later than 1 year beyond this date.

B. Persons authorized to manufacture, process, or produce these materials or products containing source material by the Department or any Agreement State, and persons who import finished products or parts, for sale or distribution must be authorized by a license issued under 10 CFR 40.52 for distribution only and are exempt from the requirements of Section 3 and RH-404.a. and b.

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RH-301. **Radioactive Material Other Than Source Material**.

a. **Exempt concentrations**.

1. Except as provided in RH-301.a.3. and RH-301.a.4., any person is exempt from the requirements for a license set forth in the Act and from these Rules to the extent that such person receives, possesses, uses, transfers, owns or acquires products or materials containing radioactive material in concentrations not in excess of those listed in Schedule C to Section 2, RH-902.

2. This section shall not be deemed to authorize the import of radioactive material or products containing radioactive material.

3. A manufacturer, processor, or producer of a product or material in an Agreement State is exempt from the requirements for a license and from these Rules to the extent that this person transfers radioactive material contained in a product or material in concentrations not in excess of those specified in RH-902. (Schedule C to Section 2) and introduced into the product or material by a licensee holding a specific license issued by the U.S. Nuclear Regulatory Commission expressly authorizing such introduction. This exemption does not apply to the transfer of radioactive material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

4. No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under RH-301.a., or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State, except in accordance with a license issued by the NRC pursuant to 10 CFR 32.11.

b. **Certain items containing radioactive material**.

1. Except for persons who apply radioactive material to, or persons who incorporate radioactive material into, the following products, or persons who initially transfer for sale or distribution the following products containing radioactive material, any person is exempt from the requirements for a license set forth in the Act and from these Rules to the extent that such person receives, possesses, uses, transfers, owns or acquires the following products:

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A. Time pieces or hands or dials containing not more than the following specified quantities of radioactive material and not exceeding the following specified levels of radiation:

i. 25 millicuries of tritium per timepiece;

ii. 5 millicuries of tritium per hand;

iii. 15 millicuries of tritium per dial (bezels when used shall be considered as part of the dial);

iv. 100 microcuries of promethium-147 per watch or 200 microcuries of promethium-147 per other timepiece;

v. 20 microcuries of promethium-147 per watch hand or 40 microcuries of promethium-147 per other timepiece hand;

vi. 60 microcuries of promethium-147 per watch dial or 120 microcuries of promethium-147 per other timepiece dial (bezels when used shall be considered as part of the dial);

vii. The levels of radiation from hands and dials containing promethium-147 will not exceed, when measured through 50 milligrams per square centimeter of absorber:

(a). For wrist watches, 0.1 millirad per hour at ten (10) centimeters from any surface;

(b). For pocket watches, 0.1 millirad per hour at one (1) centimeter from any surface;

~~RH-301.b.1.A.vii. (Cont'd)~~

(c). For any other timepiece, 0.2 millirad per hour at ten (10) centimeters from any surface.

viii. 1 microcurie (0.037 MBq) of radium-226 per timepiece in intact timepieces manufactured prior to November 30, 2007.

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B. i. Static elimination devices which contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 µCi (18.5 MBq) of polonium-210 per device.

ii. Ion generating tubes designed for ionization of air that contain, as a sealed source or sources, radioactive material consisting of a total of not more than 500 µCi (18.5 MBq) of polonium-210 per device or of a total of not more than 50 mCi (1.85 GBq) of hydrogen-3 (tritium) per device.

iii. Such devices authorized before October 23, 2012 for use under the general license then provided in RH-402.l. and equivalent regulations of the U.S. Nuclear Regulatory Commission and Agreement States and manufactured, tested, and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the NRC.

C. Balances of precision containing not more than one (1) millicurie of tritium per balance or not more than 0.5 millicuries of tritium per balance part manufactured before December 17, 2007.

D. Reserved.

E. Marine compasses containing not more than 750 millicuries of tritium gas and other marine navigational instruments containing not more than 250 millicuries of tritium gas manufactured before December 17, 2007.

F. Reserved.

~~RH-301.b.1. (Cont'd)~~

G. Ionization chamber smoke detectors containing not more than one (1) microcurie (µCi) of americium-241 per detector in the form of a foil and designed to protect life and property from fires.

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H. Electron tubes:- Provided, that each tube does not contain more than one (1) of the following specified quantities of radioactive material:

i. 150 millicuries of tritium per microwave receiver protector tube or ten (10) millicuries of tritium per any electron tube;

ii. One (1) microcurie of cobalt-60;

iii. Five (5) microcuries of nickel-63;

iv. Thirty (30) microcuries of krypton-85;

v. Five (5) microcuries of cesium-137;

vi. Thirty (30) microcuries of promethium-147;

And provided further, that the level of radiation due to radioactive material contained in each electron tube does not exceed one (1) millirad per hour at one (1) centimeter from any surface when measured through seven (7) milligrams per square centimeter of absorber.[4/]

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I. Ionizing radiation measuring instruments containing, for purposes of internal calibration or standardization, one or more sources of radioactive material: provided, that:

i. Each source contains no more than one exempt quantity set forth in Schedule B to Section 2; and

ii. Each instrument contains no more than ten (10) exempt quantities.- For purposes of RH-301.b.9., an instrument's source(s) may contain either one type or different types of radionuclides and an individual exempt quantity may be composed of fractional parts of one (1) or more of the exempt quantities in Schedule B, provided that the sum of each fraction shall not exceed unity.

~~RH-301.b.1.I. (Cont'd)~~

iii. For purposes of this RH-301.b.1.I., 0.05 microcurie of americium-241 is considered an exempt quantity under Schedule B.

J. Reserved.

2. Any person who desires to apply radioactive material to, or to incorporate radioactive material into, the products exempted in RH-301.b.1. above, or who desires to initially transfer for sale or distribution such products containing radioactive material, should apply for a specific license pursuant to 10 CFR 32.14, which license states that the product may be distributed by the licensee to persons exempt from RH-301.b.1.

c. Deleted.

d. **Gas and aerosol detectors containing radioactive material**.

1. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing radioactive material, any person is exempt from the requirements for a license set forth in the Act and from these Rules to the extent that such person receives, possesses, uses, transfers, owns or acquires radioactive material in gas and aerosol detectors designed to protect health, safety, or property, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under 10 CFR 32.26, which license authorizes the initial transfer of the product for use under RH-301.d. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007, in accordance with a specific license issued by an Agreement State under comparable provisions to 10 CFR 32.26 authorizing distribution to persons exempt from regulatory requirements.

2. Any person who desires to manufacture, process, or produce gas and aerosol detectors containing radioactive material, or to initially transfer such products for use under RH-301.d.1., should apply for a license under 10 CFR 32.26 and for a certificate of registration in accordance with 10 CFR 32.210 or equivalent Agreement State regulations.

~~RH-301. (Cont'd)~~

e. **Self-luminous products containing radioactive material**.

1. **Tritium, krypton-85, or promethium-147**.

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Except for persons who manufacture, process, produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85 or promethium-147, any person is exempt from these Rules to the extent that such person receives, possesses, uses, transfers, owns, or acquires tritium, krypton-85 or promethium-147 in self-luminous products manufactured, processed, produced, or initially transferred in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.22, which license authorizes the transfer of the product to persons who are exempt from regulatory requirements or equivalent regulations of an Agreement State. The exemption in RH-301.e. does not apply to tritium, krypton-85 or promethium-147 used in products primarily for frivolous purposes or in toys or adornments.

2. **Radium-226**.

Any person is exempt from these Rules to the extent that such person receives, possesses, uses, transfers, or owns articles containing less than 0.1 µCi (3.7 kBq) of radium-226 which were manufactured prior to November 30, 2007.

3. Any person who desires to manufacture, process, or produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147 for use under RH-301.e.1., should apply for a license under 10 CFR 32.22 and for a certificate of registration in accordance with 10 CFR 32.210 or equivalent Agreement State regulations.

f. **Radioactive drug: capsules containing carbon-14 urea for "in vivo" diagnostic use for humans**.

1. Except as provided in paragraphs RH-301.f.2. and RH-301.f.3., any person is exempt from the requirements for a license and from the rules in this Section and Section 9 provided that such person receives, possesses, uses, transfers, owns, or acquires capsules containing one (1) microcurie (37 kBq) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each, for "in vivo" diagnostic use for humans.

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2. Any person who desires to use the capsules for research involving human subjects shall apply for and receive a specific license pursuant to Section 9.

3. Any person who desires to manufacture, prepare, process, produce, package, repackage, or transfer for commercial distribution such capsules shall apply for and receive specific license pursuant to 10 CFR 32.21.

4. Nothing in RH-301.f. relieves persons from complying with applicable Food & Drug Administration (FDA), other Federal, and State requirements governing receipt, administration, and use of drugs.

g. **Certain industrial devices.**

1. Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing radioactive material designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing an ionized atmosphere, any person is exempt from the requirements for a license set forth in the Act and from these Rules to the extent that such person receives, possesses, uses, transfers, owns, or acquires radioactive material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under 10 CFR 32.30, which license authorizes the initial transfer of the device for use under RH-301.g. This exemption does not cover sources not incorporated into a device, such as calibration and reference sources.

2. Any person who desires to manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing radioactive material for use under RH-301.g.1., should apply for a license under 10 CFR 32.30 and for a certificate of registration in accordance with 10 CFR 32.210 or equivalent Agreement State regulations.

RH-302. **Carriers**.

Common and contract carriers, freight forwarders, warehousemen, and the U.S. Postal Service are exempt from the rules in this Section and Part I of Section 3, Part J of Section 3, Sections 6 through 9, and Section 12 of these Rules and the

requirements for a license set forth in the Act to the extent that they transport or store radioactive material in the regular course of carriage for another or storage incident thereto.

RH-303. **U.S. Department of Energy Contractors and U.S. Nuclear Regulatory Commission Contractors**.

Any U.S. Department of Energy (DOE) contractor or subcontractor and any U.S. Nuclear of Regulatory Commission (NRC) contractor or subcontractor of the following categories operating within this state is exempt from these Rules to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers or acquires sources of radiation:

a. Prime contractors performing work for the DOE at U.S. Government-owned or -controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;

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b. Prime contractors of the DOE performing research in or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof;

c. Prime contractors of the DOE using or operating nuclear reactors or other nuclear devices in a U.S. Government owned vehicle or vessel; and

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d. Any other prime contractor or subcontractor of the DOE or of the NRC when the State and the NRC jointly determine:

1. that the exemption of the prime contractor or subcontractor is authorized by law; and

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2. that, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

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RH-304. **Specific Exemptions**.

The Department may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the rules in this Section as it determines are authorized by law and will not result in undue hazard to public health and safety or property, and are otherwise in the public interest.

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RH-305. **Exempt Quantities**.

a. Except as provided in paragraphs c. through e. of this section, any person is exempt from these Rules to the extent that such person receives, possesses, uses, transfers, owns or acquires radioactive material in individual quantities each of which does not exceed the applicable quantity set forth in RH-901., Schedule B to Section 2.

b. Any person who possesses radioactive material received or acquired under the general license formerly provided in RH-402.a. or similar general license of the U.S. Nuclear Regulatory Commission or an Agreement State, is exempt from the requirements for a license set forth in this Section to the extent that such person possesses, uses, transfers or owns such radioactive material.

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c. This RH-305. does not authorize the production, packaging or repackaging of radioactive material for purposes of commercial distribution or the incorporation of radioactive material into products intended for commercial distribution.

d. No person may, for purposes of commercial distribution, transfer radioactive material in the individual quantities set forth in Schedule B to Section 2, knowing or having reason to believe that such quantities of radioactive material will be transferred to persons exempt under this section or equivalent regulations of the U.S. Nuclear Regulatory Commission or any Agreement State, except in accordance with a specific license issued by the U.S. Nuclear Regulatory Commission pursuant to section 32.18 of 10 CFR Part 32, which license states that the radioactive material may be transferred by the licensee to persons exempt under this section or the equivalent regulations of the U.S. Nuclear Regulatory Commission or any Agreement State.

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e. No person may, for purposes of producing an increased radiation level, combine quantities of radioactive material covered by this exemption so that the aggregate quantity exceeds the limits set forth in RH-901. (Schedule B to Section 2), except for radioactive material combined within a device placed in use before May 3, 1999, or as otherwise permitted by the rules in this Section.

RH-306.- RH-399. Reserved.

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PART D.
LICENSES

RH-400. **Types of Licenses**.

Licenses for radioactive materials are of two (2) types: general and specific.

General License - provided by rule, grants authority to a person for certain activities involving radioactive material, and is effective without the filing of an application with the Department or the issuance of a licensing document to a particular person. However, registration with the Department may be required by the particular general license.

Specific License - issued to a named person who has filed an application with the Department for the license under the provisions of these Rules.

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RH-401. **General Licenses - Source Material**.

a. **Small quantities of source material**.

1. A general license is hereby issued authorizing commercial and industrial firms; research, educational, and medical institutions; and Federal, State, and local government agencies to receive, possess, use, and transfer uranium and thorium, in their natural isotopic concentrations and in the form of depleted uranium, for research, development, educational, commercial, or operational purposes in the following forms and quantities:

A. No more than 1.5 kg (3.3 lb) of uranium and thorium in dispersible forms (e.g., gaseous, liquid, powder, etc.) at any one time. Any material processed by the general licensee that alters the chemical or physical form of the material containing source material must be accounted for as a dispersible form. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than a total of 7 kg (15.4 lb) of uranium and thorium in any one calendar year. Persons possessing source material in excess of these limits as of March 1, 2016, may continue to possess up to 7 kg (15.4 lb) of uranium and thorium at any one time for one year beyond this date, or until the Department takes final action on a pending license amendment or application for a specific license submitted on or before March 1, 2017, for such

~~l.a.1.A. (Cont'd)~~

material; and receive up to 70 kg (154 lb) of uranium or thorium in any one calendar year until December 31, 2017, or until the Department takes final action on a pending license amendment or application for a specific license submitted on or before March 1, 2017, for such material; and

B. No more than a total of 7 kg (15.4 lb) of uranium and thorium at any one time. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than a total of 70 kg (154 lb) of uranium and thorium in any one calendar year. A person may not alter the chemical or physical form of the source material possessed under this paragraph unless it is accounted for under the limits found in paragraph a.1.A. of this section; or

C. No more than 7 kg (15.4 lb) of uranium, removed during the treatment of drinking water, at any one time. A person may not remove more than 70 kg (154 lb) of uranium from drinking water during a calendar year under this paragraph; or

D. No more than 7 kg (15.4 lb) of uranium and thorium at laboratories for the purpose of determining the concentration of uranium and thorium contained within the material being analyzed at any one time. A person authorized to possess, use, and transfer source material under this paragraph may not receive more than a total of 70 kg (154 lb) of source material in any one calendar year.

2. Any person who receives, possesses, uses, or transfers source material in accordance with the general license in paragraph a. of this section:

A. Is prohibited from administering source material, or the radiation therefrom, either externally or internally, to human beings except as may be authorized by the Department in a specific license.

~~RH-401.a.2. (Cont'd)~~

B. Shall not abandon such source material. Source material may be disposed of as follows:

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i. A cumulative total of 0.5 kg (1.1 lb) of source material in a solid, non-dispersible form may be transferred each calendar year, by a person authorized to receive, possess, use, and transfer source material under this general license to persons receiving the material for permanent disposal. The recipient of source material transferred under the provisions of this paragraph is exempt from the requirements to obtain a license under this Section to the extent the source material is permanently disposed. This provision does not apply to any person who is in possession of source material under a specific license issued pursuant to these Rules; or

ii. In accordance with RH-1400.

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C. Is subject to the provisions in RH-102., RH-104. through RH-107., RH-200., RH-409.a. through d., RH-416., Part E of Section 2., RH-600. through 603., and RH-700, RH-751., and Section 4.

D. Shall respond to written requests from the Department to provide information relating to the general license within 30 calendar days of the date of the request, or other time frame specified in the request. If the person cannot provide the requested information within the allotted time, the person shall, within that same time period, request a longer period to supply the information by providing the Department a written justification for the request;

E. Shall not export such source material except in accordance with 10 CFR Part 110.

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3. Any person who receives, possesses, uses, or transfers source material in accordance with paragraph a. of this section shall conduct activities so as to minimize contamination of the facility and the environment. When activities involving such source material are permanently ceased at any site, if evidence of significant contamination is identified, the general licensee shall notify the Department in writing about such contamination and may consult with the Department as to the appropriateness of sampling and restoration activities to ensure that any

contamination or residual source material remaining at the site where source material was used under this general license is not likely to result in exposures that exceed the limits in RH-1216.

4. Any person who receives, possesses, uses or transfers source material in accordance with the general license granted in paragraph a. of this section is exempt from the provisions of Section 3 to the extent that such receipt, possession, use, and transfer are within the terms of this general license, except that such person shall comply with the provisions of RH-1216. and RH-1400. to the extent necessary to meet the provisions of paragraphs a.2.B. and a.3. of this section. However, this exemption does not apply to any person who also holds a specific license issued pursuant to these Rules.

5. No person may initially transfer or distribute source material to persons generally licensed under paragraph a.1.A. or a.1.B. of this section, or equivalent regulations of the U.S. Nuclear Regulatory Commission or of an Agreement State, unless authorized by a specific license issued in accordance with RH-405.b.1. or equivalent provisions of the NRC or of an Agreement State. This prohibition does not apply to analytical laboratories returning processed samples to the client who initially provided the sample. Initial distribution of source material to persons generally licensed by paragraph a.1. of this section before March 1, 2016, without specific authorization may continue for one year beyond this date. Distribution may also be continued until the Department takes final action on a pending application for license or license amendment to specifically authorize distribution submitted on or before March 1, 2017.

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b. **Receipt of title to source material**.

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A general license is hereby issued authorizing the receipt of title to source material without regard to quantity. This general license does not authorize any person to receive, possess, deliver, use, or transfer source material.

c. **Certain industrial products or devices**.

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1. A general license is hereby issued to receive, acquire, possess, use, or transfer, in accordance with the provisions of paragraphs c.2. through c.5. of this section, depleted uranium contained in

industrial products or devices for the purpose of providing a concentrated mass in a small volume of the product or device.

2. The general license in paragraph c.1. of this section applies only to industrial products or devices which have been manufactured or initially transferred either in accordance with a specific license issued to the manufacturer of the products or devices pursuant to RH-405.a.1. or in accordance with a specific license issued to the manufacturer by the U.S. Nuclear Regulatory Commission or an Agreement State which authorizes manufacture of the products or devices for distribution to persons generally licensed by the NRC or an Agreement State.

3. A. Persons who receive, acquire, possess, or use depleted uranium pursuant to the general license established by paragraph c.1. of this section shall file RC FORM 513, "Registration Certificate - Use of Depleted Uranium Under General License," with the General License Registration Program, Radiation Control Section, Arkansas Department of Health. The form shall be submitted within 30 days after the first receipt or acquisition of such depleted uranium. Persons possessing depleted uranium pursuant to the general license in paragraph c.1. of this section as of March 1, 2016, shall register the depleted uranium with the Department on or before March 1, 2017. The general licensee shall furnish on the form the following information and such other information as may be required by the form:

i. Name and address of the general licensee;

~~RH-401.e.3.A. (Cont'd)~~

ii. A statement that the general licensee has developed and will maintain procedures designed to establish physical control over the depleted uranium described in paragraph c.1. of this section and designed to prevent transfer of such depleted uranium in any form, including metal scrap, to persons not authorized to receive the depleted uranium; and

iii. Name and title, address, and telephone number of the individual duly authorized to act for and on

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behalf of the general licensee in supervising the procedures identified in paragraph c.3.A.ii. of this section.

B. The general licensee possessing or using depleted uranium under the general license established by paragraph c.1. of this section shall report in writing to the Department any changes in information originally furnished by the licensee in RC FORM 513, "Registration Certificate - Use of Depleted Uranium Under General License." The report shall be submitted within 30 days after the effective date of such change.

4. A person who receives, acquires, possesses, or uses depleted uranium pursuant to the general license established by paragraph c.1. of this section:

A. Shall not introduce such depleted uranium, in any form, into a chemical, physical, or metallurgical treatment or process, except a treatment or process for repair or restoration of any plating or other covering of the depleted uranium;

B. Shall not abandon such depleted uranium;

~~RH-401.c.4. (Cont'd)~~

C. Shall transfer or dispose of such depleted uranium only by transfer in accordance with the provisions of Part E of Section 2 and RH-1400. In the case where the transferee receives the depleted uranium pursuant to the general license established by paragraph c.1. of this section, the transferor shall furnish the transferee a copy of paragraph c. of this section and a copy of RC FORM 513, "Registration Certificate - Use of Depleted Uranium Under General License." In the case where the transferee receives the depleted uranium pursuant to a general license of the U.S. Nuclear Regulatory Commission or an Agreement State that is equivalent to paragraph c., the transferor shall furnish the transferee a copy of paragraph c. and a copy of RC FORM 513, "Registration Certificate - Use of Depleted Uranium Under General License," accompanied by a note explaining that use of the product or device is regulated by the governing agency, the agency who has jurisdiction where the product or device will be in use, under

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requirements substantially the same as those in paragraph c.; and

D. Shall report in writing to the Department, within 30 days of any transfer, the name and address of the person receiving the depleted uranium pursuant to such transfer.

5. Any person receiving, acquiring, possessing, using, or transferring depleted uranium pursuant to the general license established by paragraph c.1. of this section is exempt from the requirements of Section 3, except for RH-1216. and RH-1400., with respect to the depleted uranium covered by that general license.

6. The general license provided in paragraph c.1. of this section is subject to the provisions of RH-102., RH-104. through 107., RH-200., RH-409.a.-d., RH-416., RH-600. through 603., RH-700., RH-751., and Section 4.

RH-402. **General Licenses - Radioactive Material Other Than Source Material**.

NOTE: Different general licenses are issued in this section, each of which has its own specific conditions and requirements.

a. **Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere**.

NOTE: Persons possessing radioactive material in devices under a general license in RH-402.a. before January 15, 1975, may continue to possess, use, or transfer that material in accordance with the labeling requirements of RH-402.a. devices in effect on January 14, 1975.

A general license is hereby issued to commercial and industrial firms and research, educational and medical institutions, individuals in the conduct of their business, and Federal, State or local government agencies to acquire, receive, possess, use or transfer, in accordance with the provisions of RH-402.b., c. and d., radioactive material contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing light or an ionized atmosphere.

b. 1. The general license in RH-402.a. applies only to radioactive material contained in devices which have been manufactured or initially transferred and labeled in accordance with the specifications contained in:

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A. A specific license issued under RH-405.e.; or

B. An equivalent specific license issued by the U.S. Nuclear Regulatory Commission or an Agreement State; or

C. An equivalent specific license issued by a State with provisions comparable to RH-405.e.

2. The devices must have been received from one of the specific licensees described above in RH-402.b.1. or through a transfer made under RH-402.c.9.

~~RH-402. (Cont'd)~~

c. Any person who owns, receives, acquires, possesses, uses, or transfers radioactive material in a device pursuant to the general license in RH-402.a.:

1. Shall assure that all labels affixed to the device at the time of receipt and bearing the statement that removal of the label is prohibited are maintained thereon and shall comply with all instructions and precautions provided by such labels;

2. Shall assure that the device is tested for leakage of radioactive material and proper operations of the on-off mechanism and indicator, if any, at no longer than six (6) month intervals or at such other intervals as are specified in the label; however:

A. Devices containing only krypton need not be tested for leakage of radioactive material, and

B. Devices containing only tritium or not more than 100 microcuries of other beta ~~and/or~~ or gamma emitting material or ten (10) microcuries of alpha emitting material and devices held in storage in the original shipping container prior to initial installation need not be tested for any purpose;

3. Shall assure that the tests required by RH-402.c.2. and other testing, installation, servicing and removal from installation involving the radioactive materials, its shielding or containment, are performed:

A. In accordance with the instructions provided by the labels; or

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B. By a person holding a specific license from the Department, the U.S. Nuclear Regulatory Commission or an Agreement State to perform such activities;

~~RH-402.c. (Cont'd)~~

4. Shall maintain records showing compliance with the requirements of RH-402.c.2. and c.3. The records must show the results of tests. The records also must show the dates of performance of, and the names of persons performing, testing, installing, servicing, and removing from the installation radioactive material and its shielding or containment. The licensee shall retain these records as follows:

A. Each record of a test for leakage or radioactive material required by RH-402.c.2. must be retained for three (3) years after the next required leak test is performed or until the sealed source is transferred or disposed of.

B. Each record of a test of the on-off mechanism and indicator required by RH-402.c.2. must be retained for three (3) years after the next required test of the on-off mechanism and indicator is performed or until the sealed source is transferred or disposed of.

C. Each record that is required by RH-402.c.3. must be retained for three (3) years from the date of the recorded event or until the device is transferred or disposed of.

5. Shall immediately suspend operation of the device if there is a failure of, or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the on-off mechanism or indicator, or upon the detection of 185 bequerel (0.005 microcurie) or more removable radioactive material. The device may not be operated until it has been repaired by the manufacturer or other person holding a specific license to repair such devices that was issued under RH-405.e. or the U.S. Nuclear Regulatory Commission or by an Agreement State.

The device and any radioactive material from the device may only be disposed of by transfer to a person authorized by a specific license to receive the radioactive material in the device or as otherwise approved by the Department. A report containing a brief description of the event and the remedial action taken; and, in the case of detection of 0.005 microcurie or more removable

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radioactive material or failure of or damage to a source likely to result in contamination of the premises or the environs, a plan for ensuring that the premises and environs are acceptable for unrestricted use, must be furnished within thirty (30) days to:

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~~RH-402.c.5. (Cont'd)~~

Arkansas Department of Health
Radiation Control Section
ATTN: General License Registration Program
4815 West Markham Street, Slot 30
Little Rock, Arkansas 72205-3867

Under these circumstances, the criteria set out in RH-1216., ''Radiological Criteria for Unrestricted Use,'' may be applicable, as determined by the Department on a case-by-case basis;

6. Shall not abandon the device containing radioactive material;

7. Shall not export the device containing radioactive material except in accordance with U.S. Nuclear Regulatory Commission Regulations outlined in Part 110, "Export and Import of Nuclear Equipment and Material";

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8. A. Shall transfer or dispose of the device containing radioactive material only by export as provided by U.S. Nuclear Regulatory Commission Regulations outlined in Part 110, "Export and Import of Nuclear Equipment and Material," by transfer to another general licensee as authorized by RH-402.c.9., or to a person authorized to receive the device by a specific license issued under Section 2, or Section 2 that authorizes waste collection, or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State, or as otherwise approved under RH-402.c.8.C.

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B. Shall, within thirty (30) days after the transfer of the device to a specific licensee or export, furnish a report to:

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Arkansas Department of Health
Radiation Control Section
ATTN: General License Registration Program
4815 West Markham Street, Slot 30
Little Rock, Arkansas 72205-3867

The report must contain:

i. The identification of the device by manufacturer's (or initial transferor's) name, model number, and serial number;

ii. The name, address, and license number of the person receiving the device (license number not applicable if exported); and

iii. The date of the transfer.

C. Shall obtain written Department approval before transferring the device to any other specific licensee not specifically identified in RH-402.c.8.A.; however, a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if, the holder:

i. Verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use;

ii. Removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by RH-402.c.1.) so that the device is labeled in compliance with RH-1309.; however, the manufacturer, model number, and serial number must be retained;

iii. Obtains the manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license (such as leak testing procedures); and

iv. Reports the transfer under RH-402.c.8.B.

9. Shall transfer the device to another general licensee only if:

A. The device remains in use at a particular location. In this case, the transferor shall give the transferee a copy of RH-402.a.-e., RH-600., RH-1501., and RH-1502., and any

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safety documents identified in the label of the device. Within thirty (30) days of the transfer, the transferor shall report to:

~~RH-402.e.9.A. (Cont'd)~~

Arkansas Department of Health
Radiation Control Section
ATTN: General License Registration Program
4815 West Markham Street, Slot 30
Little Rock, Arkansas 72205-3867

i. The manufacturer's (or initial transferor's) name;

ii. The model number and the serial number of the device transferred;

iii. The transferee's name and mailing address for the location of use; and

iv. The name, title, and phone number of the responsible individual identified by the transferee in accordance with RH-402.c.12. to have knowledge of and authority to take actions to ensure compliance with the appropriate rules and requirements; or

B. The device is held in storage by an intermediate person in the original shipping container at its intended location of use prior to initial use by a general licensee.

10. Shall comply with the provisions of RH-1501. and RH-1502. for reporting radiation incidents, theft, or loss of licensed material, but shall be exempt from the other requirements of Section 3.

11. Shall respond to written requests from the Department to provide information relating to the general license within thirty (30) calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the General License Registration Program a written justification for the request.

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12. Shall appoint an individual responsible for having knowledge of the appropriate rules and requirements and the authority for taking required actions to comply with appropriate rules and requirements. The general licensee, through this individual, shall ensure the day-to-day compliance with appropriate rules and requirements. This appointment does not relieve the general licensee of any of its responsibility in this regard.

13. A. Shall register, in accordance with RH-402.c.13.B. and C. devices containing at least ten (10) mCi (370 MBq) of cesium-137, 0.1 mCi (3.7 MBq) of strontium-90, one (1) mCi (37 MBq) of cobalt-60, 0.1 mCi (3.7 MBq) of radium-226, one (1) mCi (37 MBq) of nickel-63, or one (1) mCi (37 MBq) of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label. Each address for a location of use, as described under RH-402.c.13.C., represents a separate general licensee and requires a separate registration and fee.

B. If in possession of a device meeting the criteria of RH-402.c.13.A., shall register these devices annually with the Department and shall pay the appropriate fee. Registration must be done by verifying, correcting, ~~and/or~~ or adding to the information provided in a request for registration received from the Department. The registration information must be submitted to the Department within thirty (30) days of the date of the request for registration or as otherwise indicated in the request. In addition, a general licensee holding devices meeting the criteria of RH-402.c.13.A. is subject to the bankruptcy notification requirement in RH-409.g.

C. In registering devices, the general licensee shall furnish the following information and any other information specifically requested by the Department:

i. Name and mailing address of the general licensee.

ii. Information about each device: the manufacturer (or initial transferor), model number, serial number, the radioisotope and activity as indicated on label.

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~~RH-402.c.13.C. (Cont'd)~~

iii. Name, title, and telephone number of the responsible person designated as a representative of the general licensee under RH-402.c.12.

iv. Address or location at which the device(s) are used ~~and/or~~ or stored. ~~-~~For portable devices, the address of the primary place of storage.

v. Certification by the responsible representative of the general licensee that the information concerning the device(s) has been verified through a physical inventory and checking of label information.

vi. Certification by the responsible representative of the general licensee that they are aware of the requirements of the general license.

D. Persons generally licensed by the U.S. Nuclear Regulatory Commission or an Agreement State with respect to devices meeting the criteria in RH-402.c.13.A. are subject to registration requirements if the devices are used in areas subject to Arkansas Department of Health jurisdiction.~~-~~ The Department will request registration information from such licensees.

14. Shall report changes to the mailing address for the location of use (including change in name of general licensee) to the:

Arkansas Department of Health
Radiation Control Section
Attention: General License Registration Program
4815 West Markham Street, Slot 30
Little Rock, Arkansas 72205-3867

within thirty (30) days of the effective date of the change. ~~-~~For a portable device, a report of address change is only required for a change in the device's primary place of storage.

~~RH-402.c. (Cont'd)~~

15. May not hold devices that are not in use for longer than twenty-four (24) months following the last principal activity use.

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A. If devices with shutters are not being used, the shutter must be locked in the closed position. -The testing required by RH-402.c.2. need not be performed during the period of storage only. -However, when devices are put back into service or transferred to another person, and have not been tested within the required test interval, they must be tested for leakage before use or transfer and the shutter tested before use.

B. Devices kept in standby for future use are excluded from the twenty-four (24) month time limit if the Department approves a plan for future use submitted by the licensee. Licensees shall submit plans at least thirty (30) days prior to the end of the twenty-four (24) months of nonuse.

C. The general licensee shall perform quarterly physical inventories of these devices while they are in standby. Records of the quarterly physical inventories shall be maintained for inspection by the Department for five (5) years after they are made.

d. The general license in RH-402.a. does not authorize the manufacture or import of devices containing radioactive material.

e. The general license provided in RH-402.a. is subject to the provisions of RH-102., RH-104. through 107., RH-200., RH-301.a.4., RH-409.a.-d., RH-416., Part E of Section 2, RH-600. through 603., RH-700., RH-751., and Section 4.

~~RH-402. (Cont'd)~~

f. **Luminous safety devices in aircraft**.

1. A general license is hereby issued to own, receive, acquire, possess and use tritium or promethium-147 contained in luminous safety devices for use in aircraft, provided each device contains not more than ten (10) curies (370 GBq) of tritium or 300 millicuries (11.1 GBq) of promethium-147 and that each device has been manufactured, assembled, or initially transferred in accordance with the specifications contained in a specific license issued to the manufacturer, assembler, or initial transferor by the Department pursuant to RH-405.h.,or by the U.S. Nuclear Regulatory Commission or an Agreement State pursuant to equivalent requirements.

2. Persons who own, receive, acquire, possess or use luminous safety devices pursuant to the general license in RH-402.f.1. are exempt

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from the requirements of Section 3, except that they shall comply with the provisions of RH-1501. and RH-1502.

3. This general license does not authorize the manufacture, assembly, repair, import, or export of luminous safety devices containing tritium or promethium-147.

4. This general license does not authorize the ownership, receipt, acquisition, possession or use of promethium-147 contained in instrument dials.

5. The general license in paragraph f.1. of this section is subject to the provisions of RH-102., RH-104. through 107., RH-200., RH-301.a.4., RH-409.a.-d., RH-416., Part E of Section 2, RH-600. through 603., RH-700., RH-751., and Section 4.

g. **Calibration and reference sources**.

1. A general license is hereby issued to those persons listed below to own, receive, acquire, possess, use, and transfer, in accordance with the provisions of paragraphs g.4. and g.5. of this section, americium-241 in the form of calibration or reference sources:

A. Any person who holds a specific license issued by the Department which authorizes receipt, possession, use, and transfer of radioactive material; and

~~RH-402.g.1. (Cont'd)~~

B. Any person who holds a specific license issued by the U.S. Nuclear Regulatory Commission which authorizes receipt, possession, use, and transfer of special nuclear material.

2. A general license is hereby issued to own, receive, possess, use, and transfer plutonium in the form of calibration or reference sources in accordance with the provisions of paragraphs g.4. and g.5. of this section to any person who holds a specific license issued by the Department which authorizes receipt, possession, use, and transfer of radioactive material.

3. A general license is hereby issued to own, receive, possess, use, and transfer radium-226 in the form of calibration or reference

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sources in accordance with the provisions of paragraphs g.4. and g.5. of this section to any person who holds a specific license issued by the Department which authorizes receipt, possession, use, and transfer of radioactive material.

4. The general licenses in paragraphs g.1. through g.3. of this section apply only to calibration or reference sources which have been manufactured or initially transferred in accordance with the specifications contained in a specific license issued to the manufacturer or initial transferor of the sources by the Department pursuant to RH-405.i., or by the U.S. Nuclear Regulatory Commission or an Agreement State pursuant to equivalent requirements.

5. The general licenses in paragraphs g.1. through g.3. of this section are subject to the provisions of RH-102., RH-104. through 107., RH-200., RH-301.a.4., RH-409.a.-d., RH-416., Part E of Section 2, RH-600. through RH-603., RH-700., RH-751., Section 3, and Section 4.- The general license in paragraph g.2. is also subject to RH-409.g.- In addition, persons who own, receive, acquire, possess, use, or transfer one (1) or more calibration or reference sources pursuant to these general licenses:

A. Shall not possess at any one time, at any one location of storage or use, more than five (5) microcuries (185 kBq) of americium-241, five (5) microcuries (185 kBq) of plutonium, or five (5) microcuries (185 kBq) of radium-226 in such sources;

~~RH-402.g.5. (Cont'd)~~

B. Shall not receive, possess, use, or transfer such source unless the source, or the storage container, bears a label which includes the following statement or a substantially similar statement which contains the information called for in the following statement:

"**The receipt, possession, use and transfer of this source, Model _____, Serial No. _____, are subject to a general license and the regulations of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. -Do not remove this label.**

CAUTION—RADIOACTIVE MATERIAL
THIS SOURCE CONTAINS AMERICIUM-241

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[PLUTONIUM OR RADIUM-226]. DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

(name of manufacturer or initial transferor)"

C. Shall not transfer, abandon, or dispose of such source except by transfer to a person authorized by a license from the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State to receive the source;

D. Shall store such source, except when the source is being used, in a closed container adequately designed and constructed to contain americium-241, plutonium, or radium-226 which might otherwise escape during storage; and

E. Shall not use such source for any purpose other than the calibration of radiation detectors or the standardization of other sources.

6. These general licenses do not authorize the manufacture, import, or export of calibration or reference sources containing americium-241, plutonium, or radium-226.

~~RH-402. (Cont'd)~~

h. **Ownership of byproduct material**.

A general license is hereby issued to own byproduct material without regard to quantity. Notwithstanding any other provision of these Rules, a general licensee under this paragraph is not authorized to manufacture, produce, transfer, receive, possess, use, import, or export byproduct material, except as authorized in a specific license.

i. **Ice detection devices**.

1. A general license is hereby issued to own, receive, acquire, possess, use, and transfer strontium-90 contained in ice detection devices, provided each device contains not more than 50 microcuries (1.85 MBq) of strontium-90 and that each device has been manufactured or initially transferred in accordance with the specifications contained in a specific license issued to the manufacturer or initial transferor by the Department pursuant to RH-405.k., or by the U.S. Nuclear Regulatory Commission or an Agreement State pursuant to equivalent requirements.

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2. Persons who own, receive, acquire, possess, use, or transfer strontium-90 contained in ice detection devices pursuant to the general license in paragraph i.1. of this section:

A. Shall, upon occurrence of visually observable damage, such as a bend or crack or discoloration from overheating, to the device, discontinue use of the device until it has been inspected, tested for leakage, and repaired by a person holding a specific license from the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State to manufacture or service such devices; or shall dispose of the device pursuant to the provisions of RH-1400;

B. Shall assure that all labels affixed to the device at the time of receipt, and which bear a statement which prohibits removal of the labels, are maintained thereon;

C. Are exempt from the requirements of Section 3 except that such persons shall comply with the provisions of RH-1400., RH-1501., and RH-1502.

3. This general license does not authorize the manufacture, assembly, disassembly, repair, import, or export of strontium-90 in ice detection devices.

~~RH-402.i. (Cont'd)~~

4. The general license in paragraph i.1. of this section is subject to the provisions of RH-102., RH-104. through 107., RH-200., RH-301.a.4., RH-409.a.-d., RH-416., Part E of Section 2, RH-600. through 603., RH-700., RH-751., and Section 4.

j. **Products containing radium-226**.

1. A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, in accordance with the provisions of RH-402.j.2. through 4., radium-226 contained in the following products manufactured prior to November 30, 2007.

A. Antiquities originally intended for use by the general public. ~~-~~For the purposes of this subparagraph, antiquities mean products originally intended for use by the general public and distributed in the late 19th and early 20th centuries, such as radium emanator jars, revigators, radium

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water jars, radon generators, refrigerator cards, radium bath salts, and healing pads.

B. Intact timepieces containing greater than one (1) microcurie (0.037 MBq), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces.

C. Luminous items installed in air, marine, or land vehicles.

D. All other luminous products, provided that no more than 100 items are used or stored at the same location at any one time.

E. Small radium sources containing no more than one (1) microcurie (0.037 MBq) of radium-226. For the purposes of this subparagraph, ''small radium sources'' means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (such as cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or as designated by the U.S. Nuclear Regulatory Commission.

~~RH-402.j. (Cont'd)~~

2. Persons who acquire, receive, possess, use, or transfer radioactive material under the general license issued in RH-402.j.1. are exempt from the provisions of Section 3, and RH-600.a., b., d.-f., and RH-601., to the extent that the receipt, possession, use, or transfer of radioactive material is within the terms of the general license; provided, however, that this exemption shall not be deemed to apply to any such person specifically licensed under this Section.

3. Any person who acquires, receives, possesses, uses, or transfers radioactive material in accordance with the general license in RH-402.j.1. shall:

A. Notify the Department should there be any indication of possible damage to the product so that it appears it could result in a loss of the radioactive material. A report containing a brief description of the event, and the remedial action taken, must be furnished within 30 days to:

Arkansas Department of Health
Radiation Control Section

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Attention: Radioactive Materials Program
4815 West Markham Street, Slot 30
Little Rock, Arkansas 72205

B. Not abandon products containing radium-226. The product, and any radioactive material from the product, may only be disposed of according to RH-1408. or by transfer to a person authorized by a specific license to receive the radium- 226 in the product or as otherwise approved by the U.S. Nuclear Regulatory Commission or an Agreement State.

C. Not export products containing radium-226 except in accordance with 10 CFR Part 110.

~~RH-402.j.3. (Cont'd)~~

D. Dispose of products containing radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005, by transfer to a person authorized to receive radium-226 by a specific license issued under Section 2, or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State, or as otherwise approved by the U.S. Nuclear Regulatory Commission or an Agreement State.

E. Respond to written requests from the Department to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the Department a written justification for the request.

4. The general license in RH-402.j.1. does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.

5. The general license in RH-402.j.1. is subject to the provisions of RH-102., RH-104. through 107., RH-200., RH-301.a.4., RH-409.a.-d., RH-416., Part E of Section 2, RH-600.c., RH-602. and 603., RH-700., RH-751., and Section 4.

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k. **Use of radioactive material for certain *in vitro* clinical or laboratory testing**.[8/]

1. A general license is hereby issued to any physician, veterinarian, clinical laboratory, or hospital to receive, acquire, possess, transfer, or use, for any of the following stated tests, in accordance with the provisions of RH-402.k.2., 3., 4., 5. and 6., the following radioactive materials in prepackaged units:

A. Carbon-14, in units not exceeding ten (10) microcuries each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

~~RH-402.k.1. (Cont'd)~~

B. Cobalt-57, in units not exceeding ten (10) microcuries each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

C. Hydrogen-3 (tritium), in units not exceeding fifty (50) microcuries each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

D. Iodine-125, in units not exceeding ten (10) microcuries each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

E. Iodine-131, in units not exceeding ten (10) microcuries each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

F. Iron-59, in units not exceeding twenty (20) microcuries each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

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G. Mock Iodine-125 reference or calibration sources, in units not exceeding 0.05 microcurie of iodine-129 and 0.005 microcurie of americium-241 each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

H. Selenium-75, in units not exceeding ten (10) microcuries each for use in *in vitro* clinical or laboratory tests not involving internal or external administration of radioactive material, or the radiation therefrom, to human beings or animals.

~~RH-402.k.2. (Cont'd)~~

2. No person shall receive, acquire, possess, use, or transfer radioactive material pursuant to the general license established by RH-402.k.1. until the individual has filed RC FORM 512, "Registration Certificate - *In Vitro* Testing with Radioactive Material under General License," with the General License Registration Program, Radiation Control Section, Arkansas Department of Health and received from the Department a validated copy of this form with registration number assigned or until he has been authorized pursuant to RH-8013. to use radioactive material under the general license in RH-402.k. The registrant shall furnish on the above form the following information and such other information as may be required by that form:

A. Name and address of the registrant;

B. The location of use; and

C. A statement that the registrant has appropriate radiation measuring instruments to carry out *in vitro* clinical or laboratory tests with radioactive materials as authorized under the general license in RH-402.k., and that such tests will be performed only by personnel competent in the use of such instruments and in the handling of the radioactive materials.

3. A person who receives, acquires, possesses, or uses radioactive material pursuant to the general license established by RH-402.k.1. shall comply with the following:

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A. The general licensee shall not possess at any one (1) time, pursuant to the general license established by RH-402.k.1. at any one location of storage or use, a total amount of iodine-125, iodine-131, selenium-75, cobalt-57, ~~and/or~~or iron-59 in excess of 200 microcuries.

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B. The general licensee shall store the radioactive material, until used, in the original shipping container or in a container providing equivalent radiation protection.

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C. The general licensee shall use the radioactive material only for the uses authorized by RH-402.k.1.

~~RH-402.k.3. (Cont'd)~~

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D. The general licensee shall not transfer the radioactive material except by transfer to a person authorized to receive it pursuant to a license issued by the Department, the U.S. Nuclear Regulatory Commission, or any Agreement State, nor transfer the radioactive material in any manner other than in the unopened, labeled shipping container as received from the supplier.

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E. The general licensee shall dispose of the Mock Iodine-125 reference or calibration sources described in RH-402.k.1.G. as required by RH-1400.

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4. The general licensee shall not receive, acquire, possess, or use radioactive material pursuant to RH-402.k.1.:

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A. Except as prepackaged units which are labeled in accordance with the provisions of a specific license issued by the U.S. Nuclear Regulatory Commission, or any Agreement State that authorizes manufacture and distribution of iodine-125, iodine-131, carbon-14, hydrogen-3 (tritium), selenium-75, iron-59, cobalt-57, or Mock Iodine-125 for distribution to persons generally licensed under RH-402.k.1.

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B. Unless the following statement or a substantially similar statement which contains the information called for in the following statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

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"This radioactive material may be received, acquired, possessed, and used only by physicians, veterinarians in the practice of veterinary medicine, clinical laboratories, or hospitals and only for *in vitro* clinical or laboratory tests not involving internal or external administration of the material, or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use, and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.

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_____

(name of manufacturer)"

~~RH-402.k. (Cont'd)~~

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5. The registrant possessing or using radioactive material under the general license of RH-402.k.1. shall report in writing to the Radiation Control Section, any changes in the information furnished by him in the RC FORM 512, "Registration Certificate - *In Vitro* Testing with Radioactive Material under General License." The report shall be furnished within thirty (30) days after the effective date of such change.

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6. Any person using radioactive material pursuant to the general license of RH-402.k.1. is exempt from the requirements of Section 3, with respect to radioactive material covered by that general license, except that such persons using the Mock Iodine-125 described in RH-402.k.1.G. shall comply with the provisions of RH-1400., RH-1501., and RH-1502.

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7. The general license in RH-402.k.1. is subject to the provisions of RH-102., RH-104. through 107., RH-200., RH-301.a.4., RH-409.a.-d., RH-416., Part E of Section 2, RH-600. through 603., RH-700., RH-751., and Section 4.

l. Reserved.

m. **Ownership of special nuclear material**.

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A general license is hereby issued to receive title to and own special nuclear material without regard to quantity. Notwithstanding any other provision of these Rules, a general licensee under this paragraph is not authorized to acquire, deliver, receive, possess, use, transfer, import, or export special nuclear material, except as authorized in a specific license.

n. **Incidentally produced radioactive material generated by the operation of a particle accelerator**.

A general license is hereby issued to possess radioactive material produced incidentally to the operation of a particle accelerator. The general license is subject to the applicable provisions of this Section and Section 3. A licensee shall transfer this radioactive material in accordance with Part E of this Section and Section 4. A licensee shall dispose of this radioactive material only by way of Department approved procedures. However, license complexity may require the Department to issue a specific license, instead, regarding the incidentally produced radioactive material.

RH-403. **Application for Specific Licenses**.

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a. Application for specific licenses shall be filed on forms supplied by the Arkansas Department of Health, Radiation Control Section, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867. The application shall set forth all applicable information called for by the form. An application for a license may request a license for one or more activities.

b. The Department may at any time after the filing of the original application and before the expiration of the license, require further statements in order to enable the Department to determine whether the application should be granted or denied or whether a license should be modified or revoked.

c. Each application shall be signed by the applicant or licensee or an individual duly authorized to act for and on his behalf.

d. In the application, the applicant may incorporate, by reference, information contained in previous applications, statements or reports filed with the Department, provided that such references are clear and specific.

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e. Applications and documents submitted to the Department in connection with the applications may be made available for public inspection except that the Department may withhold any document or part thereof from public inspection if disclosure of its contents is not required in the public interest and would adversely affect the interest of a person concerned.

f. The Department may verify information contained in applications and secure additional information deemed necessary to make a reasonable determination as to whether to issue a license and whether special conditions should be attached thereto by visiting the facility or location

where radioactive materials would be possessed or used and by discussing details of proposed possession or use of the radioactive materials with the applicant or his designated representative.

g. **Requirements for emergency response plans for certain licensees**.

1. Each application to possess radioactive materials in unsealed form, on foils or plated sources, or sealed in glass in excess of the quantities in RH-905., Schedule F to Section 2 – "Quantities of Radioactive Materials Requiring Consideration of the Need for an Emergency Plan for Responding to a Release," must contain either:

~~RH-403.g.1. (Cont'd)~~

A. An evaluation showing that the maximum dose to a person offsite due to a release of radioactive materials would not exceed 0.5 rem effective dose equivalent or 5 rem to the thyroid; or

B. An emergency plan for responding to a release of radioactive material.

2. One or more of the following factors may be used to support an evaluation submitted under RH-403.g.1.A.:

A. The radioactive material is physically separated so that only a portion could be involved in an accident;

B. All or part of the radioactive material is not subject to release during an accident because of the way it is stored or packaged;

C. The release fraction in the respirable size range would be lower than the release fraction shown in RH-905. due to the chemical or physical form of the material;

D. The solubility of the radioactive material would reduce the dose received;

E. Facility design or engineered safety features in the facility would cause the release fraction to be lower than shown in RH-905.;

F. Operating restrictions or procedures would prevent a release fraction as large as that shown in RH-905.; or

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G. Other factors appropriate for the specific facility.

3. An emergency plan for responding to a release of radioactive material submitted under RH-403.g.1.B. must include the following information:

A. **Facility description**.

A brief description of the licensee's facility and area near the site.

~~RH-403.g.3. (Cont'd)~~

B. **Types of accidents**.

An identification of each type of radioactive materials accident for which protective actions may be needed.

C. **Classification of accidents**.

A system for classifying each accident as "alert" or "site area emergency."

D. **Detection of accidents**.

Identification of the means of detecting each type of accident in a timely manner.

E. **Mitigation of consequences**.

A brief description of the means and equipment for mitigating the consequences of each type of accident, including those provided to protect workers onsite, and a description of the program for maintaining the equipment.

F. **Assessment of releases**.

A brief description of the methods and equipment to assess releases of radioactive materials.

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G. **Responsibilities**.

A brief description of the responsibilities of licensee personnel should an accident occur, including identification of personnel responsible for promptly notifying offsite response organizations and the Department; also responsibilities for developing, maintaining, and updating the plan.

~~RH-403.g.3. (Cont'd)~~

H. **Notification and coordination**.

A commitment to and a brief description of the means to promptly notify offsite response organizations and request offsite assistance, including medical assistance for the treatment of contaminated injured onsite workers when appropriate. A control point must be established. The notification and coordination must be planned so that unavailability of some personnel, parts of the facility, and some equipment will not prevent the notification and coordination. The licensee shall also commit to notify the Department immediately after notification of the appropriate offsite response organizations and not later than one hour after the licensee declares an emergency.

I. **Information to be communicated**.

A brief description of the types of information regarding facility status, radioactive releases and, if necessary, recommended protective actions.

J. **Training**.

A brief description of the frequency, performance objectives and plans for the training that the licensee will provide workers on how to respond to an emergency including any special instructions and orientation tours the licensee would offer to fire, police, medical and other emergency personnel. The training shall familiarize personnel with site-specific emergency procedures.

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Also, the training shall thoroughly prepare site personnel for their responsibilities in the event of accident scenarios postulated as most probable for the specific site, including the use of team training for such scenarios.

K. **Safe shutdown**.

A brief description of the means of restoring the facility to a safe condition after an accident.

~~RH-403.g.3. (Cont'd)~~

L. **Exercises**.

Provisions for conducting quarterly communications checks with offsite response organizations and biennial onsite exercises to test response to simulated emergencies. Quarterly communications checks with offsite response organizations must include the check and update of all necessary telephone numbers. The licensee shall invite offsite response organizations to participate in the biennial exercises. Participation of offsite response organizations in biennial exercises, although recommended, is not required. Exercises must use accident scenarios postulated as most probable for the specific site; the scenarios shall not be known to most exercise participants.

The licensee shall critique each exercise using individuals not having direct implementation responsibility for the plan. Critiques of exercises must evaluate the appropriateness of the plan, emergency procedures, facilities, equipment, training of personnel, and overall effectiveness of the response. Deficiencies found by the critiques must be corrected.

M. **Hazardous chemicals**.

A certification that the applicant has met its responsibilities under the Emergency Planning and Community Right-to-Know Act of 1986, Title III, Public Law 99-499, if applicable to the applicant's activities at the proposed place of use of the radioactive material.

4. The licensee shall allow the Department and the offsite response organizations expected to respond in case of an accident sixty (60) days to comment on the licensee's emergency plan before

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submitting it in final form to the Department. -The licensee shall provide any comments received within the sixty (60) days to the Department with the emergency plan.

h. 1. Except as provided in paragraphs h.2., h.3., and h.4. of this section, an application for a specific license to use radioactive material in the form of a sealed source or in a device that contains the sealed source must either:

~~RH-403.h.1. (Cont'd)~~

A. Identify the source or device by manufacturer and model number as registered with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210, with an Agreement State, or for a source or a device containing radium-226 or accelerator-produced radioactive material with a State under provisions comparable to 10 CFR 32.210; or

B. Contains the information identified in 10 CFR 32.210(c).

2. For sources or devices manufactured before October 23, 2012 that are not registered with the NRC under 10 CFR 32.210 or with an Agreement State, and for which the applicant is unable to provide all categories of information specified in 10 CFR 32.210(c), the application must include:

A. All available information identified in 10 CFR 32.210(c) concerning the source, and, if applicable, the device; and

B. Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. -Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.

3. For sealed sources and devices allowed to be distributed without registration of safety information in accordance with 10 CFR 32.210(g)(1), the applicant may supply only the manufacturer, model number, and radionuclide and quantity.

4. If it is not feasible to identify each sealed source and device individually, the applicant may propose constraints on the number

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and type of sealed sources and devices to be used and the conditions under which they will be used, in lieu of identifying each sealed source and device.

i. In accordance with RH-409.h., certain licensees must furnish a proposed decommissioning funding plan or a certification of financial assurance for decommissioning.

~~RH-403. (Cont'd)~~

j. An application from a medical facility, educational institution, or Federal facility to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under Section 9 or equivalent Agreement State requirements shall include:

1. A request for authorization for the production of PET radionuclides or evidence of an existing license issued under this Section or Agreement State requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides.

2. Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in RH-405.l.1.B.

3. Identification of individual(s) authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in RH-405.l.2.B.

4. Information identified in RH-405.l.1.C. on the PET drugs to be noncommercially transferred to members of its consortium.

RH-404. **General Requirements for the Issuance of Specific Licenses**.

A license application will be approved if the Department determines that:

a. The applicant is qualified by reason of training and experience to use the material in question for the purpose requested in accordance with these Rules in such a manner as to minimize danger to public health and safety or property;

b. The applicant's proposed equipment, facilities and procedures are adequate to protect health and minimize danger to public health and safety or property;

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c. The issuance of the license will not be inimical to the health and safety of the public;

d. The applicant satisfies any applicable special requirements contained in Section 2, Section 3, Sections 7 through 9, and Section 12; and

~~RH-404. (Cont'd)~~

e. In the case of an application for a license to receive and possess radioactive material for the conduct of any activity which the Department determines will significantly affect the quality of the environment, the Director of the Arkansas Department of Health, or ~~his/her~~his or her designee, before commencement of construction of the plant or facility in which the activity will be conducted, on the basis of information filed and evaluations made pursuant to Subpart A, "National Environmental Policy Act – Regulations Implementing Section 102(2)," of 10 CFR Part 51, has concluded, after weighing the environmental, economic, technical, and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of construction prior to such conclusion shall be grounds for denial of a license to receive and possess radioactive material in such plant or facility. ~~-~~Commencement of construction as defined in RH-200. may include non-construction activities if the activity has a reasonable nexus to radiological safety and security.

RH-405. **Special Requirements for the Issuance of Certain Specific Licenses**.

a. **Licensing of the manufacture and initial transfer of industrial products and devices containing depleted uranium**.

1. **Special requirements for issuance of specific licenses under RH-405.a.1**.

A. An application for a specific license to manufacture industrial products and devices containing depleted uranium, or to initially transfer such products or devices, for use pursuant to RH-401.c. or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State, will be approved if:

i. The applicant satisfies the general requirements specified in RH-404.;

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~~RH-405.a.1.A. (Cont'd)~~

ii. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, proposed uses, and potential hazards of the industrial product or device to provide reasonable assurance that possession, use, or transfer of the depleted uranium in the product or device is not likely to cause any individual to receive in one (1) year a radiation dose in excess of ten percent (10%) of the annual limits specified in RH-1200.a.; and

iii. The applicant submits sufficient information regarding the industrial product or device and the presence of depleted uranium for a mass-volume application in the product or device to provide reasonable assurance that unique benefits will accrue to the public because of the usefulness of the product or device.

B. In the case of an industrial product or device whose unique benefits are questionable, the Department will approve an application for a specific license under this paragraph only if the product or device is found to combine a high degree of utility and low probability of uncontrolled disposal and dispersal of significant quantities of depleted uranium into the environment.

C. The Department may deny an applicant for a specific license under this paragraph if the end uses of the industrial product or device cannot be reasonably foreseen.

2. **Conditions of specific licenses issued pursuant to RH-405.a.1**.

Each person licensed pursuant to RH-405.a.1. shall:

A. Maintain the level of quality control required by the license in the manufacture of the industrial product or device, and in the installation of the depleted uranium into the product or device;

B. Label or mark each unit to:

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~~RH-405.a.2.B. (Cont'd)~~

i. Identify the manufacturer or initial transferor of the product or device and the number of the license under which the product or device was manufactured or initially transferred, the fact that the product or device contains depleted uranium, and the quantity of depleted uranium in each product or device; and

ii. State that the receipt, possession, use, and transfer of the product or device are subject to a general license or the equivalent and the regulations of the NRC or of an Agreement State;

C. Assure that the depleted uranium before being installed in each product or device has been impressed with the following legend clearly legible through any plating or other covering: "**DEPLETED URANIUM**";

D. i. Furnish a copy of the general license contained in RH-401.c. and a copy of RC FORM 513, "Registration Certificate - Use of Depleted Uranium Under General License," to each person to whom the licensee transfers depleted uranium in a product or device for use pursuant to the general license contained in RH-401.c.; or

ii. Furnish a copy of the general license contained in the NRC's or Agreement State's regulation equivalent to RH-401.c. and a copy of the NRC's or Agreement State's certificate, or alternately, furnish a copy of the general license contained in RH-401.c. and a copy of RC FORM 513, "Registration Certificate - Use of Depleted Uranium Under General License," to each person to whom the licensee transfers depleted uranium in a product or device for use pursuant to the general license of the NRC or an Agreement State. If a copy of the general license in RH-401.c. and a copy of RC FORM 513, "Registration Certificate - Use of Depleted Uranium Under General License," are furnished to such person, they shall be accompanied by a note explaining that use of the product or device is regulated by the NRC or an Agreement State, depending on which agency has jurisdiction

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where the product or device will be in use, under requirements substantially the same as those in RH-401.c.;

E. i. Report to the Department all transfers of industrial products or devices to persons for use under the general license in RH-401.c. Such report shall identify each general licensee by name and address, an individual by name and title who may constitute a point of contact between the Department and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such a product or device is transferred to the generally licensed person. If no transfers have been made to persons generally licensed under RH-401.c. during the reporting period, the report shall so indicate;

ii. Report to the agency where the product or device will be in use, the NRC or an Agreement State, all transfers of industrial products or devices to persons for use under the general license in the NRC's or an Agreement State's regulations equivalent to RH-401.c. Such report shall identify each general licensee by name and address, an individual by name and title who may constitute a point of contact between the agency and the general licensee, the type and model number of device transferred, and the quantity of depleted uranium contained in the product or device. The report shall be submitted within 30 days after the end of each calendar quarter in which such product or device is transferred to the generally licensed person. If no transfers have been made to NRC general licensees or to general licensees within a particular Agreement State during the reporting period, this information shall be reported to the NRC or to the responsible Agreement State agency upon request of the appropriate governing agency; and

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F. Keep records showing the name, address, and a point of contact for each general licensee to whom the licensee transfers depleted uranium in industrial products or devices for use pursuant to the general license provided in RH-401.c. or equivalent regulations of the NRC or an Agreement State. The records shall be maintained for three (3) years from the date of transfer and shall show the date of each transfer, the quantity of depleted uranium in each product or device transferred, and compliance with the report requirements of this paragraph.

b. **Licensing of the initial transfer of source material for use under the "small quantities of source material" general license**.

1. **Special requirements for issuance of specific licenses under RH-405.b.1**.

An application for a specific license to initially transfer source material for use under RH-401.a., or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State, will be approved if:

A. The applicant satisfies the general requirements specified in RH-404.; and

B. The applicant submits adequate information on, and the Department approves the methods to be used for quality control, labeling, and providing safety instructions to recipients.

2. **Conditions of specific licenses issued pursuant to RH-405.b.1**.

A. Each person licensed under RH-405.b.1. shall label the immediate container of each quantity of source material with the type of source material and quantity of material and the words, "**RADIOACTIVE MATERIAL**."

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B. Each person licensed under RH-405.b.1. shall ensure that the quantities and concentrations of source material are as labeled and indicated in any transfer records.

~~RH-405.b.2. (Cont'd)~~

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C. Each person licensed under RH-405.b.1. shall provide the information specified in paragraph b.2.C. of this section to each person to whom source material is transferred for use

under RH-401.a. or equivalent provisions in NRC or Agreement State regulations. This information must be transferred before the source material is transferred for the first time in each calendar year to the particular recipient. The required information includes:

i. A copy of RH-401.a. and Part E of Section 2, or relevant equivalent regulations of the NRC or an Agreement State; and

ii. Appropriate radiation safety precautions and instructions relating to handling, use, storage, and disposal of the material.

D. Each person licensed under RH-405.b.1 shall report transfers as follows:

i. File a report with the Department. The report shall include the following information:

(a). The name, address, and license number of the person who transferred the source material;

(b). For each general licensee under RH-401.a. or equivalent NRC or Agreement State provisions to whom greater than 50 grams (0.11 lb) of source material has been transferred in a single calendar quarter, the name and address of the general licensee to whom source material is distributed; a responsible agent, by name ~~and/or~~ or position

and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and

~~RH-405.b.2.D. (Cont'd)~~

(c). The total quantity of each type and physical form of source material transferred in the

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reporting period to all such generally licensed recipients.

ii. File a report with the NRC and each responsible Agreement State agency that identifies all persons, operating under provisions equivalent to RH-401.a., to whom greater than 50 grams (0.11 lb) of source material has been transferred within a single calendar quarter. The report shall include the following information specific to those transfers made to NRC jurisdiction or to the Agreement State being reported to:

(a). The name, address, and license number of the person who transferred the source material;

(b). The name and address of the general licensee to whom source material was distributed; a responsible agent, by name ~~and/or~~ or position and phone number, of the general licensee to whom the material was sent; and the type, physical form, and quantity of source material transferred; and

(c). The total quantity of each type and physical form of source material transferred in the reporting period to all such generally licensed recipients within NRC jurisdiction or within the Agreement State, as appropriate.

~~RH-405.b.2. (Cont'd)~~

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iii. Submit each report by January 31 of each year covering all transfers for the previous calendar year. If no transfers were made to persons generally licensed under RH-401.a. or equivalent NRC or Agreement State provisions during the current period, a report shall be submitted to the Department indicating so. If no transfers have been made to NRC general licensees or to general licensees within a particular Agreement State during the reporting period, this information shall be reported to the NRC or to the responsible

Agreement State agency upon request of the appropriate governing agency.

E. Each person licensed under RH-405.b.1. shall maintain all information that supports the reports required by this paragraph concerning each transfer to a general licensee for a period of three (3) years after the event is included in a report to the Department, the NRC, or to an Agreement State agency.

c. – d. Reserved.

e. **Licensing of the manufacture or initial transfer of devices to persons generally licensed under RH-402.a**.

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1. An application for a specific license to manufacture or initially transfer devices containing radioactive material, excluding special nuclear material, to persons generally licensed under RH-402.a. or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State will be approved if:

A. The applicant satisfies the general requirements of RH-404.;

B. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control, labels, proposed uses, installation, servicing, leak testing, operating and safety instructions and potential hazards of the device to provide reasonable assurance that:

i. The device can be safely operated by persons not having training in radiological protection;

~~RH-405.e.1.B. (Cont'd)~~

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ii. Under ordinary conditions of handling, storage, and use of the device, the radioactive material contained in the device will not be released or inadvertently removed from the device, and it is unlikely that any person will receive in any period of one (1) calendar year a dose in excess of 10% of the limits specified in RH-1200.a.; and

iii. Under accident conditions (such as fire and explosion) associated with handling, storage, and use of the device, it is unlikely that any person

would receive an external radiation dose or dose commitment in excess of the following organ doses:

Part of body	Dose in rem
Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	15
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than one (1) square centimeter	200
Other organs	50

C. Each device bears a durable, legible, clearly visible label or labels approved by the Department, which contain in a clearly identified and separate statement:

i. Instructions and precautions necessary to assure safe installation, operation, and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information);

ii. The requirement, or lack of requirement, for leak testing, or for testing any on-off mechanism and indicator, including the maximum time interval for such testing, and the identification of radioactive material by isotope, quantity of radioactivity, and date of determination of the quantity; and

~~RH-405.e.1.C. (Cont'd)~~

iii. The information called for in the following statement in the same or substantially similar form[9/]:

"**The receipt, possession, use and transfer of this device, Model _____, [10/] Serial No. _____,[10/] are subject to a general license or the equivalent and the regulations of the U.S. NRC or of a State with which the NRC has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.**

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CAUTION – RADIOACTIVE MATERIAL

(name of manufacturer or initial transferor)"

D. Each device having a separable source housing that provides the primary shielding for the source also bears, on the source housing, a durable label containing the device model number and serial number, the isotope and quantity, the words "**Caution-Radioactive Material**," the radiation symbol described in RH-1303., and the name of the manufacturer or initial distributor.

E. Each device meeting the criteria of RH-402.c.13.A., bears a permanent (e.g., embossed, etched, stamped, or engraved) label affixed to the source housing if separable, or the device if the source housing is not separable, that includes the words "**Caution-Radioactive Material**," and, if practicable, the radiation symbol described in RH-1303.

F. The device has been registered in the Sealed Source and Device Registry.

~~RH-405.e. (Cont'd)~~

2. In the event the applicant desires that the device be required to be tested at intervals longer than six (6) months, either for proper operation of the on-off mechanism and indicator, if any, or for leakage of radioactive material or for both, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the device or similar devices and by design features which have a significant bearing on the probability or consequences of leakage of radioactive material from the device or failure of the on-off mechanism and indicator. In determining the acceptable interval for the test for leakage of radioactive material, the Department will consider information which includes, but is not limited to:

A. Primary containment (source capsule);

B. Protection of primary containment;

C. Method of sealing containment;

D. Containment construction materials;

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E. Form of contained radioactive material;

F. Maximum temperature withstood during prototype test;

G. Maximum pressure withstood during prototype tests;

H. Maximum quantity of contained radioactive material;

I. Radiotoxicity of contained radioactive material; and

J. Operating experience with identical devices or similarly designed and constructed devices.

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~~RH-405.e. (Cont'd)~~

3. In the event the applicant desires that the general licensee under RH-402.a., or under equivalent regulations of the NRC or an Agreement State, be authorized to install the device, collect the sample to be analyzed by a specific licensee for leakage of radioactive material, service the device, test the on-off mechanism and indicator or remove the device from installation, he shall include in his application written instructions to be followed by the general licensee, estimated calendar year doses associated with such activity or activities and bases for such estimates. The submitted information shall demonstrate that performance of such activity or activities by an individual untrained in radiological protection, in addition to other handling, storage and use of devices under the general license, is unlikely to cause that individual to receive a calendar year dose in excess of ten percent (10%) of the limits specified in RH-1200.a.

4. A. If a device containing radioactive material is to be transferred for use under the general license contained in RH-402.a., each person that is licensed under RH-405.e. shall provide the information specified in paragraph e.4.A. of this section to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

i. A copy of the general license contained in

RH-402.a.-e.; if paragraphs RH-402.c.2. through c.4. or RH-402.c.13. do not apply to the particular device, those paragraphs may be omitted.

ii. A copy of RH-600., RH-1501., and RH-1502.,

iii. A list of the services that can only be performed by a specific licensee;

iv. Information on acceptable disposal options including estimated costs of disposal; and

v. An indication that the Department's policy is to seek high civil penalties for improper disposal.

~~RH-405.e.4. (Cont'd)~~

B. If radioactive material is to be transferred in a device for use under an equivalent general license of the NRC or an Agreement State, each person that is licensed under RH-405.e. shall provide the information specified in paragraph e.4.B. of this section to each person to whom a device is to be transferred. This information must be provided before the device may be transferred. In the case of a transfer through an intermediate person, the information must also be provided to the intended user prior to initial transfer to the intermediate person. The required information includes:

i. A copy of the NRC or Agreement State's regulations equivalent to RH-402.a.-e., RH-600., RH-1501., and RH-1502. or a copy of RH-402.a.-e., RH-600., RH-1501., and RH-1502. If a copy of a non-governing agency's regulations is provided to a prospective general licensee in lieu of the governing agency's regulations, it shall be accompanied by a note explaining that use of the device is regulated by the governing agency, the agency who has jurisdiction where the device will be in use. If certain paragraphs of the regulations do not apply to the particular device, those paragraphs may be omitted.

ii. A list of the services that can only be performed by a specific licensee;

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iii. Information on acceptable disposal options including estimated costs of disposal; and

iv. The name or title, address, and phone number of the contact at the Department, NRC, or Agreement State from which additional information may be obtained.

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~~RH-405.e. (Cont'd)~~

5. **Material transfer reports and records**.

Each person licensed under RH-405.e. to initially transfer devices to generally licensed persons shall comply with the requirements of this subparagraph.

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A. The person shall report to the Radiation Control Section, Attention: ~~-~~General License Registration Program, all transfers of such devices to persons for use under the general license in RH-402.a. and all receipts of devices from persons licensed under RH-402.a.
~~-~~The report must be submitted on a quarterly basis on an NRC Form 653 entitled "Transfers of Industrial Devices Report (to General Licensees)" or in a clear and legible report containing all of the data required by the form.

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i. The required information for transfers to general licensees includes:

(a). The identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use.

(b). The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate rules and requirements;

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(c). The date of transfer;

(d). The type, model number, and serial number of the device transferred; and

(e). The quantity and type of radioactive material contained in the device.

~~RH-405.e.5.A. (Cont'd)~~

ii. If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

iii. For devices received from a RH-402.a. general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

iv. If the licensee makes changes to a device possessed by a RH-402.a. general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

v. The report must cover each calendar quarter, must be filed within thirty (30) days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

vi. The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

vii. If no transfers have been made to or from persons generally licensed under RH-402.a. during the reporting period, the report must so indicate.

~~RH-405.e.5. (Cont'd)~~

B. The person shall report all transfers of devices to persons for use under a general license in a U.S. Nuclear

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Regulatory Commission or Agreement State's regulations that are equivalent to RH-402.a. and all receipts of devices from general licensees in the NRC or Agreement State's jurisdiction to the NRC or responsible Agreement State agency. -The report must be submitted on an NRC Form 653 entitled "Transfers of Industrial Devices Report (to General Licensees)" or in a clear and legible report containing all of the data required by the form.

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i. The required information for transfers to general licensees includes:

-(a). The identity of each general licensee by name and mailing address for the location of use; if there is no mailing address for the location of use, an alternate address for the general licensee shall be submitted along with information on the actual location of use.

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-(b). The name, title, and phone number of the person identified by the general licensee as having knowledge of and authority to take required actions to ensure compliance with the appropriate rules and requirements;

(c). The date of transfer;

(d). The type, model number, and serial number of the device transferred; and

(e). The quantity and type of radioactive material contained in the device.

ii. If one or more intermediate persons will temporarily possess the device at the intended place of use before its possession by the user, the report must include the same information for both the intended user and each intermediate person, and clearly designate the intermediate person(s).

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~~RH-405.e.5.B. (Cont'd)~~

iii. For devices received from a general licensee, the report must include the identity of the general licensee by name and address, the type, model number, and serial number of the device received, the date of receipt, and, in the case of devices not initially transferred by the reporting licensee, the name of the manufacturer or initial transferor.

iv. If the licensee makes changes to a device possessed by a general licensee, such that the label must be changed to update required information, the report must identify the general licensee, the device, and the changes to information on the device label.

v. The report must cover each calendar quarter, must be filed within thirty (30) days of the end of the calendar quarter, and must clearly indicate the period covered by the report.

vi. The report must clearly identify the specific licensee submitting the report and must include the license number of the specific licensee.

vii. If no transfers have been made to or from a U. S. Nuclear Regulatory Commission jurisdiction or to or from a particular Agreement State during the reporting period, this information shall be reported to the NRC or to the responsible Agreement State agency upon request of the appropriate governing agency.

C. The person shall maintain all information concerning transfers and receipts of devices that supports the reports required by this subparagraph. Records required by this subparagraph must be maintained for a period of three (3) years following the date of the recorded event.

~~RH 405. (Cont'd)~~

f. **Licensing the distribution of radioactive material in exempt quantities**.

Authority to transfer possession or control by the manufacturer, processor, or producer of any equipment, device, commodity, or other product

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containing radioactive material whose subsequent possession, use, transfer, and disposal by all other persons are exempted from regulatory requirements under RH-305., or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State, may be obtained only from the NRC pursuant to 10 CFR 32.18.

g. **Licensing of the introduction of radioactive material into products in exempt concentrations**.

No person may introduce radioactive material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under RH-301.a., or equivalent regulations of the U.S. Nuclear Regulatory Commission or an Agreement State, except in accordance with a license issued by the NRC pursuant to 10 CFR 32.11.

h. **Licensing of the manufacture, assembly, repair, or initial transfer of luminous safety devices for use in aircraft**.

1. An application for a specific license to manufacture, assemble, repair, or initially transfer luminous safety devices containing tritium or promethium-147 for use in aircraft, for distribution to persons generally licensed under RH-402.f., will be approved if:

A. The applicant satisfies the general requirements specified in RH-404.;

B. The applicant submits sufficient information regarding each device pertinent to evaluation of the potential radiation exposure, including:

i. Chemical and physical form and maximum quantity of tritium or promethium-147 in each device;

ii. Details of construction and design;

iii. Details of the method of binding or containing the tritium or promethium-147;

~~RH-405.h.1.B. (Cont'd)~~

iv. Procedures for and results of prototype testing to demonstrate that the tritium or promethium-147 will not be released to the environment under the most

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severe conditions likely to be encountered in normal use;

v. Quality assurance procedures to be followed that are sufficient to ensure compliance with RH-405.h.3.;

vi. Any additional information, including experimental studies and tests, required by the Department to facilitate a determination of the safety of the device.

C. Each device will contain no more than 10 curies of tritium or 300 millicuries of promethium-147. The levels of radiation from each device containing promethium-147 will not exceed 0.5 millirad per hour at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber.

D. The Department determines that:

i. The method of incorporation and binding of the tritium or promethium-147 in the device is such that the tritium or promethium-147 will not be released under the most severe conditions which are likely to be encountered in normal use and handling of the device;

ii. The tritium or promethium-147 is incorporated or enclosed so as to preclude direct physical contact by any person with it;

iii. The device is so designed that it cannot easily be disassembled; and

iv. Prototypes of the device have been subjected to and have satisfactorily passed the tests required by RH-405.h.1.E.

~~RH-405.h.1. (Cont'd)~~

E. The applicant shall subject at least five prototypes of the device to tests as follows:

i. The devices are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions

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expected in service that could adversely affect the effective containment of tritium or promethium-147, such as temperature, moisture, absolute pressure, water immersion, vibration, shock, and weathering.

ii. The devices are inspected for evidence of physical damage and for loss of tritium or promethium-147, after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in 405.h.1.E.iii.

iii. Device designs are rejected for which the following has been detected for any unit:

(a). A leak resulting in a loss of 0.1 percent or more of the original amount of tritium or promethium-147 from the device; or

(b). Surface contamination of tritium or promethium-147 on the device of more than 2,200 disintegrations per minute per 100 square centimeters of surface area; or

(c). Any other evidence of physical damage.

F. The device has been registered in the Sealed Source and Device Registry.

2. **Labeling of devices.**

A. A person licensed under RH-405.h. to manufacture, assemble, or initially transfer devices containing tritium or promethium-147 for distribution to persons generally licensed under RH-402.f. shall, except as provided in RH-405.h.2.B., affix to each device a label containing the radiation symbol prescribed by RH-1303., such other information as may be required by the Department

~~RH-405.h.2.A. (Cont'd)~~

including disposal instructions when appropriate, and the following or a substantially similar statement which contains the information called for in the following statement[9/]:

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"The receipt, possession, use and transfer of this device, Model _____, [10/] Serial No. _____,[10/] containing _____ (identity and quantity of radioactive material) are subject to a general license or the equivalent and the regulations of the U.S. NRC or of a State with which the NRC has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION – RADIOACTIVE MATERIAL

_____

(name of manufacturer, assembler, or initial transferor)"

B. If the Department determines that it is not feasible to affix a label to the device containing all the information called for in RH-405.h.2.A., it may waive the requirements of that paragraph and require in lieu thereof that:

i. A label be affixed to the device identifying:

(a). The manufacturer, assembler, or initial transferor; and

(b). The type of radioactive material; and

ii. A leaflet bearing the following information be enclosed in or accompany the container in which the device is shipped:

(a). The name of the manufacturer, assembler, or initial transferor,

(b). The type and quantity of radioactive material,

(c). The model number,

~~RH-405.h.2.B.ii. (Cont'd)~~

(d). A statement that the receipt, possession, use, and transfer of the device are subject to a general license or the equivalent and the regulations of the U.S. NRC or of an Agreement State, and

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(e). Such other information as may be required by the Department, including disposal instructions when appropriate.

3. **Quality assurance; prohibition of transfer.**

A. Each person licensed under RH-405.h. shall visually inspect each device and shall reject any that has an observable physical defect that could adversely affect containment of the tritium or promethium-147.

B. Each person licensed under RH-405.h. shall:

i. Maintain quality assurance systems in the manufacture of the luminous safety device in a manner sufficient to provide reasonable assurance that the safety-related components of the distributed devices are capable of performing their intended functions; and

ii. Subject inspection lots to acceptance sampling procedures, by procedures specified in RH-405.h.3.C. and in the license issued under RH-405.h., to provide at least ninety-five percent (95%) confidence that the Lot Tolerance Percent Defective of 5.0 percent will not be exceeded.

C. The licensee shall subject each inspection lot to:

i. Tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of tritium or promethium-147, such as absolute pressure and water immersion.

~~RH-405.h.3.C. (Cont'd)~~

ii. Inspection for evidence of physical damage, containment failure, or for loss of tritium or promethium-147 after each stage of testing, using methods of inspection adequate for applying the following criteria for defective:

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(a). A leak resulting in a loss of 0.1 percent or more of the original amount of tritium or promethium-147 from the device;

(b). Levels of radiation in excess of 0.5 millirad (5 microgray) per hour at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber, if the device contains promethium-147; and

(c). Any other criteria specified in the license issued under RH-405.h.

D. No person licensed under RH-405.h. shall transfer to persons generally licensed under RH-402.f., or under an equivalent general license of the NRC or an Agreement State:

i. Any luminous safety device tested and found defective under any condition of a license issued under RH-405.h., or RH-405.h.3.B., unless the defective luminous safety device has been repaired or reworked, retested, and determined by an independent inspector to meet the applicable acceptance criteria; or

ii. Any luminous safety device contained within any lot that has been sampled and rejected as a result of the procedures in RH-405.h.3.B.ii., unless:

(a). A procedure for defining sub-lot size, independence, and additional testing procedures is contained in the license issued under RH-405.h.; and

~~RH-405.h.3.D.ii. (Cont'd)~~

(b). Each individual sub-lot is sampled, tested, and accepted in accordance with RH-405.h.3.B.ii. and RH-405.h.3.D.ii.(a). and any other criteria that may be required as a condition of the license issued under RH-405.h.

4. **Material transfer reports.**

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A. Each person licensed under RH-405.h. shall file an annual report with the Department, which must state the total quantity of tritium or promethium-147 transferred to persons generally licensed under RH-402.f. The report must identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of device. Each report must cover the year ending June 30 and must be filed within thirty (30) days thereafter. If no transfers have been made to persons generally licensed under RH-402.f. during the reporting period, the report must so indicate.

B. Each person licensed under RH-405.h. shall report annually all transfers of devices to persons for use under an RH-402.f. equivalent general license of the NRC or an Agreement State to the NRC or responsible Agreement State agency. The report must state the total quantity of tritium or promethium-147 transferred, identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of device. If no transfers have been made to a NRC jurisdiction or to a particular Agreement State during the reporting period, this information must be reported to the NRC or to the responsible Agreement State agency upon request of the appropriate governing agency.

~~RH-405. (Cont'd)~~

i. **Licensing of the manufacture or initial transfer of calibration or reference sources containing americium-241, plutonium, or radium-226**.

1. An application for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241, plutonium, or radium-226 for distribution to persons generally licensed under RH-402.g. will be approved if:

A. The applicant satisfies the general requirements of RH-404.;

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B. The applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:

i. Chemical and physical form and maximum quantity of americium 241, plutonium, or radium-226 in the source;

ii. Details of construction and design;

iii. Details of the method of incorporation and binding of the americium-241, plutonium, or radium-226 in the source;

iv. Procedures for and results of prototype testing of sources, which are designed to contain more than 0.005 microcuries (185 Bq) of americium-241, plutonium, or radium-226, to demonstrate that the americium-241, plutonium, or radium-226 contained in each source will not be released or be removed from the source under normal conditions of use;

v. Details of quality control procedures to be followed in manufacture of the source;

vi. Description of labeling to be affixed to the source or the storage container for the source;

vii. Any additional information, including experimental studies and tests, required by the Department to facilitate a determination of the safety of the source.

~~RH 405.i.1. (Cont'd)~~

C. Each source will contain no more than 5 microcuries (185 kBq) of americium-241, plutonium, or radium-226.

D. The Department determines, with respect to any type of source containing more than 0.005 microcuries (185 Bq) of americium-241, plutonium, or radium-226, that:

i. The method of incorporation and binding of the americium-241, plutonium, or radium-226 in the source is such that the americium-241, plutonium, or radium-226 will not be released or be removed

from the source under normal conditions of use and handling of the source; and

ii. The source has been subjected to and has satisfactorily passed appropriate tests required by RH-405.i.1.E.

E. The applicant shall subject at least five prototypes of each source that is designed to contain more than 0.005 microcuries (185 Bq) of americium-241, plutonium, or radium-226 to tests as follows:

i. The initial quantity of radioactive material deposited on each source is measured by direct counting of the source.

ii. The sources are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment or binding of americium-241, plutonium, or radium-226, such as physical handling, moisture, and water immersion.

iii. The sources are inspected for evidence of physical damage and for loss of americium-241, plutonium, or radium-226, after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in RH-405.i.1.E.iv.

~~RH-405.i.1.E. (Cont'd)~~

iv. Source designs are rejected for which the following has been detected for any unit: ~~-~~removal of more than 0.005 microcuries (185 Bq) of americium-241, plutonium, or radium-226 from the source or any other evidence of physical damage.

2. **Labeling of devices**.

Each person licensed under RH-405.i.~~.~~ shall affix to each source, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the information called for in the following statement:[9/]

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"The receipt, possession, use, and transfer of this source, Model __, Serial No. __, are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label.

CAUTION--RADIOACTIVE MATERIAL
THIS SOURCE CONTAINS AMERICIUM-241
[PLUTONIUM OR RADIUM-226].
DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE.

_____
Name of manufacturer or initial transferor"

~~RH-405.i. (Cont'd)~~

3. **Leak testing of each source**.

Each person licensed under RH-405.i. shall perform a dry wipe test upon each source containing more than 0.1 microcuries (3.7 kBq) of americium-241, plutonium, or radium-226 before transferring the source to a general licensee under RH-402.g. or under equivalent regulations of the NRC or of an Agreement State. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the filter paper shall be measured using methods capable of detecting 0.005 microcuries (185 Bq) of americium-241, plutonium, or radium-226. If a source has been shown to be leaking or losing more than 0.005 microcuries (185 Bq) of americium-241, plutonium, or radium-226 by the methods described in RH-405.i.3., the source must be rejected and must not be transferred to a general licensee under RH-402.g., or equivalent regulations of the NRC or an Agreement State.

j. **Licensing of the manufacture and distribution of radioactive material for certain *in vitro* clinical or laboratory testing under general license**.

An application for a specific license to manufacture or distribute radioactive material for use under the general license of RH-402.k. will be approved if:

1. The applicant satisfies the general requirements specified RH-404.; and

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2. The radioactive material is to be prepared for distribution in prepackaged units of:

A. Carbon-14 in units not exceeding 10 microcuries (370 kBq) each.

B. Cobalt-57 in units not exceeding 10 microcuries (370 kBq) each.

C. Hydrogen-3 (tritium) in units not exceeding 50 microcuries (1.85 MBq) each.

D. Iodine-125 in units not exceeding 10 microcuries (370 kBq) each.

~~RH-405.j.2. (Cont'd)~~

E. Mock Iodine-125 in units not exceeding 0.05 microcuries (1.85 kBq) of iodine-129 and 0.005 microcuries (185 Bq) of americium-241 each.

F. Iodine-131 in units not exceeding 10 microcuries (370 kBq) each.

G. Iron-59 in units not exceeding 20 microcuries (740 kBq) each.

H. Selenium-75 in units not exceeding 10 microcuries (370 kBq) each.

3. Each prepackaged unit bears a durable, clearly visible label:

A. Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 10 microcuries (370 kBq) of iodine-125, iodine-131, carbon-14, cobalt-57, or selenium-75; 50 microcuries (1.85 MBq) of hydrogen-3 (tritium); 20 microcuries (740 kBq) of iron-59; or Mock Iodine-125 in units not exceeding 0.05 microcuries (1.85 KBq) of iodine-129 and 0.005 microcuries (185 Bq) of americium-241 each; and

B. Displaying the radiation caution symbol described in RH-1303.a.1. and 2. and the words, "**CAUTION, RADIOACTIVE MATERIAL**" and "**Not for Internal or External Use in Humans or Animals**."

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~~RH-405.j. (Cont'd)~~

4. The following statement, as appropriate, or a substantially similar statement which contains the information called for in the statement, appears on a label affixed to each prepackaged unit or appears in a leaflet or brochure which accompanies the package:

"**This radioactive material may be received, acquired, possessed and used only by physicians, veterinarians, clinical laboratories or hospitals and only for *in vitro* clinical or laboratory tests not involving internal or external administration of the material or the radiation therefrom, to human beings or animals. Its receipt, acquisition, possession, use and transfer are subject to the regulations and a general license of the U.S. Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority.**

_____

(name of manufacturer)"

5. The label affixed to the unit, or the leaflet or brochure which accompanies the package, contains adequate information as to the precautions to be observed in handling and storing such radioactive material. In the case of the Mock Iodine-125 reference or calibration source, the information accompanying the source must also contain directions to the licensee regarding the waste disposal requirements set out in RH-1400.

k. **Licensing of the manufacture or initial transfer of ice detection devices containing strontium-90**.

1. An application for a specific license to manufacture or initially transfer ice detection devices containing strontium-90 for distribution to persons generally licensed under RH-402.i. will be approved if:

A. The applicant satisfies the general requirements of RH-404.;

B. The applicant submits sufficient information regarding each type of device pertinent to evaluation of the potential radiation exposure, including:

i. Chemical and physical form and maximum quantity of strontium-90 in the device;

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~~RH-405.k.1.B. (Cont'd)~~

ii. Details of construction and design of the source of radiation and its shielding;

iii. Radiation profile of a prototype device;

iv. Procedures for and results of prototype testing of devices to demonstrate that the strontium-90 contained in each device will not be released or be removed from the device under the most severe conditions likely to be encountered in normal handling and use;

v. Details of quality control procedures to be followed in manufacture of the device;

vi. Description of labeling to be affixed to the device;

vii. Instructions for handling and installation of the device;

viii. Any additional information, including experimental studies and tests, required by the Department to facilitate a determination of the safety of the device.

C. Each device will contain no more than 50 microcuries (1.85 MBq) of strontium-90 in an insoluble form.

D. Each device will bear durable, legible labeling which includes the radiation caution symbol prescribed by RH-1303., a statement that the device contains strontium-90 and the quantity thereof, instructions for disposal and statements that the device may be possessed pursuant to a general license, that the manufacturer or civil authorities should be notified if the device is found, that removal of the labeling is prohibited and that disassembly and repair of the device may be performed only by a person holding a specific license to manufacture or service such devices.

~~RH-405.k.1. (Cont'd)~~

E. The Department determines that:

i. The method of incorporation and binding of the strontium-90 in the device is such that the

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strontium-90 will not be released from the device under the most severe conditions which are likely to be encountered in normal use and handling of the device;

ii. The strontium-90 is incorporated or enclosed so as to preclude direct physical contact by any individual with it and is shielded so that no individual will receive a radiation exposure to a major portion of his body in excess of 0.5 rem (5 mSv) in a year under ordinary circumstances of use;

iii. The device is so designed that it cannot be easily disassembled;

iv. Prototypes of the device have been subjected to and have satisfactorily passed the tests required by RH-405.k.1.F.

v. Quality control procedures have been established to satisfy the requirements of RH-405.k.2.

F. The applicant shall subject at least five prototypes of the device to tests as follows:

i. The devices are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of strontium-90, such as temperature, moisture, absolute pressure, water immersion, vibration, shock, and weathering.

ii. The devices are inspected for evidence of physical damage and for loss of strontium-90 after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in RH-405.k.1.F.iii.

~~RH-405.k.1.F. (Cont'd)~~

iii. Device designs are rejected for which the following has been detected for any unit:

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(a). A leak resulting in a loss of 0.1 percent or more of the original amount of strontium-90 from the device; or

(b). Surface contamination of strontium-90 on the device of more than 2,200 disintegrations per minute per 100 square centimeters of surface area; or

(c). Any other evidence of physical damage.

G. The device has been registered in the Sealed Source and Device Registry.

2. **Quality assurance; prohibition of transfer.**

A. Each person licensed under RH-405.k. shall visually inspect each device and shall reject any which has an observable physical defect that could affect containment of the strontium-90.

B. Each person licensed under RH-405.k. shall test each device for possible loss of strontium-90 or for contamination by wiping with filter paper an area of at least 100 square centimeters on the outside surface of the device, or by wiping the entire surface area if it is less than 100 square centimeters. The detection on the filter paper of more than 2,200 disintegrations per minute of radioactive material per 100 square centimeters of surface wiped shall be cause for rejection of the tested device.

C. Each person licensed under RH-405.k. shall:

i. Maintain quality assurance systems in the manufacture of the ice detection device containing strontium-90 in a manner sufficient to provide reasonable assurance that the safety-related components of the distributed devices are capable of performing their intended functions; and

~~RH-405.k.2.C. (Cont'd)~~

ii. Subject inspection lots to acceptance sampling procedures, by procedures specified in RH-405.k.2.D. and in the license issued under RH-405.k., to provide at least ninety-five percent (95%)

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confidence that the Lot Tolerance Percent Defective of 5.0 percent will not be exceeded.

D. Each person licensed under RH-405.k. shall subject each inspection lot to:

i. Tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could possibly affect the effective containment of strontium-90, such as absolute pressure and water immersion.

ii. Inspection for evidence of physical damage, containment failure, or for loss of strontium-90 after each stage of testing, using methods of inspection adequate to determine compliance with the following criteria for defective:- A leak resulting in a loss of 0.1 percent or more of the original amount of strontium-90 from the device and any other criteria specified in the license issued under RH-405.k.

E. No person licensed under RH-405.k. shall transfer to persons generally licensed under RH-402.i., or under an equivalent general license of the NRC or of an Agreement State:

i. Any ice detection device containing strontium-90 tested and found defective under the criteria specified in a license issued under RH-405.k., unless the defective ice detection device has been repaired or reworked, retested, and determined by an independent inspector to meet the applicable acceptance criteria; or

~~RH-405.k.2.E. (Cont'd)~~

ii. Any ice detection device containing strontium-90 contained within any lot that has been sampled and rejected as a result of the procedures in RH-405.k.2.C.ii., unless:

(a). A procedure for defining sub-lot size, independence, and additional testing

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procedures is contained in the license issued under RH-405.k.; and

(b). Each individual sub-lot is sampled, tested, and accepted in accordance with 405.k.2.C.ii. and RH-405.k.2.E.ii.(a). and any other criteria as may be required as a condition of the license issued under RH-405.k.

l. **Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing radioactive material for medical use under Section 9, "Use of Radionuclides in the Healing Arts."**

1. An application for a specific license to manufacture, prepare, or transfer for commercial distribution radioactive drugs containing radioactive material for use by persons authorized pursuant to Section 9, "Use of Radionuclides in the Healing Arts," will be approved if:

A. The applicant satisfies the general requirements specified in RH-404.;

B. The applicant submits evidence that the applicant is at least one of the following:

i. Registered with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR Part 207, Subpart B;

ii. Permitted by the Arkansas State Board of Pharmacy as a drug manufacturer;

~~RH-405.l.1.B. (Cont'd)~~

iii. Permitted as a pharmacy by the Arkansas State Board of Pharmacy;

iv. Operating as a nuclear pharmacy within a Federal medical institution; or

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v. A Positron Emission Tomography (PET) drug production facility permitted by the Arkansas State Board of Pharmacy.

C. The applicant submits information on the radionuclide; the chemical and physical form; the maximum activity per vial, syringe, generator, or other container of the radioactive drug; and the shielding provided by the packaging to show it is appropriate for safe handling and storage of the radioactive drugs by medical use licensees; and

D. The applicant commits to the following labeling requirements:

i. A label is affixed to each transport radiation shield, whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words

"**CAUTION, RADIOACTIVE MATERIAL**"
or
"**DANGER, RADIOACTIVE MATERIAL**";

the name of the radioactive drug or its abbreviation; and the quantity of radioactivity at a specified date and time. For radioactive drugs with a half-life greater than 100 (one hundred) days, the time may be omitted.

~~RH-405.1. (Cont'd)~~

ii. A label is affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label must include the radiation symbol and the words

"**CAUTION, RADIOACTIVE MATERIAL**"
or
"**DANGER, RADIOACTIVE MATERIAL**"

and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

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2. A licensee described by paragraph l.1.B.iii. or l.1.B.iv. of this section:

A. May prepare radioactive drugs for medical use, as defined in RH-8100., provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in paragraph l.2.B. and l.2.D. of this section, or an individual under the supervision of an authorized nuclear pharmacist as specified in RH-8306.

B. May allow a pharmacist to work as an authorized nuclear pharmacist if:

i. This individual qualifies as an authorized nuclear pharmacist as defined in RH-8100.;

ii. This individual meets the requirements specified in RH-8317.b. and RH-8319. and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or

iii. This individual is designated as an authorized nuclear pharmacist in accordance with paragraph l.2.D. of this section.

C. The actions authorized in paragraphs l.2.A. and l.2.B. of this section are permitted in spite of more restrictive language in license conditions.

D. May designate a pharmacist (as defined in RH-8100.) as an authorized nuclear pharmacist if:

~~RH-405.l.2. (Cont'd)~~

i. The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and

ii. The individual practiced at a pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other pharmacies before August 8, 2009, or an earlier date as noticed by the U.S. Nuclear Regulatory Commission.

E. Shall provide to the Department:

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i. A copy of each individual's certification by a specialty board whose certification process has been recognized by the U.S. Nuclear Regulatory Commission, the Department, or an Agreement State as specified in RH-8317.a.; or

ii. The Department, U.S. Nuclear Regulatory Commission, or Agreement State license, or

iii. U.S. Nuclear Regulatory Commission master materials licensee permit, or

iv. The permit issued by a licensee or U.S. Nuclear Regulatory Commission master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist, or

v. Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the U.S. Nuclear Regulatory Commission; and

vi. A copy of the State pharmacist license, no later than 30 days after the date that the licensee allows, under paragraphs 1.2.B.i. and 1.2.B.iii. of this section, the individual to work as an authorized nuclear pharmacist.

~~RH-405.l. (Cont'd)~~

3. A licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha, beta, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

   A. Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and

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geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

B. Check each instrument for constancy and proper operation at the beginning of each day of use.

4. A licensee shall satisfy the labeling requirements in paragraph l.1.D. of this section.

5. Nothing in this paragraph l. relieves the licensee from complying with applicable U.S. Food and Drug Administration, other Federal, and State requirements governing radioactive drugs.

m. Deleted.

n. **Manufacture and distribution of sources or devices containing radioactive material for medical use**.

1. An application for a specific license to manufacture and distribute sources and devices containing radioactive material to persons licensed under Section 9, "Use of Radionuclides in the Healing Arts," for use as a calibration, transmission, or reference source or for the uses listed in RH-8600., RH-8620., RH-8630., and RH-8670. will be approved if:

A. The applicant satisfies the general requirements in RH-404.;

B. The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including:

~~RH-405.n.1.B. (Cont'd)~~

i. The radioactive material contained, its chemical and physical form, and amount;

ii. Details of design and construction of the source or device;

iii. Procedures for and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents;

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iv. For devices containing radioactive material, the radiation profile of a prototype device;

v. Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests;

vi. Procedures and standards for calibrating sources and devices;

vii. Legend and methods for labeling sources and devices as to their radioactive content;

viii. Instructions for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device; provided, that instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label;

C. The label affixed to the source or device or to the permanent storage container for the source or device, contains information on the radionuclide, quantity and date of assay, and a statement that the Department has approved distribution of the (name of source or device) to persons licensed to use radioactive material identified in RH-8404., RH-8600., RH-8620., RH-8630., and RH-8670. as appropriate, and to persons who hold an equivalent license issued by the U.S. Nuclear Regulatory Commission or an Agreement State.

~~RH-405.n. (Cont'd)~~

D. The source or device has been registered in the Sealed Source and Device Registry.

2. A. In the event the applicant desires that the source or device be required to be tested for leakage of radioactive material at intervals longer than six (6) months, he shall include in his application sufficient information to demonstrate that such longer interval is justified by performance characteristics of the source or device or similar sources or devices and by design features that have a significant

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bearing on the probability or consequences of leakage of radioactive material from the source.

B. In determining the acceptable interval for test of leakage of radioactive material, the Department will consider information that includes, but is not limited to:

i. Primary containment or source capsule;

ii. Protection of primary containment;

iii. Method of sealing containment;

iv. Containment construction materials;

v. Form of contained radioactive material;

vi. Maximum temperature withstood during prototype tests;

vii. Maximum pressure withstood during prototype tests;

viii. Maximum quantity of contained radioactive material;

ix. Radiotoxicity of contained radioactive material;

x. Operation experience with identical sources or devices or similarly designed and constructed sources or devices.

RH-406. **Special Requirements for Specific Licenses of Broad Scope**.

This section prescribes requirements for the issuance of specific licenses of broad scope for radioactive material ("broad licenses") and certain rules governing holders of such licenses.

a. The different types of broad licenses are set forth below:

1. A "Type A specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of the radioactive material specified in the license, but not exceeding quantities

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specified in the license, for any authorized purpose. The quantities specified are usually in the multicurie range.

2. A "Type B specific license of broad scope" is specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in RH-904., Schedule E to Section 2, for any authorized purpose. The possession limit for a Type B broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Schedule E to Section 2, Column I. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Schedule E to Section 2, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

3. A "Type C specific license of broad scope" is a specific license authorizing receipt, acquisition, ownership, possession, use and transfer of any chemical or physical form of radioactive material specified in RH-904., Schedule E to Section 2, for any authorized purpose. The possession limit for a Type C broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in Schedule E to Section 2, Column II. If two or more radionuclides are possessed thereunder, the possession limit is determined for each as follows:
For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in Schedule E to Section 2, Column II, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity.

~~RH-406. (Cont'd)~~

b. An application for a Type A specific license of broad scope will be approved if:

1. The applicant satisfies the general requirements specified in RH-404.;

2. The applicant has engaged in a reasonable number of activities involving the use of radioactive material; and

3. The applicant has established administrative controls and provisions relating to organization and management, procedures,

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record keeping, material control and accounting and management review that are necessary to assure safe operations, including:

A. The establishment of a radiation safety committee composed of such persons as a radiological safety officer, a representative of management and persons trained and experienced in the safe use of radioactive materials;

B. The appointment of a radiological safety officer who is qualified by training and experience in radiation protection and who is available for advice and assistance on radiological safety matters; and

C. The establishment of appropriate administrative procedures to assure:

i. Control of procurement and use of radioactive material;

ii. Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

iii. Review, approval and recording by the radiation safety committee of safety evaluations of proposed uses prepared in accordance with RH-406.b.3.C.ii. prior to use of the radioactive material.

~~RH-406. (Cont'd)~~

c. An application for a Type B specific license of broad scope will be approved if:

1. The applicant satisfies the general requirements specified in RH-404.; and

2. The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to assure safe operations, including:

A. The appointment of a radiological safety officer who is qualified by training and experience in radiation protection

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and who is available for advice and assistance on radiological safety matters; and

B. The establishment of appropriate administrative procedures to assure:

i. Control of procurement and use of radioactive material;

ii. Completion of safety evaluations of proposed uses of radioactive material which take into consideration such matters as the adequacy of facilities and equipment, training and experience of the user, and the operating or handling procedures; and

iii. Review, approval and recording by the radiological safety officer of safety evaluations of proposed uses prepared in accordance with RH- 406.c.2.B.ii. prior to use of the radioactive material.

d. An application for a Type C specific license of broad scope will be approved if:

1. The applicant satisfied the general requirements specified in RH-404.; and

~~RH-406.d. (Cont'd)~~

2. The applicant submits a statement that radioactive material will be used only by, or under the direct supervision of, individuals who have received:

A. A college degree at the bachelor level, or equivalent training and experience, in the physical or biological sciences or engineering in; and

B. At least forty (40) hours of training and experience in the safe handling of radioactive material, and in the characteristics of ionizing radiation, units of radiation dose and quantities, radiation detection instrumentation, and biological hazards of exposure to radiation appropriate to the type and forms of radioactive material to be used; and

3. The applicant has established administrative controls and provisions relating to procurement of radioactive material,

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procedures, record keeping, material control and accounting, and management review necessary to assure safe operations.

e. **Specific license of broad scope are subject to the following conditions**:

1. Persons licensed pursuant to RH-406. shall not:

A. Conduct tracer studies in the environment involving direct release of radioactive material;

B. Receive, acquire, own, possess, use or transfer devices containing 100,000 curies or more of radioactive material in sealed sources used for irradiation of materials;

C. Conduct activities for which a specific license issued by the Department under RH-405., Part I of Section 3, or Section 9 is required; or

D. Add or cause the addition of radioactive material to any food, beverage, cosmetic, drug or other product designed for ingestion or inhalation by or application to, a human being.

~~RH-406.e. (Cont'd)~~

2. Each Type A specific license of broad scope issued under this section shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiation safety committee.

3. Each Type B specific license of broad scope issued under this section shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals approved by the licensee's radiological safety officer.

4. Each Type C specific license of broad scope issued under this section shall be subject to the condition that radioactive material possessed under the license may only be used by, or under the direct supervision of, individuals who satisfy the requirements of paragraph d. of this RH-406.

RH-407. **Special Requirements for Land Disposal of Radioactive Waste**.

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a. Each person shall file an application with the Department and obtain a license as provided in this section before commencing construction of a land disposal facility. -Failure to comply with this requirement may be grounds for denial of a license.

b. **Content of application**.

An application to receive from others, possess and dispose of wastes containing or contaminated with radioactive material by land disposal must consist of general information, specific technical information, institutional information and financial information as set forth in this paragraph. -An environmental report prepared in accordance with Subpart A of 10 CFR Part 51 must accompany the application.

1. The general information must include each of the following:

A. Identity of the applicant including:

i. The full name, address, telephone number and description of the business or occupation of the applicant;

~~RH-407.b.1.A. (Cont'd)~~

ii. If the applicant is a partnership, the name and address of each partner and the principal location where the partnership does business;

iii. If the applicant is a corporation or an unincorporated association, the state where it is incorporated or organized and the principal location where it does business and the names and addresses of its directors and principal officers; and

iv. If the applicant is acting as an agent or representative of another person in filing the application, all information required under this paragraph must be supplied with respect to the other person.

B. Qualifications of the applicant:

i. The organizational structure of the applicant, both offsite and onsite, including a description of lines of authority and assignments of responsibilities,

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whether in the form of administrative directives, contract provisions, or otherwise;

ii. The technical qualifications, including training and experience, of the applicant and members of the applicant's staff to engage in the proposed activities. Minimum training and experience requirements for personnel filling key positions described in RH-407.b.1.B.i. must be provided;

iii. A description of the applicant's personnel training program; and

iv. The plan to maintain an adequate complement of trained personnel to carry out waste receipt, handling and disposal operations in a safe manner.

C. A description of:

i. The location of the proposed disposal site;

ii. The general character of the proposed activities;

~~RH-407.b.1.C. (Cont'd)~~

iii. The types and quantities of radioactive waste to be received, possessed and disposed of;

iv. Plans for use of the land disposal facility for purposes other than disposal of radioactive wastes; and

v. The proposed facilities and equipment.

D. Proposed schedules for construction, receipt of waste and first emplacement of waste at the proposed land disposal facility.

2. The specific technical information must include the following information needed for demonstration that the performance objectives of RH-407.c. and the applicable technical requirements of RH-407.d. will be met:

A. A description of the natural and demographic disposal site characteristics as determined by disposal site selection and characterization activities. The description must include

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geologic, geotechnical, hydrologic, meteorologic, climatologic and biotic features of disposal site and vicinity.

B. A description of the design features of the land disposal facility and the disposal units. For near-surface disposal, the description must include those design features related to infiltration of water; integrity of covers for disposal units; structural stability of backfill, waste and covers; contact of wastes with standing water; disposal site drainage; disposal site closure and stabilization; elimination to the extent practicable of long-term disposal site maintenance; inadvertent intrusion; occupational exposures; disposal site monitoring; and adequacy of the size of the buffer zone for monitoring and potential mitigative measures.

C. A description of the principal design criteria and their relationship to the performance objectives.

D. A description of the design basis natural events or phenomena and their relationship to the principal design criteria.

~~RH-407.b.2. (Cont'd)~~

E. A description of codes and standards which the applicant has applied to the design and which will apply to construction of the land disposal facilities.

F. A description of the construction and operation of the land disposal facility. The description must include as a minimum the methods of construction of disposal units; waste emplacement; the procedures for and areas of waste segregation; types of intruder barriers; onsite traffic and drainage systems; survey control program; methods and areas of waste storage; and methods to control surface water and groundwater access to the wastes.

The description must also include a description of the methods to be employed in the handling and disposal of wastes containing chelating agents or other non-radiological substances that might affect meeting the performance objectives in RH-407.c.

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G. A description of the disposal site closure plan, including those design features which are intended to facilitate disposal site closure and to eliminate the need for ongoing active maintenance.

H. An identification of the known natural resources at the disposal site, the exploitation of which could result in inadvertent intrusion into the low-level wastes after removal of active institutional control.

I. A description of the kind, amount, classification and specifications of the radioactive material proposed to be received, possessed and disposed of at the land disposal facility.

J. A description of the quality assurance program, tailored to LLW disposal, developed and applied by the applicant for the determination of natural disposal site characteristics and for quality assurance during the design, construction, operation and closure of the land disposal facility and the receipt, handling and emplacement of waste.

~~RH-407.b.2. (Cont'd)~~

K. A description of the radiation safety program for control and monitoring of radioactive effluents to ensure compliance with the performance objective in RH-407.c.2. and occupational radiation exposure to ensure compliance with the requirements of Section 3 and to control contamination of personnel, vehicles, equipment, buildings and the disposal site. -Both routine operations and accidents must be addressed.- The program description must include procedures, instrumentation, facilities and equipment.

L. A description of the environmental monitoring program to provide data to evaluate potential health and environmental impacts and the plan for taking corrective measures if migration of radionuclides is indicated.

M. A description of the administrative procedures that the applicant will apply to control activities at the land disposal facility.

N. **Technical analyses**.

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The specific technical information must also include the following analyses needed to demonstrate that the performance objectives of RH-407.c. will be met:

i. Pathways analyzed in demonstrating protection of the general population from releases of radioactivity must include air, soil, groundwater, surface water, plant uptake and exhumation by burrowing animals.

The analyses must clearly identify and differentiate between the roles performed by the natural disposal site characteristics and design features in isolating and segregating the wastes.

The analyses must clearly demonstrate that there is reasonable assurance that the exposure to humans from the release of radioactivity will not exceed the limits set forth in RH-407.c.2.

~~RH-407.b.2.N. (Cont'd)~~

ii. Analyses of the protection of individuals from inadvertent intrusion must include demonstration that there is reasonable assurance the waste classification and segregation requirements will be met and that adequate barriers to inadvertent intrusion will be provided.

iii. Analyses of the protection of individuals during operations must include assessments of expected exposures due to routine operations and likely accidents during handling, storage and disposal of waste. The analyses must provide reasonable assurance that exposures will be controlled to meet the requirements of Section 3.

iv. Analyses of the long-term stability of the disposal site and the need for ongoing active maintenance after closure must be based upon analyses of active natural processes such as erosion, wasting, slope failure, settlement of mass wastes and backfill, infiltration through covers over disposal areas and adjacent soils and surface drainage of the disposal site. The analyses must provide reasonable assurance that there will not be a need for ongoing

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active maintenance of the disposal site following closure.

3. The institutional information must include:

A. A certification by the Federal or State government which owns the disposal site that the Federal or State government is prepared to accept transfer of the license when the provisions of RH-407.b.7. are met and will assume responsibility for custodial care after site closure and post-closure observation and maintenance.

B. Where the proposed disposal site is on land not owned by the Federal or a State government, the applicant must submit evidence that arrangements have been made for assumption of ownership in fee by the Federal or a State government before the Department issues a license.

~~RH-407.b. (Cont'd)~~

4. The financial information must be sufficient to demonstrate that the financial qualifications of the applicant are adequate to carry out the activities for which the license is sought and meet other financial assurance requirements as specified in RH-407.e.

5. Any expiration date on a license applies only to the above ground activities and to the authority to dispose of waste. Failure to renew the license shall not relieve the licensee of responsibility for carrying out site closure, post-closure observation and transfer of the license to the site owner. An application for renewal or an application for closure must be filed at least thirty (30) days prior to license expiration.

6. **Contents of an application for closure**.

A. Prior to final closure of the disposal site or as otherwise directed by the Department, the applicant shall submit an application to amend the license for closure. This closure application must include a final revision and specific details of the disposal site closure plan included as part of the license application submitted under RH-407.b.2.G. that includes each of the following:

i. Any additional geologic, hydrologic or other disposal site data pertinent to the long-term

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containment of emplaced radioactive wastes obtained during the operational period.

ii. The results of tests, experiments or other analyses relating to backfill of excavated areas, closure and sealing, waste migration and interaction with emplacement media, or any other tests, experiments or analysis pertinent to the long-term containment of emplaced waste within the disposal site.

iii. Any proposed revision of plans for:

(a). Decontamination ~~and/or~~or dismantlement of surface facilities;

(b). Backfilling of excavated areas; or

(c). Stabilization of the disposal site for post-closure care.

~~RH-407.b.6. (Cont'd)~~

B. An environmental report or a supplement to an environmental report prepared in accordance with Subpart A of 10 CFR Part 51 must accompany the application.

C. Upon review and consideration of an application to amend the license for closure submitted in accordance with RH-407.b.6.A., the Department shall issue an amendment authorizing closure if there is reasonable assurance that the long-term performance objectives in RH-407.c. will be met.

D. Following completion of closure authorized in RH-407.b.6, the licensee shall observe, monitor and carry out necessary maintenance and repairs at the disposal site until the license is transferred by the Department in accordance with RH-407.b.7. -Responsibility for the disposal site must be maintained by the licensee for five (5) years. -A shorter or longer time period for post-closure observation and maintenance may be established and approved as part of the site closure plan, based on site-specific conditions.

7. **Transfer of license**.

Following closure and the period of post-closure observation and maintenance, the licensee may apply for an amendment to transfer

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the license to the disposal site owner. -The license shall be transferred when the Department finds:

A. That the closure of the disposal site has been made in conformance with the licensee's disposal site closure plan, as amended and approved as part of the license;

B. That reasonable assurance has been provided by the licensee that the performance objectives in RH-407.c. are met;

C. That any funds and necessary records for care will be transferred to the disposal site owner;

D. That the post-closure monitoring program is operational for implementation by the disposal site owner; and

~~RH-407.b.7. (Cont'd)~~

E. That the Federal or State government agency which will assume responsibility for institutional control of the disposal site is prepared to assume responsibility and ensure that the institutional requirements found necessary under RH-407.d.10.B. will be met.

c. **Performance objectives**.

1. **General requirement**.

Land disposal facilities must be sited, designed, operated, closed and controlled after closure so that reasonable assurance exists that exposures to humans are within the limits established in the performance objectives in RH-407.c.2. through 5.

2. **Protection of the general population from releases of radioactivity**.

Concentrations of radioactive material which may be released to the general environment in ground water, surface water, air, soil, plants or animals must not result in an annual dose exceeding an equivalent of 25 millirems to the whole body, 75 millirems to the thyroid and 25 millirems to any other organ of any member of the public. -Reasonable effort should be made to maintain releases of radioactivity in effluents to the general environment as low as is reasonably achievable.

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3. **Protection of individuals from inadvertent intrusion**.

Design, operation and closure of the land disposal facility must ensure protection of any individual inadvertently intruding into the disposal site and occupying the site or contacting the waste at any time after active institutional controls over the disposal site are removed.

4. **Protection of individuals during operations**.

Operations at the land disposal facility must be conducted in compliance with the standards for radiation protection set out in Section 3, except for releases of radioactivity in effluents from the land disposal facility which shall be governed by RH-407.c.2. Every reasonable effort shall be made to maintain radiation exposures as low as is reasonably achievable.

~~RH-407.c. (Cont'd)~~

5. **Stability of the disposal site after closure**.

The disposal facility must be sited, designed, used, operated and closed to achieve long-term stability of the disposal site and to eliminate to the extent practicable the need for ongoing active maintenance of the disposal site following closure so that only surveillance, monitoring or minor custodial care are required.

d. **Technical requirements for land disposal facilities**.

1. **Disposal site suitability for near-surface disposal**.

A. The purpose of this section is to specify the minimum characteristics a disposal site must have to be acceptable for use as a near-surface disposal facility. The primary emphasis in disposal site suitability is given to isolation of wastes (a matter having long-term impacts) and to disposal site features that ensure that the long-term performance objectives in RH-407.c. are met, as opposed to short-term convenience or benefits.

B. The disposal site shall be capable of being characterized, modeled, analyzed and monitored.

C. Within the region or state where the facility is to be located, a disposal site should be selected so that projected

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population growth and future developments are not likely to affect the ability of the disposal facility to meet the performance objectives in RH-407.c.

D. Areas must be avoided having known natural resources which, if exploited, would result in failure to meet the performance objectives in RH-407.c.

E. The disposal site must be generally well drained and free of areas of flooding or frequent ponding. Waste disposal shall not take place in a 100-year flood plain, coastal high-hazard area or wetland.

F. Upstream drainage areas must be minimized to decrease the amount of runoff which could erode or inundate waste disposal units.

~~RH-407.d.1. (Cont'd)~~

G. The disposal site must provide sufficient depth to the water table that ground water intrusion, perennial or otherwise, into the waste will not occur. The Department will consider an exception to this requirement to allow disposal below the water table if it can be conclusively shown that disposal site characteristics will result in molecular diffusion being the predominant means of radionuclide movement and the rate of movement will result in the performance objectives in RH-407.c. being met. In no case will waste disposal be permitted in the zone of fluctuation of the water table.

H. The hydrogeologic unit used for disposal shall not discharge ground water to the surface within the disposal site.

I. Areas must be avoided where tectonic processes such as faulting, folding, seismic activity or vulcanism may occur with such frequency and extent to significantly affect the ability of the disposal site to meet the performance objectives in RH-407.c. or may preclude defensible modeling and prediction of long-term impacts.

J. Areas must be avoided where surface geologic processes such as mass wasting, erosion, slumping, land-sliding or weathering occur with such frequency and extent to

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significantly affect the ability of the disposal site to meet the performance objectives in RH-407.c. or may preclude defensible modeling and prediction of long-term impacts.

K. The disposal site must not be located where nearby facilities or activities could adversely impact the ability of the site to meet the performance objectives in RH-407.c. or significantly mask the environmental monitoring program.

2. **Disposal site design for near-surface disposal**.

A. Site design features must be directed toward long-term isolation and avoidance of the need for continuing active maintenance after site closure.

~~RH-407.d.2. (Cont'd)~~

B. The disposal site design and operation must be compatible with the disposal site closure and stabilization plan and lead to disposal site closure that provides reasonable assurance the performance objectives in RH-407.c. will be met.

C. The disposal site must be designed to complement and improve, where appropriate, the ability of the disposal site's natural characteristics to assure that the performance objectives in RH-407.c. will be met.

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D. Covers must be designed to minimize to the extent practicable water infiltration, to direct percolating or surface water away from the disposed waste and to resist degradation by surface geologic processes and biotic activity.

E. Surface features must direct surface water drainage away from disposal units at velocities and gradients which will not result in erosion that will require ongoing active maintenance in the future.

F. The disposal site must be designed to minimize to the extent practicable the contact of water with waste during storage, the contact of standing water with waste during disposal and the contact of percolating or standing water with wastes after disposal.

3. **Near-surface disposal facility operation and disposal site closure**.

A. Wastes designated as Class A pursuant to RH-407.d.6., must be segregated from other wastes by placing in disposal units which are sufficiently separated from disposal units for the other waste classes so that any interaction between Class A wastes and other wastes will not result in the failure to meet the performance objectives in RH-407.c.~~.~~ ~~-~~This segregation is not necessary for Class A wastes if they meet the stability requirements in RH-407.d.7.B. of this Part.

~~RH-407.d.3. (Cont'd)~~

B. Wastes designated as Class C pursuant to RH-407.d.6. must be disposed of so that the top of the waste is a minimum of five (5) meters below the top surface of the cover or must be disposed of with intruder barriers that are designed to protect against an inadvertent intrusion for at least 500 years.

C. All wastes shall be disposed of in accordance with the requirements of RH-407.d.3.D. through K.

D. Wastes must be emplaced in a manner that maintains the package integrity during emplacement, minimizes the void spaces between packages and permits the void spaces to be filled.

E. Void spaces between waste packages must be filled with earth or other material to reduce future subsidence within the fill.

F. Waste must be placed and covered in a manner that limits the radiation dose rate at the surface of the cover to levels that at a minimum will permit the licensee to comply with all provisions of RH-1208. at the time the license is transferred pursuant to RH-407.b.7.

G. The boundaries and locations of each disposal unit (e.g., trenches) must be accurately located and mapped by means of a land survey. ~~-~~Near-surface disposal units must be marked in such a way that the boundaries of each unit can be easily defined. ~~-~~Three (3) permanent survey marker control points, referenced to United States Geological

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Survey (USGS) or National Geodetic Survey (NGS) survey control stations, must be established in the site to facilitate surveys. The USGS or NGS control stations must provide horizontal and vertical controls as checked against USGS or NGS record files.

H. Buffer zone of land must be maintained between any buried waste and the disposal site boundary and beneath the disposed waste. The buffer zone shall be of adequate dimensions to carry out environmental monitoring activities specified in RH-407.d.4. and take mitigative measures if needed.

~~RH-407.d.3. (Cont'd)~~

I. Closure and stabilization measures as set forth in the approved site closure plan must be carried out as each disposal unit (e.g., each trench) is filled and covered.

J. Active waste disposal operations must not be have an adverse effect on completed closure and stabilization measures.

K. Only wastes containing or contaminated with radioactive materials shall be disposed of at the disposal site.

4. **Environmental monitoring**.

A. At the time a license application is submitted, the applicant shall have conducted a preoperational monitoring program to provide basic environmental data on the disposal site characteristics. The applicant shall obtain information about the ecology, meteorology, climate, hydrology, geology, geochemistry and seismology of the disposal site. For those characteristics that are subject to variation, data must cover at least a twelve (12) month period.

B. The licensee must have plans for taking corrective measures if migration of radionuclides would indicate that the performance objectives in RH-407.c. may not be met.

C. During the land disposal facility site construction and operation, the licensee shall maintain a monitoring program. Measurements and observations must be made and recorded to provide data to evaluate the potential health and environmental impacts during both the construction

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and the operation of the facility and to enable the evaluation of long-term effects and the need for mitigative measures. The monitoring system must be capable of providing early warning of releases of radionuclides from the disposal site before they leave the site boundary.

D. After the disposal site is closed, the licensee responsible for post-operational surveillance of the disposal site shall maintain a monitoring system based on the operating history and the closure and stabilization of the disposal site. The monitoring system must be capable of providing early warning of releases of radionuclides from the disposal site before they leave the site boundary.

~~RH-407.d. (Cont'd)~~

5. The Department may, upon request or on its own initiative, authorize provisions other than those set forth in RH-407.d.2. through 4. for the segregation and disposal of waste and for the design and operation of a land disposal facility on a specific basis, if it finds reasonable assurance of compliance with the performance objectives in RH-407.c.

6. **Classification of waste for near-surface disposal**.

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Determination of the classification of radioactive waste involves two considerations. First, consideration must be given to the concentration of long-lived radionuclides (and their shorter-lived precursors) whose potential hazard will persist long after such precautions as institutional controls, improved waste form and deeper disposal have ceased to be effective. These precautions delay the time when long-lived radionuclides could cause exposures. In addition, the magnitude of the potential dose is limited by the concentration and availability of the radionuclide at the time of exposure. Second, consideration must be given to the concentration of shorter-lived radionuclides for which requirements on institutional controls, waste form and disposal methods are effective.

A. Classes of waste:

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i. Class A waste is waste that is usually segregated from other waste classes at the disposal site. The physical form and characteristics of Class A waste must meet the minimum requirements set forth in RH-407.d.7.A. If Class A waste also meets the

stability requirements set forth in RH-407.d.7.B., it is not necessary to segregate the waste for disposal.

ii. Class B waste is waste that must meet more rigorous requirements on waste form to ensure stability after disposal. The physical form and characteristics of Class B waste must meet both the minimum and stability requirements set forth in RH-407.d.7.

~~RH-407.d.6.A. (Cont'd)~~

iii. Class C waste is waste that not only must meet more rigorous requirements on waste form to ensure stability but also requires additional measures at the disposal facility to protect against inadvertent intrusion. The physical form and characteristics of Class C waste must meet both the minimum and stability requirements set forth in RH-407.d.7.

iv. Waste that is not generally acceptable for near-surface disposal is waste for which waste form and disposal methods must be different, and in general more stringent, than those specified for Class C waste. In the absence of specific requirements in this section, proposals for disposal of this waste may be submitted to the Department for approval, pursuant to RH-407.d.9.

B. **Classification determined by long-lived radionuclides**.

If radioactive waste contains only radionuclides listed in Table 1 to RH-407., classification shall be determined as follows:

i. If the concentration does not exceed 0.1 times the value in Table 1, the waste is Class A.

ii If the concentration exceeds 0.1 times the value in Table 1 but does not exceed the value in Table 1, the waste is Class C.

iii. If the concentration exceeds the value in Table 1, the waste is not generally acceptable for near-surface disposal.

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iv. For wastes containing mixtures of radionuclides listed in Table 1, the total concentration shall be determined by the sum of fractions rule described in the RH-407.d.6.F.

~~RH-407.d.6.B. (Cont'd)~~

TABLE 1 TO RH-407.

Radionuclide	Concentration (Curies per cubic meter)
C-14	8
C-14 in activated metal	80
Ni-59 in activated metal	220
Nb-94 in activated metal	0.2
Tc-99	3
I-129	0.08
Alpha emitting transuranic nuclides with half-life greater than five years	100[a]
Pu-241	3500 [a]
Cm-242	20000 [a]

[a] Units are nanocuries per gram.

C. **Classification determined by short-lived radionuclides**.

If radioactive waste does not contain any of the radionuclides listed in Table 1, classification shall be determined based on the concentrations shown in Table 2 to RH-407. However, as specified in RH-407.d.6.E. of this section, if radioactive waste does not contain any nuclides listed in either Table 1 or 2, it is Class A.

i. If the concentration exceeds the value in Column 1, the waste is Class A.

ii. If the concentration exceeds the value in Column 1, but does not exceed the value in Column 2, the waste is Class B.

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iii. If the concentration exceeds the value in Column 2, but does not exceed the value in Column 3, the waste is Class C.

iv. If the concentration exceeds the value in Column 3, the waste is not generally acceptable for near-surface disposal.

~~RH-407.d.6.C. (Cont'd)~~

v. For wastes containing mixtures of the nuclides listed in Table 2, the total concentration shall be determined by the sum of fractions rule described in RH-407.d.6.F.

TABLE 2 TO RH-407.

Radionuclide	Concentration (Curies per cubic meter)		
	Col. 1	Col. 2	Col. 3
Total of all nuclides less than 5 year half-life	700	([a])	([a])
H-3	40	([a])	([a])
Co-60	700	([a])	([a])
Ni-63	3.5	70	700
Ni-63 in activated metal	35	700	7000
Sr-90	0.04	150	7000
Cs-137	1	44	4600

[a] There are no limits established for these radionuclides in Class B or C wastes.- Practical consideration such as the effects of external radiation and internal heat generation on transportation, handling, and disposal will limit the concentrations for these wastes. -These wastes shall be Class B unless the concentrations of other nuclides in Table 2 determine the waste to be Class C independent of these nuclides.

D. **Classification determined by both long and short-lived radionuclides**.

If radioactive waste contains a mixture of radionuclides, some of which are listed in Table 1 and some of which are listed in Table 2, classification shall be determined as follows:

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~~RH-407.d.6.D. (Cont'd)~~

i. If the concentration of a nuclide listed in Table 1 does not exceed 0.1 times the value listed in Table 1, the class shall be that determined by the concentration of nuclides listed in Table 2.

ii. If the concentration of a nuclide listed in Table 1 exceeds 0.1 times the value listed in Table 1 but does not exceed the value in Table 1, the waste shall be Class C, provided the concentration of nuclides listed in Table 2 does not exceed the value shown in Column 3 of Table 2.

E. **Classification of wastes with radionuclides other than those listed in Tables 1 and 2**.

If radioactive waste does not contain any nuclides listed in either Table 1 or 2, it is Class A.

F. **The sum of the fractions rule for mixtures of radionuclides**.

For determining classification for waste that contains a mixture of radionuclides, it is necessary to determine the sum of fractions by dividing each nuclide's concentration by the appropriate limit and adding the resulting values. The appropriate limits must all be taken from the same column of the same table. The sum of the fractions for the column must be less than 1.0 if the waste class is to be determined by that column.

Example: A waste contains Sr-90 in a concentration of 50 Ci/m^3 and Cs-137 in a concentration of 22 Ci/m^3. Since the concentrations both exceed the values in Column1, Table 2, they must be compared to Column 2 values. For Sr-90 fraction, 50/150 = 0.33; for Cs-137 fraction, 22/44 = 0.5; the sum of the fractions = 0.83. Since the sum is less than 1.0, the waste is Class B.

G. **Determination of concentrations in wastes**.

The concentration of a radionuclide may be determined by indirect methods such as use of scaling factors which relate the inferred concentration of one radionuclide to another that is measured, or radionuclide material accountability, if

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there is reasonable assurance that the indirect methods can be correlated with actual measurements. The concentration of a radionuclide may be averaged over the volume of the waste or weight of the waste if the units are expressed as ~~nanocuries per gram.~~

~~RH-407.d. (Cont'd)~~

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7. **Waste characteristics**.

A. The following requirements are minimum requirements for all classes of waste and are intended to facilitate handling at the disposal site and provide protection of health and safety of personnel at the disposal site.

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i. Waste must not be packaged for disposal in cardboard or fiberboard boxes.

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ii. Liquid waste must be solidified or packaged in sufficient absorbent material to absorb twice the volume of the liquid.

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iii. Solid waste containing liquid shall contain as little freestanding and noncorrosive liquid as is reasonably achievable, but in no case shall the liquid exceed one percent (1%) of the volume.

iv. Waste must not be readily capable of detonation or of explosive decomposition or reaction at normal pressures and temperatures, or of explosive reaction with water.

v. Waste must not contain or be capable of generating, quantities of toxic gases, vapors or fumes harmful to persons transporting, handling, or disposing of the waste. This does not apply to radioactive gaseous waste packaged in accordance with RH-407.d.7.A.vii.

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vi. Waste must not be pyrophoric. Pyrophoric materials contained in waste shall be treated, prepared, and packaged to be nonflammable.

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vii. Waste in a gaseous form must be packaged at a pressure that does not exceed 1.5 atmospheres at 20^0C. Total activity must not exceed 100 curies per container.

viii. Waste containing hazardous, biological pathogenic, or infectious material must be treated to reduce to the maximum extent practicable the potential hazard from the non-radiological materials.

~~RH-407.d.7. (Cont'd)~~

B. The requirements in this section are intended to provide stability of the waste. Stability is intended to ensure that the waste does not structurally degrade and affect overall stability of the site through slumping, collapse, or other failure of the disposal unit and thereby lead to water infiltration. Stability is also a factor in limiting exposure to an inadvertent intruder, since it provides a recognizable and non-dispersible waste.

i. Waste must have structural stability. A structurally stable waste form will generally maintain its physical dimensions and its form, under the expected disposal conditions such as weight of overburden and compaction equipment, the presence of moisture and microbial activity, and internal factors such as radiation effects and chemical changes. Structural stability can be provided by the waste form itself, processing the waste to a stable form, or placing the waste in a disposal container or structure that provides stability after disposal.

ii. Notwithstanding the provisions in RH-407.d.7.A.ii. and iii., liquid wastes or wastes containing liquid, must be converted into a form that contains as little freestanding and noncorrosive liquid as is reasonably achievable, but in no case shall the liquid exceed one percent (1%) of the volume of the waste when the waste is in a disposal container designed to ensure stability, or 0.5% of the volume of the waste for waste processed to a stable form.

iii. Void spaces within the waste and between the waste and its package must be reduced to the extent practicable.

8. Each package must be clearly labeled to identify whether it is Class A waste, Class B waste, or Class C waste in accordance with RH-407.d.6.

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9. The Department may, upon request or on its own initiative, authorize other provisions for the classification and characteristics of waste on a specific basis, if, after evaluation of the specific characteristics of the waste, disposal site, and method of disposal, it finds reasonable assurance of compliance with the performance objectives in RH-407.c.

10. **Institutional requirements**.

A. **Land ownership**.

Disposal of radioactive waste received from other persons may be permitted only on land owned in fee by the Federal or a State government.

B. **Institutional control**.

The land owner or custodial agency shall carry out an institutional control program to physically control access to the disposal site following transfer of control of the disposal site from the disposal site operator. The institutional control program must also include, but not be limited to, carrying out an environmental monitoring program at the disposal site, periodic surveillance, minor custodial care and other requirements as determined by the Department, and administration of funds to cover the costs for these activities. The period of institutional controls will be determined by the Department, but institutional controls may not be relied upon for more than 100 years following transfer of control of the disposal site to the owner.

~~RH-407. (Cont'd)~~

e. **Funding for disposal site closure and stabilization**.

1. The applicant shall provide assurance that sufficient funds will be available to carry out disposal site closure and stabilization, including decontamination or dismantlement of land disposal facility structures; and closure and stabilization of the disposal site so that following transfer of the disposal site to the site owner, the need for ongoing active maintenance is eliminated to the extent practicable and only minor custodial care, surveillance and

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monitoring are required. -These assurances shall be based on Department-approved cost estimates reflecting the Department-approved plan for disposal site closure and stabilization. –The applicant's cost estimates must take into account total capital costs that would be incurred if an independent contractor were hired to perform the closure and stabilization work.

2. In order to avoid unnecessary duplication and expense, the Department will accept financial sureties that have been consolidated with earmarked financial or surety arrangements established to meet requirements of other Federal or State agencies ~~and/or~~or local governing bodies for such decontamination, closure and stabilization.- The Department will accept this arrangement only if they are considered adequate to satisfy these requirements and that the portion of the surety which covers the closure of the disposal site is clearly identified and committed for use in accomplishing these activities.

3. The licensee's surety mechanism will be annually reviewed by the Department to assure that sufficient funds are available for completion of the closure plan, assuming that the work has to be performed by an independent contractor.

4. The amount of surety liability should change in accordance with the predicted cost of future closure and stabilization.- Factors affecting closure and stabilization cost estimates include inflation; increases in the amount of disturbed land; changes in engineering plans; closure and stabilization that has already been accomplished and any other conditions affecting costs. -This will yield a surety that is at least sufficient at all times to cover the costs of closure of the disposal units that are expected to be used before the next license renewal.

~~RH 407.e. (Cont'd)~~

5. The term of the surety mechanism must be open-ended unless it can be demonstrated that another arrangement would provide an equivalent level of assurance. –This assurance could be provided with a surety mechanism which is written for a specified period of time (e.g., five (5) years) yet which must be automatically renewed unless the party who issues the surety notifies the Department and the beneficiary (the licensee) not less than ninety (90) days prior to the renewal date of its intention not to renew.- In such a situation, the licensee must submit a replacement surety within thirty (30) days after notification of cancellation.- If the licensee fails to

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provide a replacement surety acceptable to the Department, the site owner may collect on the original surety.

6. Proof of forfeiture must not be necessary to collect the surety so that in the event that the licensee could not provide an acceptable replacement surety within the required time, the surety shall be automatically collected prior to its expiration. The conditions described above would have to be clearly stated on any surety instrument which is not open-ended and must be agreed to by all parties. Liability under the surety mechanism must remain in effect until the closure and stabilization program has been completed and approved by the Department, and the license has been transferred to the site owner.

7. Financial surety arrangements generally acceptable to the Department include surety bonds, cash deposits, certificates of deposits, deposits of government securities, escrow accounts, irrevocable letters or lines of credit, trust funds and combinations of the above or such other types of arrangements as may be approved by the Department. However, self-insurance or any arrangement which essentially constitutes pledging the assets of the licensee will not satisfy the surety requirement for private sector applicants since this provides no additional assurance other than that which already exists through license requirements.

RH-408. **Issuance of Specific Licenses**.

Upon a determination that an application meets the requirements of the Act and these Rules of the Department, the Department will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate and necessary to effectuate the purposes of the Act.

RH-409. **Specific Terms and Conditions of Licenses**.

a. Each license issued pursuant to these Rules shall be subject to all the provisions of the Act, now or hereafter in effect, and to all rules and orders of the Department.

b. 1. No license issued or granted pursuant to these Rules nor any right under a license shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Department shall, after securing full information, find

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that the transfer is in accordance with the provisions of the Act and shall give its consent in writing.

2. An application for transfer of license must include:

A. The identity, technical, and financial qualifications of the proposed transferee; and

B. Financial assurance for decommissioning information required by RH-409.h.

c. Each person licensed by the Department pursuant to these Rules shall confine his possession and use of the licensed material to the locations and purposes authorized in the license. Except as otherwise provided in the license, a license issued pursuant to these Rules shall carry with it the right to receive, acquire, receive title to, own, possess, and use radioactive material. Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of Section 4 of these Rules.

d. The Department may incorporate, in any license issued pursuant to these Rules, at the time of issuance, or thereafter by appropriate rule or order, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of radioactive material as it deems appropriate or necessary in order to:

1. Protect health or to minimize danger to life or property;

2. Require such reports and the keeping of such records and to provide for such inspections of activities under the license as may be necessary or appropriate to effectuate the purposes of the Act and rules thereunder; and

3. Prevent loss or theft of licensed material.

~~RH-409. (Cont'd)~~

e. Each licensee shall notify the Department in writing when the licensee decides to permanently discontinue all activities involving materials authorized under the license. This notification requirement applies to all specific licenses issued under these Rules.

f. Licensees required to submit emergency plans by RH-403.g. shall follow the emergency plan approved by the Department. Proposed changes to the plan may not be implemented without prior application to and prior approval by the Department.

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g. **Bankruptcy notification**.

1. Each general licensee that is required to register by RH-402.c.13., each general licensee under RH-402.g.2., and each specific licensee shall notify the Department in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of Title 11 (Bankruptcy) of the United States Code by or against:

A. The licensee;

B. An entity (as that term is defined in 11 U.S.C. 101(15)) controlling the licensee or listing the license or licensee as property of the estate; or

C. An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

2. This notification must indicate:

A. The bankruptcy court in which the petition for bankruptcy was filed;

B. The case name and number; and

C. The date of the filing of the petition.

~~RH-409. (Cont'd)~~

h. **Financial assurance and record keeping for decommissioning**.

1. A. Each applicant for a specific license authorizing the possession and use of unsealed radioactive material of half-life greater than 120 days and in quantities exceeding 10^5 times the applicable quantities set forth in Appendix E to Section 2 shall submit a decommissioning funding plan as described in RH-409.h.5. -The decommissioning funding plan must also be submitted when a combination of isotopes is involved if R divided by 10^5 is greater than 1 (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in Appendix E to Section 2.

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B. Each holder of, or applicant for, a specific license authorizing the possession and use of sealed sources or plated foils of half-life greater than 120 days and in quantities exceeding 10^{12} times the applicable quantities set forth in Appendix E to Section 2 (or when a combination of isotopes is involved if R, as defined in RH-409.h.1.A., divided by 10^{12} is greater than 1) shall submit a decommissioning funding plan as described in RH-409.h.5. The decommissioning funding plan must be submitted to the Department by July 1, 2016.

C. Each applicant for a specific license authorizing the possession and use of more than 100 mCi of source material in a readily dispersible form shall submit a decommissioning funding plan as described in RH-409.h.5.

2. Each applicant for a specific license authorizing possession and use of radioactive material of half-life greater than 120 days ~~and/or~~or source material, in quantities specified in RH-409.h.4., shall either:

A. Submit a decommissioning funding plan as described in RH-409.h.5.; or

~~RH-409.h.2. (Cont'd)~~

B. Submit a certification that financial assurance for decommissioning has been provided in the amount prescribed by RH-409.h.4. using one of the methods described in RH-409.h.6. ~~-~~For an applicant, this certification may state that the appropriate assurance will be obtained after the application has been approved and the license issued but prior to the receipt of licensed material. If the applicant defers execution of the financial instrument until after the license has been issued, a signed original of the financial instrument obtained to satisfy the requirements of RH-409.h.6. must be submitted to the Department before receipt of licensed material.~~-~~ If the applicant does not defer execution of the financial instrument, the applicant shall submit to the Department, as part of the certification, a signed original of the financial instrument obtained to satisfy the requirements of RH-409.h.6.

3. A. Each holder of a specific license issued on or after July 27, 1993, which is of a type described in RH-409.h.1. or h.2.,

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shall provide financial assurance for decommissioning in accordance with the criteria set forth in RH-409.h.

B. Each holder of a specific license issued before July 27, 1993, and of a type described in RH-409.h.1., shall submit, on or before July 27, 1993, a decommissioning funding plan or a certification of financial assurance for decommissioning in an amount at least equal to $1,125,000 in accordance with the criteria set forth in RH-409.h. If the licensee submits the certification of financial assurance rather than a decommissioning funding plan at this time, the licensee shall include a decommissioning funding plan in any application for license renewal.

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C. Each holder of a specific license issued before July 27, 1993, and of a type described in RH-409.h.2. shall submit, on or before July 27, 1993, a decommissioning funding plan or a certification of financial assurance for decommissioning in accordance with the criteria set forth in RH-409.h.

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~~RH-409.h.3. (Cont'd)~~

D. If, in surveys made under RH-1300.a., residual radioactivity in the facility and environment, including the subsurface, is detected at levels that would, if left uncorrected, prevent the site from meeting the RH-1216. criteria for unrestricted use, the licensee must submit a decommissioning funding plan within one year of when the survey is completed.

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4. **Table of required amounts of financial assurance for decommissioning by quantity of material**.

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Licensees required to submit the $1,125,000 amount must do so by December 2, 2006. Licensees required to submit the $113,000 or $225,000 amount must do so by June 2, 2007. Licensees having possession limits exceeding the upper bounds of this table must base financial assurance on a decommissioning funding plan.

Greater than 10^4 but less than or equal to 10^5 times the applicable quantities in Appendix E to Section 2 in unsealed form. (For a combination of isotopes, if R, as defined in RH-409.h.1.A., divided by 10^4 is greater than 1 but R divided by 10^5 is less than or equal to 1) …….…… $1,125,000

Greater than 10^3 but less than or equal to 10^4 times the applicable quantities in Appendix E to Section 2 in unsealed form.
(For a combination of isotopes, if R, as defined in RH-409.h.1.A., divided by 10^3 is greater than 1 but R divided by 10^4 is less than or equal to 1)
……. $225,000

Greater than 10^{10} but less than or equal to 10^{12} times the applicable quantities in Appendix E to Section 2 in sealed sources or plated foils.
(For a combination of isotopes, if R, as defined in RH-409.h.1.A., divided by 10^{10} is greater than 1, but R divided by 10^{12} is less than or equal to 1)
…… $113,000

Greater than 10 mCi but less than or equal to 100 mCi of source material in a readily dispersible form……..…… $225,000

~~RH-409.h. (Cont'd)~~

5. A. Each decommissioning funding plan must be submitted for review and approval and must contain:

i. A detailed cost estimate for decommissioning, in an amount reflecting:

(a). The cost of an independent contractor to perform all decommissioning activities;

(b). The cost of meeting the RH-1216. criteria for unrestricted use, provided that, if the applicant or licensee can demonstrate its ability to meet the provisions of RH-1217., the cost estimate may be based on meeting the RH-1217. criteria;

(c). The volume of onsite subsurface material containing residual radioactivity that will require remediation to meet the criteria for license termination; and

(d). An adequate contingency factor.

ii. Identification of and justification for using the key assumptions contained in the DCE;

iii. A description of the method of assuring funds for decommissioning from RH-409.h.6., including means for adjusting cost estimates and associated

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funding levels periodically over the life of the facility;

iv. A certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning; and

v. A signed original of the financial instrument obtained to satisfy the requirements of RH-409.h.6. (unless a previously submitted and accepted financial instrument continues to cover the cost estimate for decommissioning).

~~RH-409.h.5. (Cont'd)~~

B. At the time of license renewal and at intervals not to exceed 3 years, the decommissioning funding plan must be resubmitted with adjustments as necessary to account for changes in costs and the extent of contamination. -If the amount of financial assurance will be adjusted downward, this can not be done until the updated decommissioning funding plan is approved. -The decommissioning funding plan must update the information submitted with the original or prior approved plan, and must specifically consider the effect of the following events on decommissioning costs:

i. Spills of radioactive material producing additional residual radioactivity in onsite subsurface material;

ii. Waste inventory increasing above the amount previously estimated;

iii. Waste disposal costs increasing above the amount previously estimated;

iv. Facility modifications;

v. Changes in authorized possession limits;

vi. Actual remediation costs that exceed the previous cost estimate;

vii. Onsite disposal; and

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viii. Use of a settling pond.

6. The financial instrument must include the licensee's name, license number, and the name, address, and other contact information of the issuer, and, if a trust is used, the trustee. When any of the foregoing information changes, the licensee must, within 30 days, submit financial instruments reflecting such changes. The financial instrument submitted must be a signed original or signed original duplicate, except where a copy of the signed original is specifically permitted. Financial assurance for decommissioning must be provided by one or more of the following methods:

~~RH-409.h.6. (Cont'd)~~

A. **Prepayment**.

Prepayment is the deposit prior to the start of operation into an account segregated from licensee assets and outside the licensee's administrative control of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment must be made into a trust account, and the trustee and the trust must be acceptable to the Department.

B. **A surety method, insurance, or other guarantee method**.

These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, or letter of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix A to Section 2.

For commercial corporations that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in Appendix B to Section 2. For commercial corporations that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in Appendix C to Section 2.
For nonprofit entities, such as colleges, universities, and nonprofit hospitals, a guarantee of funds by the applicant or licensee may be used if the guarantee and test are as contained in Appendix D to Section 2.

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Except for an external sinking fund, a parent company guarantee or a guarantee by the applicant or licensee may not be used in combination with any other financial methods to satisfy the requirements of RH-409.h. A guarantee by the applicant or licensee may not be used in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

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~~RH-409.h.6.B. (Cont'd)~~

i. The surety method or insurance must be open-ended or, if written for a specified term, such as five (5) years, must be renewed automatically unless ninety (90) days or more prior to the renewal date, the issuer notifies the Department, the beneficiary, and the licensee of its intention not to renew. The surety method or insurance must also provide that the full face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the licensee fails to provide a replacement acceptable to the Department within thirty (30) days after receipt of notification of cancellation.

ii. The surety method or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the Department. An acceptable trustee includes an appropriate State or Federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.

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iii. The surety method or insurance must remain in effect until the Department has terminated the license.

C. **An external sinking fund in which deposits are made at least annually, coupled with a surety method, insurance, or other guarantee method, the value of which may decrease by the amount being accumulated in the sinking fund**.

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An external sinking fund is a fund established and maintained by setting aside funds periodically in an account segregated from licensee assets and outside the licensee's administrative control in which the total amount of funds would be sufficient to pay decommissioning costs at the time termination of operation is expected.

An external sinking fund must be in the form of a trust. If the other guarantee method is used, no surety or insurance may be combined with the external sinking fund. The

~~).h.6. (Cont'd)~~

surety, insurance, or other guarantee provisions must be as stated in RH-409.h.6.B.

D. In the case of State or local government licensees, a statement of intent containing a cost estimate for decommissioning or an amount based on the table in RH-409.h.4., and indicating that funds for decommissioning will be obtained when necessary.

E. When a government entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such government entity.

7. Each person licensed under these Rules shall keep records of information important to decommissioning of the facility in an identified location until the site is released for unrestricted use. Before licensed activities are transferred or assigned in accordance with RH-409.b., licensees shall transfer all records described in this paragraph to the new licensee. In this case, the new licensee will be responsible for maintaining these records until the license is terminated.

If records important to the decommissioning of a facility are kept for other purposes, reference to these records and their locations may be used. Information the Department considers important to decommissioning consists of:

A. Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site. These records may be limited to instances when contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants may have spread to inaccessible areas as in

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the case of possible seepage into porous materials such as concrete. ~~-~~These records must include any known information on identification of involved nuclides, quantities, forms, and concentrations.

B. As-built drawings and modifications of structures and equipment in restricted areas where radioactive materials are used ~~and/or~~or stored, and of locations of possible inaccessible contamination such as buried pipes which may be subject to contamination. ~~-~~If required drawings are referenced, each relevant document need not be indexed

~~RH-409.h.7. (Cont'd)~~

individually.~~-~~ If drawings are not available, the licensee shall substitute appropriate records of available information concerning these areas and locations.

C. Except for areas containing only sealed sources (provided the sources have not leaked and no contamination remains after any leak) or radioactive materials having only half-lives of less than sixty-five (65) days or depleted uranium used only for shielding or as penetrators in unused munitions, a list contained in a single document and updated every two (2) years, consisting of the following:

i. All areas designated and formerly designated restricted areas as defined in RH-1100.;

ii. All areas outside of restricted areas that require documentation under RH-409.h.7.A.;

iii. All areas outside of restricted areas where current and previous wastes have been buried as documented under RH-1500.h.;

iv. All areas outside of restricted areas which contain material such that, if the license expired, the licensee would be required to either decontaminate the area to meet the criteria for decommissioning in RH-1215. through RH-1220 or apply for approval for disposal under RH-1401.

D. Records of the cost estimate performed for the decommissioning funding plan or of the amount certified for decommissioning, and records of the funding method

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used for assuring funds if either a funding plan or certification is used.

8. In providing financial assurance under RH-409.h., each licensee must use the financial assurance funds only for decommissioning activities and each licensee must monitor the balance of funds held to account for market variations. The licensee must replenish the funds, and report such actions to the Department, as follows:

A. If, at the end of a calendar quarter, the fund balance is below the amount necessary to cover the cost of decommissioning, but is not below seventy-five percent

~~RH-409.h.8. (Cont'd)~~

(75%) of the cost, the licensee must increase the balance to cover the cost, and must do so within 30 days after the end of the calendar quarter.

B. If, at any time, the fund balance falls below seventy-five percent (75%) of the amount necessary to cover the cost of decommissioning, the licensee must increase the balance to cover the cost, and must do so within 30 days of the occurrence.

C. Within 30 days of taking the actions required by RH-409.h.8.A. or RH-409.h.8.B., the licensee must provide a written report of such actions to the Department, and state the new balance of the fund.

i. Each portable gauge licensee shall use a minimum of two (2) independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal, whenever portable gauges are not under the control and constant surveillance of the licensee.

j. Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum 99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with RH-8531. The licensee shall record the results of each test and retain each record for 3 years after the record is made. The licensee shall report the results of any test that exceeds the permissible concentration listed in RH-8531.a. at the time of generator elution, in accordance with RH-8805.

k. 1. Authorization under RH-403.j. to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer

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to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.

2. Each licensee authorized under RH-403.j. to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall:

~~RH-409.k.2. (Cont'd)~~

A. Satisfy the labeling requirements in RH-405.l.1.D. for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium.

B. Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test, instrument check, and instrument adjustment requirements in RH-405.l.3.

C. A licensee that is a pharmacy authorized under RH-403.j. to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be:

i. An authorized nuclear pharmacist that meets the requirements in RH-405.l.2.B., or

ii. An individual under the supervision of an authorized nuclear pharmacist as specified in RH-8306.

D. A pharmacy, authorized under RH-403.j. to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of RH-405.l.2.E.

RH-410. **Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas**.

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a. Except as provided in RH-411.b., each specific license shall expire at the end of the day, in the month and year stated therein.

b. Each specific license revoked by the Department expires with the Department's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by Department Order.

~~RH-410. (Cont'd)~~

c. Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of radioactive material until the Department notifies the licensee in writing that the license is terminated. During this time, the licensee shall:

1. Limit actions involving radioactive material to those related to decommissioning; and

2. Continue to control entry to restricted areas until they are suitable for release in accordance with Department requirements.

d. Within sixty (60) days of the occurrence of any of the following, each licensee shall provide notification to the Department in writing of such occurrence, and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with Department requirements, or submit within twelve (12) months of notification a decommissioning plan, if required by RH-410.g., and begin decommissioning upon approval of that plan if:

1. The license has expired pursuant to RH-410.a. or RH-410.b.; or

2. The licensee has decided to permanently cease principal activities, as defined in this Section, at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Department requirements; or

3. No principal activities under the license have been conducted for a period of twenty-four (24) months; or

4. No principal activities have been conducted for a period of twenty-four (24) months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release in accordance with Department requirements.

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e. Coincident with the notification required by RH-410.d., the licensee shall maintain in effect all decommissioning financial assurances established by the licensee pursuant to RH-409.h. in conjunction with a license issuance or renewal or as required by RH-410. The amount of the financial assurance must be increased, or may be decreased, as appropriate, to cover the detailed cost estimate for decommissioning established pursuant to RH-410.g.4.E.

1. Any licensee who has not provided financial assurance to cover the detailed cost estimate submitted with the decommissioning plan shall do so when this rule becomes effective July 1, 2002.

2. Following approval of the decommissioning plan, a licensee may reduce the amount of the financial assurance as decommissioning proceeds and radiological contamination is reduced at the site with the approval of the Department.

f. The Department may grant a request to extend the time periods established in RH-410.d. if the Department determines that this relief is not detrimental to the public health and safety and is otherwise in the public interest. The request must be submitted no later than thirty (30) days before notification pursuant to RH-410.d. The schedule for decommissioning set forth in RH-410.d. may not commence until the Department has made a determination on the request.

g. 1. A decommissioning plan must be submitted if required by license conditions or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the Department and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

A. Procedures would involve techniques not applied routinely during cleanup or maintenance operations;

B. Workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

C. Procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

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D. Procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

2. The Department may approve an alternate schedule for submittal of a decommissioning plan required in RH-410.d. if the Department determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

3. Procedures such as those listed in RH-410.g.1. with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

4. The proposed decommissioning plan for the site or separate building or outdoor area must include:

A. A description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;

B. A description of planned decommissioning activities;

C. A description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

D. A description of the planned final radiation survey; and

E. An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and a plan for assuring the availability of adequate funds for completion of decommissioning.

F. For decommissioning plans calling for completion of decommissioning later than 24 months after plan approval, the plan shall include a justification for the delay based on the criteria in RH-410.i.

~~RH-410.g. (Cont'd)~~

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5. The proposed decommissioning plan will be approved by the Department if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.

h. 1. Except as provided in RH-410.i., licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than twenty-four (24) months following the initiation of decommissioning.

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2. Except as provided in RH-410.i., when decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than twenty-four (24) months following the initiation of decommissioning.

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i. The Department may approve a request for an alternative schedule for completion of decommissioning of the site separate building or outdoor area, and license termination if appropriate, if the Department determines that the alternative is warranted by consideration of the following:

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1. Whether it is technically feasible to complete decommissioning within the allotted twenty-four (24) month period;

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2. Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted twenty-four (24) month period;

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3. Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

4. Whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and

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5. Other site-specific factors which the Department may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

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j. **As the final step in decommissioning, the licensee shall**:

1. Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed, up-to-date RC FORM 530, "Certificate of Disposition of Materials," or equivalent information; and

2. Conduct a radiation survey of the premises where the licensed activities were carried out, and submit a report of the results of this survey, unless the licensee demonstrates in some other manner that the premises are suitable for release in accordance with the criteria for decommissioning in RH-1216., RH-1217., ~~and/or~~or RH-1218. The licensee shall, as appropriate:

   A. Report levels of gamma radiation in units of microroentgen (millisieverts) per hour at one meter from surfaces, and report levels of radioactivity, including alpha and beta, in units of disintegrations per minute or microcuries (megabecquerels) per 100 square centimeters—removable and fixed—for surfaces, microcuries (megabecquerels) per milliliter for water, and picocuries (becquerels) per gram for solids such as soils or concrete; and

   B. Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

k. **Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Department determines that**:

1. Radioactive material has been properly disposed;

2. Reasonable effort has been made to eliminate residual radioactive contamination, if present; and

3. A. A radiation survey has been performed which demonstrates that the premises are suitable for release in accordance with the criteria for decommissioning in RH-1216., RH-1217., ~~and/or~~ or RH-1218.; or

   B. Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release in accordance with the criteria for decommissioning in RH-1216., RH-1217.,~~ and/or~~ or RH-1218.

~~RH-410.k. (Cont'd)~~

4. Records required by RH-600. have been received.

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RH-411. **Renewal of Licenses**.

a. Application for renewal of specific licenses shall be filed in accordance with Part D, RH-403.

b. In any case in which a licensee, not less than thirty (30) days prior to expiration of this existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until the application has been finally approved or disapproved by the Department.

RH-412. **Amendment of Licenses and Sealed Source and Device Registration Certificates**.

Applications for amendment of a license shall be filed in accordance with RH-403. and shall specify the respects in which the licensee desires his license to be amended and the grounds for the amendment. -Applications for amendment of sealed source and device registration certificates shall be filed in accordance with 10 CFR 32.210 and any other applicable provisions and shall specify the respects in which the certificate holder desires his certificate to be amended and the grounds for the amendment.

RH-413. **Department Action on Application to Renew or Amend**.

In considering an application to renew or amend a license or to amend a sealed source and device registration certificate, the Department will apply the applicable criteria set forth in RH-404., RH-405., and RH-406. and in Sections 2, 3, 4, 5, 6, 7, 8, and 9.

RH-414. Deleted. -See RH-409.b.

RH-415. Reserved.

RH-416. **Modification, Suspension, and Revocation of Licenses and Registration Certificates**.

a. The terms and conditions of each license and registration certificate issued under these Rules shall be subject to revision or modification. A license may be suspended or revoked by reason of amendments to the Act, or by reason of rules or orders issued by the Department.

b. Any license or registration certificate may be revoked, suspended, or modified, in whole or in part, for any of the following:

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1. Any material false statement in the application or any statement of fact required under provisions of the Act or of these Rules;

2. Conditions revealed by such application or statement of fact or any report, record, or inspection or other means that would warrant the Department to refuse to grant a license on an original application;

3. Violation of, or failure to observe any of, the terms and conditions of the Act or the license or of any rule or order of the Department; or

4. Existing conditions that constitute a substantial threat to public health or safety or the environment.

c. Except in cases of willful violation or those in which the public health, interest, or safety requires otherwise, no license or registration certificate shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefor, facts or conduct that may warrant such action shall have been called to the attention of the licensee or certificate holder in writing, and the licensee or certificate holder shall have been accorded opportunity to demonstrate or achieve compliance with all lawful requirements.

RH-417.- RH-499. Reserved.

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PART E.
TRANSFER OF MATERIAL

RH-500. **Authorization for Transfer**.

No licensee shall transfer radioactive material except as authorized pursuant to this Part.

RH-501. **Conditions of Transfer**.

a. Except as otherwise provided in the license and subject to the provisions of paragraphs b. and c. of this section, any licensee may transfer radioactive material, subject to acceptance by the transferee, to:

1. The Department;

2. The U.S. Department of Energy;

3. Any person exempt from these Rules to the extent permitted under such exemption;

4. Any person in an Agreement State, subject to the jurisdiction of that State, who has been exempted from the licensing requirements and regulations of that State, to the extent permitted under such exemption;

5. Any person in U.S. Nuclear Regulatory Commission (NRC) jurisdiction, subject to the jurisdiction of the NRC, who has been exempted from the licensing requirements and regulations of the NRC, to the extent permitted under such exemption;

6. Any person authorized to receive such material under terms of a general license or a specific license or their equivalents issued by the Department, the NRC, or an Agreement State; or

7. As otherwise authorized by the Department in writing.

b. Before transferring radioactive material to a specific licensee of the Department, the NRC, or an Agreement State, or to a general licensee who is required to register with the Department, the NRC, or an Agreement State prior to receipt of the radioactive material, the licensee transferring the material shall verify that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

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c. The following methods for the verification required by RH-501.b. are acceptable:

1. The transferor may have in his possession, and read, a current copy of the transferee's specific license or registration certificate.

2. The transferor may have in his possession a written certification by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date;

3. For emergency shipments the transferor may accept oral certification by the transferee that he is authorized by license or registration certificate to receive the type, form, and quantity of radioactive material to be transferred, specifying the license or registration certificate number, issuing agency, and expiration date; provided, that the oral certification is confirmed in writing within ten (10) days;

4. The transferor may obtain other sources of information compiled by a reporting service from official records of the Department, the NRC, or the licensing agency of an Agreement State as to the identity of licensees and the scope and expiration dates of licenses and registrations; or

5. When none of the methods of verification in RH-501.c.1. through 4. are readily available or when a transferor desires to verify that information received by one of such methods is correct or up-to-date, the transferor may obtain and record confirmation from the Department, the NRC, or the licensing agency of an Agreement State that the transferee is licensed to receive the radioactive material.

d. The transferor shall keep a copy of the verification documentation as a record for three (3) years.

RH-502. **Preparation and Transport**.

Preparation for shipment and transport of radioactive material shall be in accordance with the provisions of Section 4.

RH-503.- RH-599. Reserved.

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PART F.
RECORDS, REPORTS, INSPECTIONS, AND TESTS

RH-600. **Records**.

a. **Receipt, transfer, and disposal**.

Each person who receives radioactive material pursuant to a license issued pursuant to the rules in this Section, Part I of Section 3, Part J of Section 3, and Sections 7, 8, and 9 of these Rules shall keep records showing the receipt, transfer, and disposal of the radioactive material as follows:

1. The licensee shall retain each record of receipt of radioactive material as long as the material is possessed and for three (3) years following transfer or disposal of the material.

2. The licensee who transferred the material shall retain each record of transfer for three (3) years after each transfer; however, persons in paragraph a. receiving source material shall retain each record of transfer for this material until the Department terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

3. The licensee who disposed of the material shall retain each record of disposal of radioactive material until the Department terminates each license that authorizes disposal of the material.

4. If radioactive material is combined or mixed with other licensed material and subsequently treated in a manner that makes direct correlation of a receipt record with a transfer, export, or disposition record impossible, the licensee may use evaluative techniques (such as first-in-first-out) to make the records that are required by this Section account for 100 percent (100%) of the material received.

b. **Record retention periods**.

1. The licensee shall retain each record that is required by the rules in this Section, Part I of Section 3, Part J of Section 3, and Sections 7, 8, and 9 or by license condition for the period specified by the appropriate rule or license condition. If a retention period is not otherwise specified by rule or license condition, the record must be retained until the Department terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

~~RH-600.b. (Cont'd)~~

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2. If there is a conflict between the Department's rules in this Section, Part I of Section 3, Part J of Section 3, and Sections 7, 8, and 9, license condition, or other written Department approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the rules in this Section, Part I of Section 3, Part J of Section 3, and Sections 7, 8, and 9 for such records shall apply unless the Department, pursuant to RH-304., has granted a specific exemption from the record retention requirements specified in the rules in this Section, Part I of Section 3, Part J of Section 3, and Sections 7, 8, and 9.

c. **Record maintenance.**

Each record required by this Section, Part I of Section 3, Part J of Section 3, and Sections 7, 8, and 9 must be legible throughout the specified retention period. The record may be the original or a reproduced copy or microform if such reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by Department rules. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

d. Prior to license termination, each licensee previously or currently authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, shall forward the following records to the Department:

1. Records of disposal of licensed material made under RH-1401., RH-1402., a previous RH-1403. that authorized certain burials[11/], RH-1404., RH-1405., RH-1408.; and

2. Records required by RH-1500.c.2.D.

e. If licensed activities are transferred or assigned in accordance with RH-409.b., each licensee previously or currently authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

~~RH-600.e (Cont'd)~~

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1. Records of disposal of licensed material made under RH-1401., RH-1402., a previous RH-1403. that authorized certain burials[11/], RH-1404., RH-1405., RH-1408.; and

2. Records required by RH-1500.c.2.D.

f. Prior to license termination, each licensee shall forward the records required by RH-409.h.7. to the Department.

RH-601. **Reporting Requirements**.

a. **Immediate report**.

Each licensee shall notify the Department as soon as possible but not later than four (4) hours after the discovery of an event that prevents immediate protective actions necessary to avoid exposures to radiation or radioactive materials that could exceed regulatory limits or releases of licensed material that could exceed regulatory limits. (Events may include fires, explosions, toxic gas releases, et cetera.)

b. **Twenty-four hour report**.

Each licensee shall notify the Department within twenty-four (24) hours after the discovery of any of the following events involving licensed material:

1. An unplanned contamination event that:

A. Requires access to the contamination area, by workers or the public, to be restricted for more than twenty-four (24) hours by imposing additional radiological controls or by prohibiting entry into the area;

B. Involves a quantity of material greater than five (5) times the lowest annual limit on intake specified in Appendix G to Section 3 for the material; and

C. Has access to the area restricted for a reason other than to allow isotopes with a half-life of less than twenty-four (24) hours to decay prior to decontamination.

2. An event in which equipment is disabled or fails to function as designed when:

~~RH-601.b.2. (Cont'd)~~

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A. The equipment is required by rule or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding regulatory limits, or to mitigate the consequences of an accident;

B. The equipment is required to be available and operable when it is disabled or fails to function; and

C. No redundant equipment is available and operable to perform the required safety function.

3. An event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body.

4. An unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material when:

A. The quantity of material involved is greater than five (5) times the lowest annual limit on intake specified in Appendix G to Section 3 for the material; and

B. The damage affects the integrity of the licensed material or its container.

c. **Preparation and submission of reports**.

Reports made by licensees in response to the requirements of this section must be made as follows:

1. Licensees shall make reports required by paragraphs a. and b. of this section by telephone to the Department at 1-800-633-1735.- To the extent that the information is available at the time of notification, the information provided in these reports must include:

A. The caller's name, title, and call back telephone number;

B. A description of the event, including date and time;

C. The exact location of the event;

~~RH-601.c.1. (Cont'd)~~

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D. The isotopes, quantities, and chemical and physical form of the licensed material involved; and

E. Any personnel radiation exposure data available.

2. **Written report**.

Each licensee that makes a report required by paragraph a. or b. of this section shall submit a written follow-up report within thirty (30) days of the initial report. Written reports prepared pursuant to other rules may be submitted to fulfill this requirement if the reports contain all of the necessary information and the appropriate distribution is made. These written reports must be sent to the Arkansas Department of Health, Radiation Control Section Chief, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867. The reports must include the following:

A. Complete information required by paragraph c.1. of this section;

B. The probable cause of the event, including all factors that contributed to the event and the manufacturer and model number (if applicable) of any equipment that failed or malfunctioned;

C. Corrective actions taken or planned to prevent occurrence of similar or identical events in the future and the results of any evaluations or assessments; and

D. The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

RH-602. **Inspections**.

a. Each licensee shall afford to the Department at all reasonable times opportunity to inspect radioactive material and the premises and facilities wherein such radioactive material is used or stored.

b. Each licensee shall make available to the Department for inspection, upon reasonable notice, records kept by the licensee pursuant to these Rules.

RH-603. **Tests**.

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Upon instruction from the Department, each licensee shall perform or cause to have performed and shall permit the Department to perform, such reasonable tests as the Department deems appropriate or necessary, including, but not limited to, tests of:

a. Radioactive material;

b. Facilities wherein radioactive materials are used or stored;

c. Radiation detection and monitoring instruments; and

d. Other equipment and devices used in connection with utilization or storage of licensed material.

RH-604.- RH-699. Reserved.

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PART G.
ENFORCEMENT

RH-700. **Violations**.

a. An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any rule or order issued thereunder. Any person who willfully violates any provision of the Act or any rule or order issued thereunder may be guilty of a felony, misdemeanor, or crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law. Arkansas Code Annotated §20-21-204 describes criminal and civil penalties which may be assessed.

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b. **Impounding**.

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Sources of radiation shall be subject to impounding pursuant to Section 5 of these Rules.

RH-701.- RH-749. Reserved.

PART H.
RECIPROCITY AND ADDITIONAL REQUIREMENTS

RH-750. **Reciprocal Recognition of Licenses**.

a. **Licenses of Byproduct, Source, and Special Nuclear Material in Quantities Not Sufficient to Form a Critical Mass**.

1. Subject to these rules, any person who holds a specific license from the NRC or an Agreement State, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this State for a period not in excess of 180 days in any calendar year provided that:

A. The licensing document does not limit the activity authorized by such document to specified installations or locations;

B. The out-of-state licensee notifies the Department in writing at least three (3) days prior to engaging in such activity. Such notification shall indicate the exact location, period, and type of proposed possession and use within this State, and shall be accompanied by a copy of the pertinent licensing document. -If, for a specific case, the three (3) day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the Department, obtain permission to proceed sooner;

C. The out-of-state licensee complies with all applicable rules of the Department and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable rules of the Department;

D. The out-of-state licensee supplies such other information as the Department may request; and

E. The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in RH-750.a.1. except by transfer to a person:

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i. Specifically licensed by the Department or by the NRC to receive such material, or

ii. Exempt from the requirements for a license for such material under RH-301.a.

2. Notwithstanding the provisions of RH-750.a.1., any person who holds a specific license issued by the NRC or an Agreement State authorizing the holder to manufacture, transfer, install, or service a device described in RH-401., RH-402.a., and RH-402.h. within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service such a device in this State provided that:

A. Reserved.

B. The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by the NRC or an Agreement State.

C. Such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited."

3. The Department may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by the NRC or an Agreement State, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

b. **Licenses of Naturally Occurring and Accelerator-Produced Radioactive Material**.

1. Subject to these rules and Section 7, any person who holds a specific license from a Licensing State, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this State for a period not in excess of 180 days in any calendar year provided that:

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A. The licensing document does not limit the activity authorized by such document to specified installations or locations;

B. The out-of-state licensee notifies the Department in writing at least three (3) days prior to engaging in such activity. Such notification shall indicate the exact location, period, and type of proposed possession and use within this State, and shall be accompanied by a copy of the pertinent licensing document. -If, for a specific case, the three (3) day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the Department, obtain permission to proceed sooner;

C. The out-of-state licensee complies with all applicable rules of the Department and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable rules of the Department;

D. The out-of-state licensee supplies such other information as the Department may request; and

E. The out-of-state licensee shall not transfer or dispose of radioactive material possessed or used under the general license provided in RH-750.b.1. except by transfer to a person:

i. Specifically licensed by the Department or by another Licensing State to receive such material, or

ii. Exempt from the requirements for a license for such material under these Rules.

2. Notwithstanding the provisions of RH-750.b.1., any person who holds a specific license issued by a Licensing State authorizing the holder to manufacture, transfer, install, or service a device described in RH-401., RH-402.a., and RH-402.h. within areas subject to the jurisdiction of the licensing body is hereby granted a general license to install, transfer, demonstrate, or service such a device in this State provided that:

A. Reserved.

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B. The device has been manufactured, labeled, installed, and serviced in accordance with applicable provisions of the specific license issued to such person by a Licensing State.

C. Such person shall assure that any labels required to be affixed to the device under regulations of the authority which licensed manufacture of the device bear a statement that "Removal of this label is prohibited."

3. The Department may withdraw, limit, or qualify its acceptance of any specific license or equivalent licensing document issued by a Licensing State, or any product distributed pursuant to such licensing document, upon determining that such action is necessary in order to prevent undue hazard to public health and safety or property.

c. **Recognition of Agreement State Licenses**.

1. Before radioactive materials can be used at a temporary job site within the State at any Federal facility, the jurisdictional status of the job site shall be determined. If the jurisdictional status is unknown, the Federal agency should be contacted to determine if the job site is under exclusive Federal jurisdiction.

A. In areas of exclusive Federal jurisdiction, the general license is subject to all the applicable rules, regulations, orders and fees of the NRC, and

B. Authorizations for use of radioactive materials at job sites under exclusive Federal jurisdiction shall be obtained from the NRC by either:

i. Filing a NRC Form-241 in accordance with 10 CFR 150.20(b); or

ii. By applying for a specific NRC license.

2. Before radioactive material can be used at a temporary job site in another State, authorization shall be obtained for the State if it is an Agreement State, or from the NRC for any non-Agreement State, either by filing for reciprocity or applying for a specific license.

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RH-751. **Additional Requirements**.

The Department may, by rule, or order, impose upon any licensee such requirements in addition to those established in the rules in this Section as it deems appropriate or necessary to minimize danger to public health and safety or property.

RH-752.- RH-899. Reserved.

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PART I.
SCHEDULES

RH-900. Schedule A to Section 2. -Deleted.

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RH-901. **SCHEDULE B TO SECTION 2**

EXEMPT QUANTITIES

Radioactive Material	Micro-curies	Radioactive Material	Micro-curies
Antimony-122 (Sb-122)	100	Europium-154 (Eu-154)	1
Antimony-124 (Sb-124)	10	Europium-155 (Eu-155)	10
Antimony-125 (Sb-125)	10	Fluorine-18 (F-18)	1,000
Arsenic-73 (As-73)	100	Gadolinium-153 (Gd-153)	10
Arsenic-74 (As-74)	10	Gadolinium-159 (Gd-159)	100
Arsenic-76 (As-76)	10	Gallium-67 (Ga-67)	100
Arsenic-77 (As-77)	100	Gallium-72 (Ga-72)	10
Barium-131 (Ba-131)	10	Germanium-68 (Ge-68)	10
Barium-133 (Ba-133)	10	Germanium-71 (Ge-71)	100
Barium-140 (Ba-140)	10	Gold-195 (Au-195)	10
Bismuth-210 (Bi-210)	1	Gold-198 (Au-198)	100
Bromine-82 (Br-82)	10	Gold-199 (Au-199)	100
Cadmium-109 (Cd-109)	10	Hafnium-181 (Hf-181)	10
Cadmium-115m (Cd-115m)	10	Holmium-166 (Ho-166)	100
Cadmium-115 (Cd-115)	100	Hydrogen-3 (H-3)	1,000
Calcium-45 (Ca-45)	10	Indium-111 (In-111)	100
Calcium-47 (Ca-47)	10	Indium-113m (In-113m)	100
Carbon-14 (C-14)	100	Indium-114m (In-114m)	10
Cerium-141 (Ce-141)	100	Indium-115m (In-115m)	100
Cerium-143 (Ce-143)	100	Indium-115 (In-115)	10
Cerium-144 (Ce-144)	1	Iodine-123 (I-123)	100
Cesium-129 (Cs-129)	100	Iodine-125 (I-125)	1
Cesium-131 (Cs-131)	1,000	Iodine-126 (I-126)	1
Cesium-134m (Cs-134m)	100	Iodine-129 (I-129)	0.1
Cesium-134 (Cs-134)	1	Iodine-131 (I-131)	1
Cesium-135 (Cs-135)	10	Iodine-132 (I-132)	10
Cesium-136 (Cs-136)	10	Iodine-133 (I-133)	1
Cesium-137 (Cs-137)	10	Iodine-134 (I-134)	10
Chlorine-36 (Cl-36)	10	Iodine-135 (I-135)	10
Chlorine-38 (Cl-38)	10	Iridium-192 (Ir-192)	10
Chromium-51 (Cr-51)	1,000	Iridium-194 (Ir-194)	100
Cobalt-57 (Co-57)	100	Iron-52 (Fe-52)	10
Cobalt-58m (Co-58m)	10	Iron-55 (Fe-55)	100
Cobalt-58 (Co-58)	10	Iron-59 (Fe-59)	10
Cobalt-60 (Co-60)	1	Krypton-85 (Kr-85)	100
Copper-64 (Cu-64)	100	Krypton-87 (Kr-87)	10
Dysprosium-165 (Dy-165)	10	Lanthanum-140 (La-140)	10
Dysprosium-166 (Dy-166)	100	Lutetium-177 (Lu-177)	100
Erbium-169 (Er-169)	100	Manganese-52 (Mn-52)	10
Erbium-171 (Er-171)	100	Manganese-54 (Mn-54)	10
Europium-152 (Eu-152) 9.2 h	100	Manganese-56 (Mn-56)	10
Europium-152 (Eu-152) 13 yr	1	Mercury-197m (Hg-197m)	100

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RH-901. **SCHEDULE B TO SECTION 2**

EXEMPT QUANTITIES

Radioactive Material	Micro-curies	Radioactive Material	Micro-curies
Mercury-197 (Hg-197)	100	Samarium-153 (Sm-153)	100
Mercury-203 (Hg-203)	10	Scandium-46 (Sc-46)	10
Molybdenum-99 (Mo-99)	100	Scandium-47 (Sc-47)	100
Neodymium-147 (Nd-147)	100	Scandium-48 (Sc-48)	10
Neodymium-149 (Nd-149)	100	Selenium-75 (Se-75)	10
Nickel-59 (Ni-59)	100	Silicon-31 (Si-31)	100
Nickel-63 (Ni-63)	10	Silver-105 (Ag-105)	10
Nickel-65 (Ni-65)	100	Silver-110m (Ag-110m)	1
Niobium-93m (Nb-93m)	10	Silver-111 (Ag-111)	100
Niobium-95 (Nb-95)	10	Sodium-22 (Na-22)	10
Niobium-97 (Nb-97)	10	Sodium-24 (Na-24)	10
Osmium-185 (Os-185)	10	Strontium-85 (Sr-85)	10
Osmium-191m (Os-191m)	100	Strontium-89 (Sr-89)	1
Osmium-191 (Os-191)	100	Strontium-90 (Sr-90)	0.1
Osmium-193 (Os-193)	100	Strontium-91 (Sr-91)	10
Palladium-103 (Pd-103)	100	Strontium-92 (Sr-92)	10
Palladium-109 (Pd-109)	100	Sulphur-35 (S-35)	100
Phosphorus-32 (P-32)	10	Tantalum-182 (Ta-182)	10
Platinum-191 (Pt-191)	100	Technetium-96 (Tc-96)	10
Platinum-193m (Pt-193m)	100	Technetium-97m (Tc-97m)	100
Platinum-193 (Pt-193)	100	Technetium-97 (Tc-97)	100
Platinum-197m (Pt-197m)	100	Technetium-99m (Tc-99m)	100
Platinum-197 (Pt-197)	100	Technetium-99 (Tc-99)	10
Polonium-210 (Po-210)	0.1	Tellurium-125m (Te-125m)	10
Potassium-42 (K-42)	10	Tellurium-127m (Te-127m)	10
Potassium-43 (K-43)	10	Tellurium-127 (Te-127)	100
Praseodymium-142 (Pr-142)	100	Tellurium-129m (Te-129m)	10
Praseodymium-143 (Pr-143)	100	Tellurium-129 (Te-129)	100
Promethium-147 (Pm-147)	10	Tellurium-131m (Te-131m)	10
Promethium-149 (Pm-149)	10	Tellurium-132 (Te-132)	10
Rhenium-186 (Re-186)	100	Terbium-160 (Tb-160)	10
Rhenium-188 (Re-188)	100	Thallium-200 (Tl-200)	100
Rhodium-103m (Rh-103m)	100	Thallium-201 (Tl-201)	100
Rhodium-105 (Rh-105)	100	Thallium-202 (Tl-202)	100
Rubidium-81 (Rh-81)	10	Thallium-204 (Tl-204)	10
Rubidium-86 (Rb-86)	10	Thulium-170 (Tm-170)	10
Rubidium-87 (Rb-87)	10	Thulium-171 (Tm-171)	10
Ruthenium-97 (Ru-97)	100	Tin-113 (Sn-113)	10
Ruthenium-103 (Ru-103)	10	Tin-125 (Sn-125)	10
Ruthenium-105 (Ru-105)	10	Tungsten-181 (W-181)	10
Ruthenium-106 (Ru-106)	1	Tungsten-185 (W-185)	10
Samarium-151 (Sm-151)	10	Tungsten-187 (W-187)	100

RH-901. **SCHEDULE B TO SECTION 2**

EXEMPT QUANTITIES

Radioactive Material	Micro-curies	Radioactive Material	Micro-curies
Vanadium-48 (V-48)	10	Zinc-65 (Zn-65)	10
Xenon-131m (Xe-131m)	1,000	Zinc-69m (Zn-69m)	100
Xenon-133 (Xe-133)	100	Zinc-69 (Zn-69)	1,000
Xenon-135 (Xe-135)	100	Zirconium-93 (Zr-93)	10
Ytterbium-175 (Yb-175)	100	Zirconium-95 (Zr-95)	10
Yttrium-87 (Y-87)	10	Zirconium-97 (Zr-97)	10
Yttrium-88 (Y-88)	10		
Yttrium-90 (Y-90)	10	Any radioactive	
Yttrium-91 (Y-91)	10	material not listed above,	
Yttrium-92 (Y-92)	100	other than alpha emitting	
Yttrium-93 (Y-93)	100	radioactive material	0.1

RH-902. **SCHEDULE C TO SECTION 2**

EXEMPT CONCENTRATIONS

Element (atomic number)	**Isotope**	Column I **Gas concentration** µCi/ml[a/]	Column II **Liquid and solid concentration** µCi/ml[b/]
Antimony (51)	Sb-122	----------	3×10^{-4}
	Sb-124	----------	2×10^{-4}
	Sb-125	----------	1×10^{-3}
Argon (18)	A-37	1×10^{-3}	----------
	A-41	4×10^{-7}	----------
Arsenic (33)	As-73	----------	5×10^{-3}
	As-74	----------	5×10^{-4}
	As-76	----------	2×10^{-4}
	As-77	----------	8×10^{-4}
Barium (56)	Ba-131	----------	2×10^{-3}
	Ba-140	----------	3×10^{-4}
Beryllium (4)	Be-7	----------	2×10^{-2}
Bismuth (83)	Bi-206	----------	4×10^{-4}
Bromine (35)	Br-82	4×10^{-7}	3×10^{-3}
Cadmium (48)	Cd-109	----------	2×10^{-3}
	Cd-115m	----------	3×10^{-4}
	Cd-115	----------	3×10^{-4}
Calcium (20)	Ca-45	----------	9×10^{-5}
	Ca-47	----------	5×10^{-4}
Carbon (6)	C-14	1×10^{-6}	8×10^{-3}
Cerium (58)	Ce-141	----------	9×10^{-4}
	Ce-143	----------	4×10^{-4}
	Ce-144	----------	1×10^{-4}
Cesium (55)	Cs-131	----------	2×10^{-2}
	Cs-134m	----------	6×10^{-2}
	Cs-134	----------	9×10^{-5}
Chlorine (17)	Cl-38	9×10^{-7}	4×10^{-3}
Chromium (24)	Cr-51	----------	2×10^{-2}
Cobalt (27)	Co-57	----------	5×10^{-3}
	Co-58	----------	1×10^{-3}
	Co-60	----------	5×10^{-4}
Copper (29)	Cu-64	----------	3×10^{-3}
Dysprosium (66)	Dy-165	----------	4×10^{-3}
	Dy-166	----------	4×10^{-4}
Erbium (68)	Er-169	----------	9×10^{-4}
	Er-171	----------	1×10^{-3}
Europium (63)	Eu-152 -	----------	6×10^{-4}
	(T/2=9.2 hrs)	----------	----------
	Eu-155	----------	2×10^{-3}
Fluorine (9)	F-18	2×10^{-6}	8×10^{-3}
Gadolinium (64)	Gd-153	----------	2×10^{-3}
	Gd-159	----------	8×10^{-4}
Gallium (31)	Ga-72	----------	4×10^{-4}

Germanium (32)	Ge-71	----------	2×10^{-2}

RH-902. **Schedule C to Section 2. Exempt Concentrations.** (Cont'd)

Element (atomic number)	**Isotope**	Column I **Gas concentration** µCi/ml[a/]	Column II **Liquid and solid concentration** µCi/ml[b/]
Gold (79)	Au-196	----------	2×10^{-3}
	Au-198	----------	5×10^{-4}
	Au-199	----------	2×10^{-3}
Hafnium (72)	Hf-181	----------	7×10^{-4}
Hydrogen (1)	H-3	5×10^{-6}	3×10^{-2}
Indium (49)	In-113m	----------	1×10^{-2}
	In-114m	----------	2×10^{-4}
Iodine (53)	I-126	3×10^{-9}	2×10^{-5}
	I-131	3×10^{-9}	2×10^{-5}
	I-132	8×10^{-8}	6×10^{-4}
	I-133	1×10^{-8}	7×10^{-5}
	I-134	2×10^{-7}	1×10^{-3}
Iridium (77)	Ir-190	----------	2×10^{-3}
	Ir-192	----------	4×10^{-4}
	Ir-194	----------	3×10^{-4}
Iron (26)	Fe-55	----------	8×10^{-3}
	Fe-59	----------	6×10^{-4}
Krypton (36)	Kr-85m	1×10^{-6}	----------
	Kr-85	3×10^{-6}	----------
Lanthanum (57)	La-140	----------	2×10^{-4}
Lead (82)	Pb-203	----------	4×10^{-3}
Lutetium (71)	Lu-177	----------	1×10^{-3}
Manganese (25)	Mn-52	----------	3×10^{-4}
	Mn-54	----------	1×10^{-3}
	Mn-56	----------	1×10^{-3}
Mercury (80)	Hg-197m	----------	2×10^{-3}
	Hg-197	----------	3×10^{-3}
	Hg-203	----------	2×10^{-4}
Molybdenum (42)	Mo-99	----------	2×10^{-3}
Neodymium (60)	Nd-147	----------	6×10^{-4}
	Nd-149	----------	3×10^{-3}
Nickel (28)	Ni-65	----------	1×10^{-3}
Niobium (Columbium)(41)	Nb-95	----------	1×10^{-3}
	Nb-97	----------	9×10^{-3}
Osmium (76)	Os-185	----------	7×10^{-4}
	Os-191m	----------	3×10^{-2}
	Os-191	----------	2×10^{-3}
	Os-193	----------	6×10^{-4}
Palladium (46)	Pd-103	----------	3×10^{-3}
	Pd-109	----------	9×10^{-4}
Phosphorus (15)	P-32	----------	2×10^{-4}

RH-902. **Schedule C to Section 2. Exempt Concentrations.** (Cont'd)

Element (atomic number)	**Isotope**	Column I **Gas concentration** µCi/ml[a/]	Column II **Liquid and solid concentration** µCi/ml[b/]
Platinum (78)	Pt-191	----------	1×10^{-3}
	Pt-193m	----------	1×10^{-2}
	Pt-197m	----------	1×10^{-2}
	Pt-197	----------	1×10^{-3}
Potassium (19)	K-42	----------	3×10^{-3}
Praseodymium (50)	Pr-142	----------	3×10^{-4}
	Pr-143	----------	5×10^{-4}
Promethium (61)	Pm-147	----------	2×10^{-3}
	Pm-149	----------	4×10^{-4}
Rhenium (75)	Re-183	----------	6×10^{-3}
	Re-186	----------	9×10^{-4}
	Re-188	----------	6×10^{-4}
Rhodium (45)	Rh-103m	----------	1×10^{-1}
	Rh-105	----------	1×10^{-3}
Rubidium (37)	Rb-86	----------	7×10^{-4}
Ruthenium (44)	Ru-97	----------	4×10^{-4}
	Ru-103	----------	8×10^{-4}
	Ru-105	----------	1×10^{-3}
	Ru-106	----------	1×10^{-4}
Samarium (62)	Sm-153	----------	8×10^{-4}
Scandium (21)	Sc-46	----------	4×10^{-4}
	Sc-47	----------	9×10^{-4}
	Sc-48	----------	3×10^{-4}
Selenium (34)	Se-75	----------	3×10^{-3}
Silicon (14)	Si-31	----------	9×10^{-3}
Silver (47)	Ag-105	----------	1×10^{-3}
	Ag-110m	----------	3×10^{-4}
	Ag-111	----------	4×10^{-4}
Sodium (11)	Na-24	----------	2×10^{-3}
Strontium (38)	Sr-85	----------	1×10^{-4}
	Sr-89	----------	1×10^{-4}
	Sr-91	----------	7×10^{-4}
	Sr-92	----------	7×10^{-4}
Sulfur (16)	S-35	9×10^{-8}	6×10^{-4}
Tantalum (73)	Ta-182	----------	4×10^{-4}
Technetium (43)	Tc-96m	----------	1×10^{-1}
	Tc-96	----------	1×10^{-3}
Tellurium (52)	Te-125m	----------	2×10^{-3}
	Te-127m	----------	6×10^{-4}
	Te-127	----------	3×10^{-3}
	Te-129m	----------	3×10^{-4}

	Te-131m	----------	6×10^{-4}
	Te-132	----------	3×10^{-4}

RH-902. **Schedule C to Section 2. Exempt Concentrations.** (Cont'd)

Element (atomic number)	**Isotope**	Column I **Gas concentration** µCi/ml[a/]	Column II **Liquid and solid concentration** µCi/ml[b/]
Terbium (65)	Tb-160	----------	4×10^{-4}
Thallium (81)	Tl-200	----------	4×10^{-3}
	Tl-201	----------	3×10^{-3}
	Tl-202	----------	1×10^{-3}
	Tl-204	----------	1×10^{-3}
Thulium (69)	Tm-170	----------	5×10^{-4}
	Tm-171	----------	5×10^{-3}
Tin (50)	Sn-113	----------	9×10^{-4}
	Sn-125	----------	2×10^{-4}
Tungsten (Wolfram)(74)	W-181	----------	4×10^{-3}
	W-187	----------	7×10^{-4}
Vanadium (23)	V-48	----------	3×10^{-4}
Xenon (54)	Xe-131m	4×10^{-6}	----------
	Xe-133	3×10^{-6}	----------
	Xe-135	1×10^{-6}	----------
Ytterbium (70)	Yb-175	----------	1×10^{-3}
Yttrium (39)	Y-90	----------	2×10^{-4}
	Y-91m	----------	3×10^{-2}
	Y-91	----------	3×10^{-4}
	Y-92	----------	6×10^{-4}
	Y-93	----------	3×10^{-4}
Zinc (30)	Zn-65	----------	1×10^{-3}
	Zn-69m	----------	7×10^{-4}
	Zn-69	----------	2×10^{-2}
Zirconium (40)	Zr-95	----------	6×10^{-4}
	Zr-97	----------	2×10^{-4}
Beta ~~and/or~~or gamma emitting radioactive material not listed above with half-life less than 3 years	--------	1×10^{-10}	1×10^{-6}

RH-902. **Schedule C to Section 2. Exempt Concentrations.** (Cont'd)

Notes :

1. Many radioisotopes disintegrate into isotopes which are also radioactive. In expressing the concentrations in Schedule C, the activity stated is that of the parent isotope and takes into account the daughters.

2. For purposes of RH-301.a. where there is involved a combination of isotopes, the limit for the combination should be derived as follows:

   Determine for each isotope in the product the ratio between the concentration present in the product and the exempt concentration established in Schedule C for the specific isotope when not in combination. The sum of such ratios may not exceed "1" (i.e., unity).

   Example:

$$\frac{\text{Concentration of Isotope A in Product}}{\text{Exempt concentration of Isotope A}} + \frac{\text{Concentration of Isotope B in Product}}{\text{Exempt concentration of Isotope B}} \leq 1$$

Footnotes for Schedule C to Section 2:

a/ Values are given in Column 1 only for those materials normally used as gases.

b/ µCi/gm for solids.

RH-903. Schedule D.- Deleted. -Refer to Section 9.

RH-904. **SCHEDULE E TO SECTION 2**

LIMITS FOR BROAD LICENSES

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Radioactive Material	Column I (Curies)	Column II (Curies)
Antimony-122	1	0.01
Antimony-124	1	0.01
Antimony-125	1	0.01
Arsenic-73	10	0.1
Arsenic-74	1	0.01
Arsenic-76	1	0.01
Arsenic-77	10	0.1
Barium-131	10	0.1
Barium-140	1	0.01
Beryllium-7	10	0.1
Bismuth-210	0.1	0.001
Bromine-82	10	0.1
Cadmium-109	1	0.01
Cadmium-115m	1	0.01
Cadmium-115	10	0.1
Calcium-45	1	0.01
Calcium-47	10	0.1
Carbon-14	100	1
Cerium-141	10	0.1
Cerium-143	10	0.1
Cerium-144	0.1	0.001
Cesium-131	100	1
Cesium-134m	100	1
Cesium-134	0.1	0.001
Cesium-135	1	0.01
Cesium-136	10	0.1
Cesium-137	0.1	0.001
Chlorine-36	1	0.01
Chlorine-38	100	1
Chronmium-51	100	1
Cobalt-57	10	0.1
Cobalt-58m	100	1
Cobalt-58	1	0.01
Cobalt-60	0.1	0.001
Copper-64	10	0.1
Dysprosium-165	100	1
Dysprosium-166	10	0.1
Erbium-169	10	0.1
Erbium-171	10	0.1

RH-904. **Schedule E to Section 2. Limits for Broad Licenses.** (Cont'd)

Radioactive Material	Column I (Curies)	Column II (Curies)
Europium-152 9.2 h	10	0.1
Europium-152 13 y	0.1	0.001
Europium-154	0.1	0.001
Europium-155	1	0.01
Fluorine-18	100	1
Gadolinium-153	1	0.01
Gadolinium-159	10	0.1
Gallium-72	10	0.1
Germanium-71	100	1
Gold-198	10	0.1
Gold-199	10	0.1
Hafnium-181	1	0.01
Holmium-166	10	0.1
Hydrogen-3	100	1
Indium-113m	100	1
Indium-114m	1	0.01
Indium-115m	100	1
Indium-115	1	0.01
Iodine-125	0.1	0.001
Iodine-126	0.1	0.001
Iodine-129	0.1	0.001
Iodine-131	0.1	0.001
Iodine-132	10	0.1
Iodine-133	1	0.01
Iodine-134	10	0.1
Iodine-135	1	0.01
Iridium-192	1	0.01
Iridium-194	10	0.1
Iron-55	10	0.1
Iron-59	1	0.01
Krypton-85	100	1
Krypton-87	10	0.1
Lanthanum-140	1	0.01
Lutetium-177	10	0.1
Manganese-52	1	0.01
Manganese-54	1	0.01
Manganese-56	10	0.1
Mercury-197m	10	0.1
Mercuty-197	10	0.1
Mercury-203	1	0.01

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RH-904. **Schedule E to Section 2. Limits for Broad Licenses.** (Cont'd)

Radioactive Material	Column I (Curies)	Column II (Curies)
Molybdenum-99	10	0.1
Neodymium-147	10	0.1
Neodymium-149	10	0.1
Nickel-59	10	0.1
Nickel-63	1	0.01
Nickel-65	10	0.1
Niobium-93m	1	0.01
Niobium-95	1	0.01
Niobium-97	100	1
Osmium-185	1	0.01
Osmium-191m	100	1
Osmium-191	10	0.1
Osmium-193	10	0.1
Palladium-103	10	0.1
Palladium-109	10	0.1
Phosphorus-32	1	0.01
Platinum-191	10	0.1
Platinum-193m	100	1
Platinum-193	10	0.1
Platinum-197m	100	1
Platinum-197	10	0.1
Polonium-210	0.01	0.0001
Potassium-42	1	0.01
Praseodymium-142	10	0.1
Praseodymium-143	10	0.1
Promethium-147	1	0.01
Promethium-149	10	0.1
Radium-226	0.01	0.0001
Rhenium-186	10	0.1
Rhenium-188	10	0.1
Rhodium-103m	1,000	10
Rhodium-105	10	0.1
Rubidium-86	1	0.01
Rubidium-87	1	0.01
Ruthenium-97	100	1
Ruthenium-103	1	0.01
Ruthenium-105	10	0.1
Ruthenium-106	0.1	0.001

RH-904. **Schedule E to Section 2. Limits for Broad Licenses.** (Cont'd)

Radioactive Material	Column I (Curies)	Column II (Curies)
Samarium-151	1	0.01
Samarium-153	10	0.1
Scandium-46	1	0.01
Scandium-47	10	0.1
Scandium-48	1	0.01
Selenium-75	1	0.01
Silicon-31	10	0.1
Silver-105	1	0.01
Silver-110m	0.1	0.001
Silver-111	10	0.1
Sodium-22	0.1	0.001
Sodium-24	1	0.01
Strontium-85m	1,000	10
Strontium-85	1	0.01
Strontium-89	1	0.01
Strontium-90	0.01	0.0001
Strontium-91	10	0.1
Strontium-92	10	0.1
Sulfur-35	10	0.1
Tantalum-182	1	0.01
Technetium-96	10	0.1
Technetium-97m	10	0.1
Technetium-97	10	0.1
Technetium-99m	100	1
Technetium-99	1	0.01
Tellurium-125m	1	0.01
Tellurium-127m	1	0.01
Tellurium-127	10	0.1
Tellurium-129m	1	0.01
Tellurium-129	100	1
Tellurium-131m	10	0.1
Tellurium-132	1	0.01
Terbium-160	1	0.01
Thallium-200	10	0.1
Thallium-201	10	0.1
Thallium-202	10	0.1
Tallium-204	1	0.01
Thulium-170	1	0.01
Thulium-171	1	0.01

RH-904. **Schedule E to Section 2. Limits for Broad Licenses.** (Cont'd)

Radioactive Material	Column I (Curies)	Column II (Curies)
Tin-113	1	0.01
Tin-125	1	0.01
Tungsten-181	1	0.01
Tungsten-185	1	0.01
Tungsten-187	10	0.1
Vanadium-48	1	0.01
Xenon-131m	1,000	10
Xenon-133	100	1
Xenon-135	100	1
Ytterbium-175	10	0.1
Yttrium-90	1	0.01
Yttrium-91	1	0.01
Yttrium-92	10	0.1
Yttrium-93	1	0.01
Zinc-65	1	0.01
Zinc-69m	10	0.1
Zinc-69	100	1
Zirconium-93	1	0.01
Zirconium-95	1	0.01
Zirconium-97	1	0.01
Any radioactive material other than alpha emitting radioactive material, source material, or special nuclear material not listed above	0.1	0.001

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RH-905. **SCHEDULE F TO SECTION 2**

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QUANTITIES OF RADIOACTIVE MATERIALS REQUIRING CONSIDERATION OF THE NEED FOR AN EMERGENCY PLAN FOR RESPONDING TO A RELEASE

Radioactive material [a/] [b/]	Release Fraction	Quantity (Curies)
Actinium-228	0.001	4,000
Americium-241	.001	2
Americium-242	.001	2
Americium-243	.001	2
Antimony-124	.01	4,000
Antimony-126	.01	6,000
Barium-133	.01	10,000
Barium-140	.01	30,000
Bismuth-207	.01	5,000
Bismuth-210	.01	600
Cadmium-109	.01	1,000
Cadmium-113	.01	80
Calcium-45	.01	20,000
Californium-252	.001	9 (20 mg)
Carbon-14 (Non CO)	.01	50,000
Cerium-141	.01	10,000
Cerium-144	.01	300
Cesium-134	.01	2,000
Cesium-137	.01	3,000
Chlorine-36	.5	100
Chromium-51	.01	300,000
Cobalt-60	.001	5,000
Copper-64	.01	200,000
Curium-242	.001	60
Curium-243	.001	3
Curium-244	.001	4
Curium-245	.001	2
Europium-152	.01	500
Europium-154	.01	400
Europium-155	.01	3,000
Gadolinium-153	.01	5,000
Germanium-68	.01	2,000
Gold-198	.01	30,000
Hafnium-172	.01	400
Hafnium-181	.01	7,000
Holmium-166m	.01	100
Hydrogen-3	.5	20,000
Iodine-125	.5	10
Iodine-131	.5	10
Indium-114m	.01	1,000

RH-905. **SCHEDULE F TO SECTION 2** (Cont'd)

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Radioactive material [a/] [b/]	Release Fraction	Quantity (Curies)
Iridium-192	.001	40,000
Iron-55	.01	40,000
Iron-59	.01	7,000
Krypton-85	1.0	6,000,000
Lead-210	.01	8
Maganese-56	.01	60,000
Mercury-203	.01	10,000
Molybdenum-99	.01	30,000
Neptunium-237	.001	2
Nickel-63	.01	20,000
Niobium-94	.01	300
Phosphorus-32	.5	100
Phosphorus-33	.5	1,000
Polonium-210	.01	10
Potassium-42	.01	9,000
Promethium-145	.01	4,000
Promethium-147	.01	4,000
Radium-226	.001	100
Ruthenium-106	.01	200
Samarium-151	.01	4,000
Scandium-46	.01	3,000
Selenium-75	.01	10,000
Silver-110m	.01	1,000
Sodium-22	.01	9,000
Sodium-24	.01	10,000
Strontium-89	.01	3,000
Strontium-90	.01	90
Sulfur-35	.5	900
Technetium-99	.01	10,000
Technetium-99m	.01	400,000
Tellurium-127m	.01	5,000
Tellurium-129m	.01	5,000
Terbium-160	.01	4,000
Thulium-170	.01	4,000
Tin-113	.01	10,000
Tin-123	.01	3,000
Tin-126	.01	1,000
Titanium-44	.01	100
Vanadium-48	.01	7,000
Xenon-133	1.0	900,000
Yttrium-91	.01	2,000
Zinc-65	.01	5,000
Zirconium-93	.01	400
Zirconium-95	.01	5,000

RH-905. **SCHEDULE F TO SECTION 2** (Cont'd)

Radioactive material [a/] [b/]	Release Fraction	Quantity (Curies)
Any other beta-gamma emitter	.01	10,000
Mixed fission products	.01	1,000
Mixed corrosion products	.01	10,000
Contaminated equipment, beta-gamma	.001	10,000
Irradiated material, any form other than solid noncombustible	.01	1,000
Irradiated material, solid noncombustible	.001	10,000
Mixed radioactive waste, beta-gamma	.01	1,000
Packaged mixed waste, beta-gamma [b/]	.001	10,000
Any other alpha emitter	.001	2
Contaminated equipment, alpha	.0001	20
Packaged waste, alpha [b/]	.0001	20
Combinations of radioactive materials listed above [a/]	----	----

Footnotes for Schedule F to Section 2:

[a/] For combinations of radioactive materials, consideration of the need for an emergency plan is required if the sum of the ratios of the quantity of each radioactive material authorized to the quantity listed for that material in Schedule F to Section 2 exceeds one.

[b/] Waste packaged in Type B containers does not require an emergency plan.

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APPENDIX A TO SECTION 2

CRITERIA RELATING TO USE OF FINANCIAL TESTS AND PARENT COMPANY GUARANTEE FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on obtaining a parent company guarantee that funds will be available for decommissioning costs and on a demonstration that the parent company passes a financial test. This appendix establishes criteria for passing the financial test and for obtaining the parent company guarantee.

II. Financial Test

A. To pass the financial test, the parent company must meet the criteria of either paragraph A.1. or A.2. of this section. For purposes of applying the Appendix A criteria, tangible net worth must be calculated to exclude all intangible assets and the net book value of the nuclear facility and site, and total net worth, which may include intangible assets, must be calculated to exclude the net book value and goodwill of the nuclear facility and site.

1. The parent company must have:

   a. Two of the following three ratios: A ratio of total liabilities to total net worth less than 2.0; a ratio of the sum of net income plus depreciation, depletion, and amortization to total liabilities greater than 0.1; and a ratio of current assets to current liabilities greater than 1.5; and

   b. Net working capital and tangible net worth each at least six (6) times the amount of decommissioning funds being assured by a parent company guarantee for the total of all nuclear facilities or parts thereof (or prescribed amount if a certification is used); and

   c. Tangible net worth of at least $21 million; and

   d. Assets located in the United States amounting to at least ninety percent (90%) of total assets or at least six (6) times the current decommissioning cost estimates for the total of all facilities or parts therof (or prescribed amount if a certificate is used).

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~~**Appendix A to Section 2.** (Cont'd)~~

2. The parent company must have:

   a. A current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, A, or BBB (including adjustments of + and -) as issued by Standard and Poor's or Aaa, Aa, A, or Baa (including adjustment of 1, 2, or 3) as issued by Moody's; and

   b. Total net worth at least six (6) times the amount of decommissioning funds being assured by a parent company guarantee for the total of all nuclear facilities or parts thereof (or prescribed amount if a certification is used); and

   c. Tangible net worth of at least $21 million; and

   d. Assets located in the United States amounting to at least ninety percent (90%) of the total assets or at least six (6) times the current decommissioning cost estimates for the total of all facilities or parts thereof (or prescribed amount if certification is used).

B. The parent company's independent certified public accountant must compare the data used by the parent company in the financial test, which is derived from the independently audited, year-end financial statements for the latest fiscal year, with the amounts in such financial statement. The accountant must evaluate the parent company's off-balance sheet transactions and provide an opinion on whether those transactions could materially adversely affect the parent company's ability to pay for decommissioning costs. -The accountant must verify that a bond rating, if used to demonstrate passage of the financial test, meets the requirements of paragraph A. of this section. -In connection with the auditing procedure, the licensee shall inform the Department within ninety (90) days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

C. 1. After the initial financial test, the parent company must annually pass the test and provide documentation of its continued eligibility to use the parent company guarantee to the Department within ninety (90) days after the close of each succeeding fiscal year.

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~~**Appendix A to Section 2.** (Cont'd)~~

2. If the parent company no longer meets the requirements of paragraph A. of this Appendix, the licensee must send notice to the Department of intent to establish alternate financial assurance as specified in the Department's rules.

The notice must be sent by certified mail within ninety (90) days after the end of the fiscal year for which the yearend financial data show that the parent company no longer meets the financial test requirements. The licensee must provide alternate financial assurance within 120 days after the end of such fiscal year.

III. **Parent Company Guarantee**

The terms of a parent company guarantee which an applicant or licensee obtains must provide that:

A. The parent company guarantee will remain in force unless the guarantor sends notice of cancellation by certified mail to the licensee and the Department. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by both the licensee and the Department, as evidenced by the return receipts.

B. If the licensee fails to provide alternate financial assurance as specified in the Department's rules within ninety (90) days after receipt by the licensee and Department of a notice of cancellation of the parent company guarantee from the guarantor, the guarantor will provide alternative financial assurance that meets the provisions of the Department's rules in the name of the licensee.

C. The parent company guarantee and financial test provisions must remain in effect until the Department has terminated the license, accepted in writing the parent company's alternate financial assurances, or accepted in writing the licensee's financial assurances.

D. A standby trust to protect public health and safety and the environment must be established for decommissioning costs before the parent company guarantee agreement is submitted. The trustee and trust must be acceptable to the Department. An acceptable trustee includes an appropriate State or Federal government agency or an entity which has the authority to act as a trustee, whose trust operations are regulated and examined by a Federal or State agency. The Department has the right to change the trustee. An acceptable trust will meet the regulatory criteria

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established in these Rules that govern the issuance of the license for which the guarantor has accepted the obligation to pay for decommissioning costs.

~~**Appendix A to Section 2.** (Cont'd)~~

E. The guarantor must agree that it would be subject to Department orders to make payments under the guarantee agreement.

F. The guarantor must agree that if the guarantor admits in writing its inability to pay its debts generally, or makes a general assignment for the benefit of creditors, or any proceeding is instituted by or against the guarantor seeking to adjudicate it as bankrupt or insolvent, or seeking dissolution, liquidation, winding-up, reorganization, arrangement, adjustment, protection, relief or composition of it or its debts under any law relating to bankruptcy, insolvency, or reorganization or relief of debtors, or seeking the entry of an order for relief or the appointment of a receiver, trustee, custodian, or other similar official for the guarantor or for any substantial part of its property, or the guarantor takes any action to authorize or effect any of the actions stated in this paragraph, then the Department may:

1. Declare that the financial assurance guaranteed by the parent company guarantee agreement is immediately due and payable to the standby trust set up to protect the public health and safety and the environment, without diligence, presentment, demand, protest or any other notice of any kind, all of which are expressly waived by guarantor; and

2. Exercise any and all of its other rights under applicable law.

G. 1. The guarantor must agree to notify the Department, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of title 11 (Bankruptcy) of the United States Code, or the occurrence of any other event listed in paragraph F of this section, by or against:

a. The guarantor;

b. The licensee;

c. An entity (as that term is defined in 11 U.S.C. 101(15)) controlling the licensee or listing the license or licensee as property of the estate; or

d. An affiliate (as that term is defined in 11 U.S.C. 101(2)) of the licensee.

~~**Appendix A to Section 2.** (Cont'd)~~

2. This notification must include:

   a. A description of the event, including major creditors, the amounts involved, and the actions taken to assure that the amount of funds guaranteed by the parent company guarantee for decommissioning will be transferred to the standby trust as soon as possible;

   b. If a petition of bankruptcy was filed, the identity of the bankruptcy court in which the petition for bankruptcy was filed; and

   c. The date of filing of any petitions.

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APPENDIX B TO SECTION 2

CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF GUARANTEE FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Section II of this Appendix. The terms of the self-guarantee are in Section III of this Appendix. This Appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

II. Financial Test

A. To pass the financial test, a company must meet all of the criteria set forth in this section. For purposes of applying the Appendix B criteria, tangible net worth must be calculated to exclude all intangible assets and the net book value of the nuclear facility and site, and total net worth, which may include intangible assets, must be calculated to exclude the net book value and goodwill of the nuclear facility and site. These criteria include:

1. Tangible net worth of at least $21 million, and total net worth at least ten (10) times the amount of decommissioning funds being assured by a self-guarantee for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor for the total of all nuclear facilities or parts thereof (or the current amount required if certification is used).

2. Assets located in the United States amounting to at least ninety percent (90%) of total assets or at least ten (10) times the amount of decommissioning funds being assured by a self-guarantee, for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor for the total of all nuclear facilities or parts thereof (or the current amount required if certification is used).

3. A current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A (including adjustments of + and -) as issued by Standard and Poor's, or Aaa, Aa, or A (including adjustments of 1, 2, or 3) as issued by Moody's.

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B. To pass the financial test, a company must meet all of the following additional requirements:

1. The company must have at least one class of equity securities registered under the Securities Exchange Act of 1934.

2. The company's independent certified public accountant must compare the data used by the company in the financial test, which is derived from the independently audited, year-end financial statements for the latest fiscal year, with the amounts in such financial statement. The accountant must evaluate the company's off-balance sheet transactions and provide an opinion on whether those transactions could materially adversely affect the company's ability to pay for decommissioning costs. The accountant must verify that a bond rating, if used to demonstrate passage of the financial test, meets the requirements of Section II, paragraph A. of this Appendix. In connection with the auditing procedure, the licensee shall inform the Department within ninety (90) days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

3. After the initial financial test, the company must annually pass the test and provide documentation of its continued eligibility to use the self-guarantee to the Department within ninety (90) days after the close of each succeeding fiscal year.

C. If the licensee no longer meets the requirements of Section II.A. of this Appendix, the licensee must send immediate notice to the Department of its intent to establish alternate financial assurance as specified in the Department's rules within 120 days of such notice.

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III. **Company Self-Guarantee**

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail to the Department. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the Department, as evidenced by the return receipt.

~~**Appendix B to Section 2.** (Cont'd)~~

B. The licensee shall provide alternate financial assurance as specified in the Department's rules within ninety (90) days following receipt by the Department of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the Department has terminated the license or until another financial assurance method acceptable to the Department has been put in effect by the licensee.

D. The licensee will promptly forward to the Department and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission pursuant to the requirements of section 13 of the Securities and Exchange Act of 1934.

E. 1. If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poor's or in any category of "A3" and above by Moody's, the licensee will notify the Department in writing within twenty (20) days after publication of the change by the rating service.

2. If the licensee's most recent bond issuance ceases to be rated in any category of A or above by both Standard and Poor and Moody's, the licensee no longer meets the requirements of Section II.A of this Appendix.

F. The applicant or licensee must provide to the Department a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Department, the licensee

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will set up and fund a trust in the amount guaranteed by the self-guarantee agreement.

G. 1. A standby trust to protect public health and safety and the environment must be established for decommissioning costs before the self-guarantee agreement is submitted.

~~Appendix B to Section 2.~~ ~~(Cont'd)~~

2. The trustee and trust must be acceptable to the Department. An acceptable trustee includes an appropriate State or Federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency. The Department has the right to change the trustee. An acceptable trust will meet the regulatory criteria established in these Rules that govern the issuance of the license for which the guarantor has accepted the obligation to pay for decommissioning costs.

H. The guarantor must agree that if the guarantor admits in writing its inability to pay its debts generally, or makes a general assignment for the benefit of creditors, or any proceeding is instituted by or against the guarantor seeking to adjudicate it as bankrupt or insolvent, or seeking dissolution, liquidation, winding-up, reorganization, arrangement, adjustment, protection, relief or composition of it or its debts under any law relating to bankruptcy, insolvency, or reorganization or relief of debtors, or seeking the entry of an order for relief or the appointment of a receiver, trustee, custodian, or other similar official for the guarantor or for any substantial part of its property, or the guarantor takes any action to authorize or effect any of the actions stated in this paragraph, then the Department may:

1. Declare that the financial assurance guaranteed by the self-guarantee agreement is immediately due and payable to the standby trust set up to protect the public health and safety and the environment, without diligence, presentment, demand, protest or any other notice of any kind, all of which are expressly waived by guarantor; and

2. Exercise any and all of its other rights under applicable law.

I. The guarantor must notify the Department, in writing, immediately following the occurrence of any event listed in paragraph H. of this

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section, and must include a description of the event, including major creditors, the amounts involved, and the actions taken to assure that the amount of funds guaranteed by the self-guarantee agreement for decommissioning will be transferred to the standby trust as soon as possible.

APPENDIX C TO SECTION 2

CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF GUARANTEE FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING BY COMMERCIAL COMPANIES THAT HAVE NO OUTSTANDING RATED BONDS

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I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of Section II of this Appendix. The terms of the self-guarantee are in Section III of this Appendix. This Appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

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II. Financial Test

A. To pass the financial test, a company must meet all of the criteria set forth in this section. For purposes of applying the Appendix C criteria, tangible net worth must be calculated to exclude all intangible assets and the net book value of the nuclear facility and site, and total net worth, which may include intangible assets, must be calculated to exclude the net book value and goodwill of the nuclear facility and site. These criteria include:

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1. Tangible net worth of at least $21 million, and total net worth of at least ten (10) times the amount of decommissioning funds being assured by a self-guarantee for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor for the total of all nuclear facilities or parts thereof (or the current amount required if certification is used).

2. Assets located in the United States amounting to at least ninety percent (90%) of total assets or at least ten (10) times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor.

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3. A ratio of cash flow divided by total liabilities greater than 0.15 and a ratio of total liabilities divided by total net worth less than 1.5.

B. In addition, to pass the financial test, a company must meet all of the following additional requirements:

1. The company's independent certified public accountant must compare the data used by the company in the financial test, which is derived from the independently audited year-end financial statements for the latest fiscal year, with the amounts in such financial statement. The accountant must evaluate the company's off-balance sheet transactions and provide an opinion on whether those transactions could materially adversely affect the company's ability to pay for decommissioning costs. In connection with the auditing procedure, the licensee shall inform the Department within ninety (90) days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

2. After the initial financial test, the company must annually pass the test and provide documentation of its continued eligibility to use the self-guarantee to the Department within ninety (90) days after the close of each succeeding fiscal year.

3. If the licensee no longer meets the requirements of Section II.A. of this Appendix, the licensee must send notice to the Department of its intent to establish alternate financial assurance as specified in the Department's rules. The notice must be sent by certified mail, return receipt requested, within ninety (90) days after the end of the fiscal year for which the year-end financial data show that the licensee no longer meets the financial test requirements. The licensee must provide alternative financial assurance within 120 days after the end of such fiscal year.

III. **Company Self-Guarantee**

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail, return receipt requested, to the Department. Cancellation may not occur until an alternative financial assurance mechanism is in place.

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B. The licensee shall provide alternative financial assurance as specified in the Department's rules within ninety (90) days following receipt by the Department of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the Department has terminated the license or until another financial assurance method acceptable to the Department has been put in effect by the licensee.

D. The applicant or licensee must provide to the Department a written guarantee (a written commitment by a corporate officer) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Department, the licensee will fund the standby trust in the amount of the current cost estimates for decommissioning.

E. A standby trust to protect public health and safety and the environment must be established for decommissioning costs before the self-guarantee agreement is submitted. -The trustee and trust must be acceptable to the Department. -An acceptable trustee includes an appropriate State or Federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency. -The Department will have the right to change the trustee. An acceptable trust will meet the regulatory criteria established in these Rules that govern the issuance of the license for which the guarantor has accepted the obligation to pay for decommissioning costs.

F. The guarantor must agree that if the guarantor admits in writing its inability to pay its debts generally, or makes a general assignment for the benefit of creditors, or any proceeding is instituted by or against the guarantor seeking to adjudicate it as bankrupt or insolvent, or seeking dissolution, liquidation, winding-up, reorganization, arrangement, adjustment, protection, relief or composition of it or its debts under any law relating to bankruptcy, insolvency, or reorganization or relief of debtors, or seeking the entry of an order for relief or the appointment of a receiver, trustee, custodian, or other similar official for the guarantor or for any substantial part of its property, or the guarantor takes any action to authorize or effect any of the actions stated in this paragraph, then the Department may:

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1. Declare that the financial assurance guaranteed by the self-guarantee agreement is immediately due and payable to the standby trust set up to protect the public health and safety and the environment, without diligence, presentment, demand, protest or any other notice of any kind, all of which are expressly waived by guarantor; and

2. Exercise any and all of its other rights under applicable law.

G. The guarantor must notify the Department, in writing, immediately following the occurrence of any event listed in paragraph F of this section, and must include a description of the event, including major creditors, the amounts involved, and the actions taken to assure that the amount of funds guaranteed by the self-guarantee agreement for decommissioning will be transferred to the standby trust as soon as possible.

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APPENDIX D TO SECTION 2

CRITERIA RELATING TO USE OF FINANCIAL TESTS AND SELF GUARANTEE FOR PROVIDING REASONABLE ASSURANCE OF FUNDS FOR DECOMMISSIONING BY NONPROFIT COLLEGES, UNIVERSITIES, AND HOSPITALS

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I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the applicant or licensee passes the financial test of Section II of this Appendix. The terms of the self-guarantee are in Section III of this Appendix. This Appendix establishes criteria for passing the financial test for the self-guarantee and establishes the terms for a self-guarantee.

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II. Financial Test

A. For colleges and universities, to pass the financial test, a college or university must meet either the criteria in paragraph II.A.1. or the criteria in paragraph II.A.2. of this Appendix.

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1. For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A (including adjustments of + or -) as issued by Standard and Poor's or Aaa, Aa, or A (including adjustments of 1, 2, or 3) as issued by Moody's.

2. For applicants or licensees that do not issue bonds, unrestricted endowment consisting of assets located in the United States of at least $50 million, or at least thirty (30) times the total current decommissioning cost estimate (or the current amount required if certification is used), whichever is greater, for all decommissioning activities for which the college or university is responsible as self-guaranteeing licensee.

B. For hospitals, to pass the financial test, a hospital must meet either the criteria in paragraph II.B.1. or the criteria in paragraph II.B.2. of this Appendix.

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1. For applicants or licensees that issue bonds, a current rating for its most recent uninsured, uncollateralized, and unencumbered bond issuance of AAA, AA, or A (including adjustments of + or -) as issued by Standard and Poor's or Aaa, Aa, or A (including adjustments of 1, 2 or 3) as issued by Moody's.

2. For applicants or licensees that do not issue bonds, all the following tests must be met:

   a. (Total Revenues less total expenditures) divided by total revenues must be equal to or greater than 0.04.

   b. Long term debt divided by net fixed assets must be less than or equal to 0.67.

   c. (Current assets and depreciation fund) divided by current liabilities must be greater than or equal to 2.55.

   d. Operating revenues must be at least 100 times the total current decommissioning cost estimate (or the current amount required if certification is used) for all decommissioning activities for which the hospital is responsible as self-guaranteeing licensee.

C. In addition, to pass the financial test, a licensee must meet all the following requirements:

1. The licensee's independent certified public accountant must compare the data used by the licensee in the financial test, which is derived from the independently audited year-end financial statements for the latest fiscal year, with the amounts in such financial statement. The accountant must evaluate the licensee's off-balance sheet transactions and provide an opinion on whether those transactions could materially adversely affect the licensee's ability to pay for decommissioning costs. The accountant must verify that a bond rating, if used to demonstrate passage of the financial test, meets the requirements of Section II of this Appendix. In connection with the auditing procedure, the licensee shall inform the Department within ninety (90) days of any matters coming to the auditor's attention which cause the auditor to believe that the data specified in the financial test should be adjusted and that the licensee no longer passes the test.

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2. After the initial financial test, the licensee must repeat passage of the test and provide documentation of its continued eligibility to use the self-guarantee to the Department within ninety (90) days after the close of each succeeding fiscal year.

3. If the licensee no longer meets the requirements of Section I of this Appendix, the licensee must send notice to the Department of its intent to establish alternate financial assurance as specified in the Department's rules. The notice must be sent by certified mail, return receipt requested, within ninety (90) days after the end of the fiscal year for which the year-end financial data show that the licensee no longer meets the financial test requirements. The licensee must provide alternative financial assurance within 120 days after the end of such fiscal year.

III. **Self-Guarantee**

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail, ~~and/or~~ return receipt requested, to the Department. Cancellation may not occur unless an alternative financial assurance mechanism is in place.

B. The licensee shall provide alternative financial assurance as specified in the Department's rules within ninety (90) days following receipt by the Department of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the Department has terminated the license or until another financial assurance method acceptable to the Department has been put in effect by the licensee.

D. The applicant or licensee must provide to the Department a written guarantee (a written commitment by a corporate officer or officer of the institution) which states that the licensee will fund and carry out the required decommissioning activities or, upon issuance of an order by the Department, the licensee will fund the standby trust in the amount of the current cost estimates for decommissioning.

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E. 1. If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poor's or Moody's, the licensee shall notify the Department in writing within twenty (20) days after publication of the change by the rating service.

2. If the licensee's most recent bond issuance ceases to be rated in any category of "A" and above by Standard and Poor's or in any category of "A3" and above by Moody's, the licensee no longer meets the requirements of Section II.A. of this Appendix.

F. 1. A standby trust to protect public health and safety and the environment must be established for decommissioning costs before the self-guarantee agreement is submitted.

2. The trustee and trust must be acceptable to the Department.- An acceptable trustee includes an appropriate State or Federal government agency or an entity which has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency. -The Department has the right to change the trustee. -An acceptable trust will meet the regulatory criteria established in these Rules that govern the issuance of the license for which the guarantor has accepted the obligation to pay for decommissioning costs.

G. The guarantor must agree that if the guarantor admits in writing its inability to pay its debts generally, or makes a general assignment for the benefit of creditors, or any proceeding is instituted by or against the guarantor seeking to adjudicate it as bankrupt or insolvent, or seeking dissolution, liquidation, winding-up, reorganization, arrangement, adjustment, protection, relief or composition of it or its debts under any law relating to bankruptcy, insolvency, or reorganization or relief of debtors, or seeking the entry of an order for relief or the appointment of a receiver, trustee, custodian, or other similar official for guarantor or for any substantial part of its property, or the guarantor takes any action to authorize or effect any of the actions stated in this paragraph, then the Department may:

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1. Declare that the financial assurance guaranteed by the self-guarantee agreement is immediately due and payable to the standby trust set up to protect the public health and safety and the environment, without diligence, presentment, demand, protest or any other notice of any kind, all of which are expressly waived by guarantor; and

2. Exercise any and all of its other rights under applicable law.

H. The guarantor must notify the Department, in writing, immediately following the occurrence of any event listed in paragraph G of this section, and must include a description of the event, including major creditors, the amounts involved, and the actions taken to assure that the amount of funds guaranteed by the self-guarantee agreement for decommissioning will be transferred to the standby trust as soon as possible.

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APPENDIX E TO SECTION 2
QUANTITIES FOR USE WITH RH-409.h.

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Material	Microcuries	Material	Microcuries
Americium-241	0.01	Gadolinium-159	100
Antimony-122	100	Gallium-72	10
Antimony-124	10	Germanium-71	100
Antimony-125	10	Gold-198	100
Arsenic-73	100	Gold-199	100
Arsenic-74	10	Hafnium-181	10
Arsenic-76	10	Holmium-166	100
Arsenic-77	100	Hydrogen-3	1,000
Barium-131	10	Indium-113m	100
Barium-133	10	Indium-114m	10
Barium-140	10	Indium-115m	100
Bismuth-210	1	Indium-115	10
Bromine-82	10	Iodine-125	1
Cadmium-109	10	Iodine-126	1
Cadmium-115m	10	Iodine-129	0.1
Cadmium-115	100	Iodine-131	1
Calcium-45	10	Iodine-132	10
Calcium-47	10	Iodine-133	1
Carbon-14	100	Iodine-134	10
Cerium-141	100	Iodine-135	10
Cerium-143	100	Iridium-192	10
Cerium-144	1	Iridium-194	100
Cesium-131	1,000	Iron-55	100
Cesium-134m	100	Iron-59	10
Cesium-134	1	Krypton-85	100
Cesium-135	10	Krypton-87	10
Cesium-136	10	Lanthanum-140	10
Cesium-137	10	Lutetium-177	100
Chlorine-36	10	Manganese-52	10
Chlorine-38	10	Manganese-54	10
Chromium-51	1,000	Manganese-56	10
Cobalt-58m	10	Mercury-197m	100
Cobalt-58	10	Mercury-197	100
Cobalt-60	1	Mercury-203	10
Copper-64	100	Molybdenum-99	100
Dysprosium-165	10	Neodymium-147	100
Dysprosium-166	100	Neodymium-149	100
Erbium-169	100	Nickel-59	100
Erbium-171	100	Nickel-63	10
Europium-152 9.2h	100	Nickel-65	100
Europium-152 13yr	1	Niobium-93m	10
Europium-154	1	Niobium-95	10
Europium-155	10	Niobium-97	10
Fluorine-18	1,000	Osmium-185	10
Gadolinium-153	10	Osmium-191m	100

Material	Microcuries	Material	Microcuries
Osmium-191	100	Technetium-99m	100
Osmium-193	100	Technetium-99	10
Palladium-103	100	Tellurium-125m	10
Palladium-109	100	Tellurium-127m	10
Phosphorus-32	10	Tellurium-127	100
Platinum-191	100	Tellurium-129m	10
Platinum-193m	100	Tellurium-129	100
Platinum-193	100	Tellurium-131m	10
Platinum-197m	100	Tellurium-132	10
Platinum-197	100	Terbium-160	10
Plutonium-239	0.01	Thallium-200	100
Polonium-210	0.1	Thallium-201	100
Potassium-42	10	Thallium-202	100
Praseodymium-142	100	Thallium-204	10
Praseodymium-143	100	Thorium (natural)[a/]	100
Promethium-147	10	Thulium-170	10
Promethium-149	10	Thulium-171	10
Radium-226	0.01	Tin-113	10
Rhenium-186	100	Tin-125	10
Rhenium-188	100	Tungsten-181	10
Rhodium-103m	100	Tungsten-185	10
Rhodium-105	100	Tungsten-187	100
Rubidium-86	10	Uranium (natural)[b/]	100
Rubidium-87	10	Uranium-233	0.01
Ruthenium-97	100	U-234 – U-235	0.01
Ruthenium-103	10	Vanadium-48	10
Ruthenium-105	10	Xenon-131m	1,000
Ruthenium-106	1	Xenon-133	100
Samarium-151	10	Xenon-135	100
Samarium-153	100	Ytterbium-175	100
Scandium-46	10	Yttrium-90	10
Scandium-47	100	Yttrium-91	10
Scandium-48	10	Yttrium-92	100
Selenium-75	10	Yttrium-93	100
Silicon-31	100	Zinc-65	10
Silver-105	10	Zinc-69m	100
Silver-110m	1	Zinc-69	1,000
Silver-111	100	Zirconium-93	10
Sodium-24	10	Zirconium-95	10
Strontium-85	10	Zirconium-97	10
Strontium-89	1		
Strontium-90	0.1	Any alpha emitting	0.01
Strontium-91	10	radionuclide not	
Strontium-92	10	listed above or	
Sulfur-35	100	mixtures of alpha	
Tantalum-182	10	emitters of unknown	
Technetium-96	10	composition	
Technetium-97m	100		
Technetium-97	100		

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Material	Microcuries
Any radionuclide other than alpha emitting radionuclides, not listed above or mixtures of beta emitters of unknown composition	0.1

Note:

Where there is involved a combination of radionuclides in known amounts, the limit for the combination should be derived as follows:- Determine, for each radionuclide in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific radionuclide when not in combination. -The sum of such ratios for all radionuclides in the combination may not exceed "1" (i.e., "unity").

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Footnotes for Appendix E to Section 2:

a/ Based on alpha disintegration rate of Th-232, Th-230, and their daughter products.

b/ Based on alpha disintegration rate of U-238, U-234, and U-235.

FOOTNOTES TO SECTION 2

1/ Attention is directed to the fact that regulation by the State of source material, byproduct material, and special nuclear material in quantities not sufficient to form a critical mass is subject to the provisions of the agreement between the State and the U.S. Nuclear Regulatory Commission and to 10 CFR Part 150 of the Commission's regulations.

2/ The requirements specified in RH-300.c.1.E.i. and ii. need not be met by counterweights manufactured prior to December 31, 1969, provided that such counterweights are impressed with the legend, "**CAUTION - RADIOACTIVE MATERIAL - URANIUM**," as previously required by these Rules.

3/ Deleted.

4/ For purposes of this subparagraph, "electron tubes" include spark gap tubes, power tubes, gas tubes including glow lamps, receiving tubes, microwaves tubes, indicator tubes, pick-up tubes, radiation detection tubes and any other completely sealed tube that is designed to conduct or control electrical currents.

5/ Deleted.

6/ Deleted.

7/ Deleted.

8/ The New Drug provisions of the Federal Food, Drug and Cosmetic Act also govern the availability and use of any specific diagnostic drugs in interstate commerce.

9/ Sources licensed under RH-405.e., RH-105.h. or RH-405.i. prior to January 19, 1975 may bear labels authorized by the rules in effect on January 1, 1975.

10/ The model, serial number, and the name of the manufacturer or initial transferor may be omitted from this label provided they are elsewhere specified in labeling affixed to the device.

11/ A previous RH-1403. permitted certain burials of small quantities of licensed materials in soil before January 1, 1983, without specific Department authorization. As of January 1, 1983, these burials had to receive specific approval by the Department, in accordance with the revised RH-1403. Disposal by burial in soil came to be regulated under RH-1401.

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SECTION 3.
STANDARDS FOR PROTECTION AGAINST RADIATION

(FOOTNOTES APPEAR AT THE END OF THIS SECTION)

PART A.
GENERAL

RH-1000. **Authority**.- Act 8 of Second Extraordinary Session of 1961, as amended.

RH-1001. **Effective Date**.

The provisions of these Rules shall become effective on January 1, 1963, except where another effective date is specifically noted.

RH-1002. **Purpose and Scope**.

a. This Section establishes standards for protection against ionizing radiation resulting from activities conducted pursuant to licenses or registrations issued by the Department.

b. It is the purpose of the Rules in this Section to control the receipt, possession, use, transfer, and disposal of licensed material by any licensee or registrant in such a manner that the total dose to an individual (including doses resulting from licensed and unlicensed radioactive material and from radiation sources other than background radiation) does not exceed the standards for protection against radiation prescribed in the rules in this Section.- However, nothing in this Section shall be construed as limiting actions that may be necessary to protect health and safety.

RH-1003. **Communications**.

Except where otherwise specified, all communications concerning these Rules may be addressed to the Arkansas Department of Health, Radiation Control Section, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

RH-1004. **Radiation Protection Programs**.

a. Each licensee or registrant shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities or x-ray equipment use and sufficient to ensure compliance with the provisions of this Section. (See RH-1500. for recordkeeping requirements relating to these programs.)

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b. The licensee or registrant shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

c. The licensee or registrant shall periodically (at least annually) review the radiation protection program content and implementation.

d. To implement the ALARA requirements in RH-1004.b., and not withstanding the requirements in RH-1208., a constraint on air emissions of radioactive material to the environment, excluding radon-222 and its daughters, shall be established by licensees such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of ten (10) mrem (0.1 mSv) per year from these emissions. -If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the exceedance as provided in RH-1504. and promptly take appropriate corrective action to ensure against recurrence.

RH-1005.- RH-1099. Reserved.

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PART B.
DEFINITIONS

RH-1100. **Definitions**.

Absorbed dose - The energy imparted by ionizing radiation per unit mass of irradiated material. -The units of absorbed dose are the rad and the gray (Gy).

Accelerator-produced material - Any material made radioactive by a particle accelerator.

Act - Act 8 of Second Extraordinary Session of 1961, as amended.

Activity - The rate of disintegration (transformation or decay of radioactive material). -The units of activity are the curie (Ci) and the becquerel (Bq).

Adult - An individual 18 or more years of age.

Agreement State - Any state with which the Atomic Energy Commission or the U.S. Nuclear Regulatory Commission has entered into an effective agreement under subsection 274 b. of the Atomic Energy Act of 1954 (68 Stat. 919), including any amendments thereto.- Non-agreement State means any other State.

Airborne radioactive material - Radioactive material dispersed in the air in the form of dusts, fumes, particulates, mists, vapors, or gases.

Airborne radioactivity area - A room, enclosure, or area in which airborne radioactive materials, composed wholly or partly of licensed material, exist in concentrations:

1. In excess of the derived air concentrations (DACs) specified in Appendix G to Section 3, or

2. To such a degree that an individual present in the area without respiratory protective equipment could exceed, during the hours an individual is present in a week, an intake of 0.6 percent of the annual limit on intake (ALI) or 12 DAC-hours.

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Air-purifying respirator - A respirator with an air purifying filter, cartridge, or canister that removes specific air contaminants by passing ambient air through the air-purifying element.

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~~RH-1100. (Cont'd)~~

ALARA (acronym for "as low as is reasonably achievable") - Making every reasonable effort to maintain exposures to radiation as far below the dose limits in this Section as is practical consistent with the purpose for which the licensed activity or x-ray equipment use is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of x-ray equipment, nuclear energy and licensed materials in the public interest.

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Annual limit on intake (ALI) - The derived limit for the amount of radioactive material taken into the body of an adult worker by inhalation or ingestion in a year. ALI is the smaller value of intake of a given radionuclide in a year by the reference man that would result in a committed effective dose equivalent of 5 rems (0.05 Sv) or a committed dose equivalent of 50 rems (0.5 Sv) to any individual organ or tissue. (ALI values for intake by ingestion and by inhalation of selected radionuclides are given in Table I, Columns 1 and 2, of Appendix G to Section 3).

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Assigned protection factor (APF) - The expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users. Operationally, the inhaled concentration can be estimated by dividing the ambient airborne concentration by the APF.

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Atmosphere-supplying respirator - A respirator that supplies the respirator user with breathing air from a source independent of the ambient atmosphere, and includes supplied-air respirators (SARs) and self-contained breathing apparatus (SCBA) units.

Background radiation - Radiation from cosmic sources, naturally occurring radioactive materials, including radon (except as a decay product of source or special nuclear material) and global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee or registrant.

Becquerel (Bq) – One becquerel is equal to one disintegration per second (dps).

Bioassay (radiobioassay) - The determination of kinds, quantities or concentrations and, in some cases, the locations of radioactive material in the human body, whether by direct measurement (in vivo counting) or by analysis and evaluation of materials excreted or removed from the human body.

~~RH 1100. (Cont'd)~~

Byproduct material -

1. Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material;

2. The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute "byproduct material" within this definition;

3. A. Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or

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B. Any material that:

i. Has been made radioactive by use of a particle accelerator; and

ii. Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and

4. Any discrete source of naturally occurring radioactive material, other than source material, that:

A. The U.S. Nuclear Regulatory Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and

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B. Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.

~~RH-1100. (Cont'd)~~

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Class (or lung class or inhalation class) - A classification scheme for inhaled material according to its rate of clearance from the pulmonary region of the lung. Materials are classified as D, W, or Y, which applies to a range of clearance half-times: for Class D (Days) of less than 10 days, for Class W (Weeks) from 10 to 100 days, and for Class Y (Years) of greater than 100 days.

Collective dose - The sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

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Committed dose equivalent ($H_{T,50}$) - The dose equivalent to organs or tissues of reference (T) that will be received from

an intake of radioactive material by an individual during the 50-year period following the intake.

Committed effective dose equivalent ($H_{E,50}$) - The sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the committed dose equivalent to these organs or tissues ($H_{E,50} = \Sigma\ w_T H_{T,50}$).

Constraint (dose constraint) - a value above which specified licensee or registrant actions are required.

Controlled area - An area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason.

Critical Group - the group of individuals reasonably expected to receive the greatest exposure to residual radioactivity for any applicable set of circumstances.

Curie (Ci) - One curie is that amount of radioactive material which disintegrates at the rate of 37 billion atoms per second.

Declared pregnant woman- - A woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.- The declaration remains in effect until the declared woman withdraws the declaration in writing or is no longer pregnant.

Decommission - to remove a facility or site safely from service and reduce residual radioactivity to a level that permits:

1. Release of the property for unrestricted use and termination of the license; or

2. Release of the property under restricted conditions and termination of the license.

~~RH 1100. (Cont'd)~~

Deep-dose equivalent (H_d) - (which applies to external whole-body exposure) The dose equivalent at a tissue depth of one (1) cm (1000 mg/cm^2).

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Demand respirator - An atmosphere-supplying respirator that admits breathing air to the facepiece only when a negative pressure is created inside the facepiece by inhalation.

Department - The Arkansas Department of Health or its duly authorized representatives.

Department of Energy (DOE) - The Department of Energy established by the Department of Energy Organization Act (Public Law 95-91, 91 Stat. 565, 42 U.S.C. 7101 et seq.) to the extent that the DOE, or its duly authorized representatives, exercises functions formerly vested in the U.S. Atomic Energy Commission, its Chairman, members, officers, and components and transferred to the U.S. Energy Research and Development Administration and to the Administrator thereof pursuant to Sections 104 (b), (c), and (d) of the Energy Reorganization Act of 1974 (Public Law 93-438, 88 Stat. 1233 at 1237, 42 U.S.C. 5814) and retransferred to the Secretary of Energy pursuant to Section 301(a) of the Department of Energy Organization Act (Public Law 95-91, 91 Stat. 565 at 577-578, 42 U.S.C. 7151).

Derived air concentration (DAC) - The concentration of a given radionuclide in air which, if breathed by the reference man for a working year of 2,000 hours under conditions of light work (inhalation rate 1.2 cubic meters of air per hour), results in an intake of one ALI. -DAC values are given in Table I, Column 3, of Appendix G to Section 3.

Derived air concentration-hour (DAC-hour) - The product of the concentration of radioactive material in air (expressed as a fraction or multiple of the derived air concentration for each radionuclide) and the time of exposure to that radionuclide, in hours.- A licensee may take 2,000 DAC-hours to represent one ALI, equivalent to a committed effective dose equivalent of 5 rems (0.05 Sv).

Director - Director of the Arkansas Department of Health.

Discrete source – A radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.

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Disposable respirator - A respirator for which maintenance is not intended and that is designed to be discarded after excessive breathing resistance, sorbent exhaustion, physical damage, or end-of-service-life renders it unsuitable for use. Examples of this type of respirator are a disposable half-mask respirator or a disposable escape-only self-contained breathing apparatus (SCBA).

Distinguishable from background - the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.

Dose or radiation dose - A generic term that means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent, as defined in other Paragraphs of this Section.

Dose equivalent (H_T) - The product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. -The units of dose equivalent are the rem and sievert (Sv).

Dosimetry processor - An individual or an organization that processes and evaluates individual monitoring equipment in order to determine the radiation dose delivered to the equipment.

Effective dose equivalent (H_E) - The sum of the products of the dose equivalent to the organ or tissue (H_T) and the weighting factors (w_T) applicable to each of the body organs or tissues that are irradiated ($H_E = \Sigma \ w_T H_T$).

Embryo/fetus - The developing human organism from conception until the time of birth.

Entrance or access point - Any location through which an individual could gain access to radiation areas or to

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radioactive materials. -This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

Exposure - Being exposed to ionizing radiation or to radioactive material.

External dose - That portion of the dose equivalent received from radiation sources outside the body.

Extremity - Hand, elbow, arm below the elbow, foot, knee, and leg below the knee.

~~RH 1100. (Cont'd)~~

Eye dose equivalent - The external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm^2).

Filtering facepiece (dust mask) – A negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of the filtering medium, not equipped with elastomeric sealing surfaces and adjustable strap.

Fit factor – A quantitative estimate of the fit of a particular respirator to a specific individual, and typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator when worn.

Fit test – The use of a protocol to qualitatively or quantitatively evaluate the fit of a respirator on an individual.

Generally applicable environmental radiation standards - Standards issued by the Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act of 1954, as amended, that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

Government agency - Any executive department, commission, independent establishment, corporation wholly or partly owned by the United States of America, which is an instrumentality of the United States, or any board, bureau,

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division, service, office, officer, authority, administration, or other establishment in the executive branch of the Government.

Gray - See RH-1102., "Units of Radiation Dose."

Helmet - A rigid respirator inlet covering that also provides head protection against impact and penetration.

High radiation area - An area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 mSv) in one (1) hour at thirty (30) centimeters from the radiation source or thirty (30) centimeters from any surface that the radiation penetrates.

Hood - A respiratory inlet covering that completely covers the head and neck and may also cover portions of the shoulders and torso.

Individual - Any human being.

~~RH-1100. (Cont'd)~~

Individual monitoring:

1. The assessment of dose equivalent by the use of devices designed to be worn by an individual;

2. The assessment of committed effective dose equivalent by bioassay (see "bioassay") or by determination of the time-weighted air concentrations to which an individual has been exposed, i.e., DAC-hours; or

3. The assessment of dose equivalent by the use of survey data.

Individual Monitoring Devices (individual monitoring equipment) - Devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers, and personal ("lapel") air sampling devices.

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Internal dose - That portion of the dose equivalent received from radioactive material taken into the body.

Lens dose equivalent (LDE) - applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm^2).

License - Except where otherwise specified, a license issued pursuant to these Rules.

Licensed material - Source material, special nuclear material, or byproduct material received, possessed, used, transferred, or disposed of under a general license provided by rule or a specific license issued by the Department.

Licensee - The holder of a license.

Limits (dose limits) - The permissible upper bounds of radiation doses.

Loose-fitting facepiece - A respiratory inlet covering that is designed to form a partial seal with the face.

Lost or missing licensed material - Licensed material whose location is unknown. It includes material that has been shipped but has not reached its destination and whose location cannot be readily traced in the transportation system.

Member of the public - Any individual except when that individual is receiving an occupational dose.

~~RH 1100. (Cont'd)~~

Minor - An individual less than 18 years of age.

Monitoring (radiation monitoring, radiation protection monitoring) - The measurement of radiation levels, concentrations, surface area concentrations or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses.

Nationally tracked source - A sealed source containing a quantity equal to or greater than Category 1 or Category 2 levels of any radioactive material listed in Appendix D of

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this Section. -In this context a sealed source is defined as radioactive material that is sealed in a capsule or closely bonded, in a solid form and which is not exempt from regulatory control.- It does not mean material encapsulated solely for disposal, or nuclear material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.- Category 1 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 1 threshold. -Category 2 nationally tracked sources are those containing radioactive material at a quantity equal to or greater than the Category 2 threshold but less than the Category 1 threshold.

Negative pressure respirator (tight fitting) - A respirator in which the air pressure inside the facepiece is negative during inhalation with respect to the ambient air pressure outside the respirator.

Nonstochastic effect - Health effects, the severity of which varies with the dose and for which a threshold is believed to exist. -Radiation-induced cataract formation is an example of a nonstochastic effect (also called a deterministic effect).

Occupational dose - The dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to radioactive material from licensed and unlicensed, registered and unregistered -sources of radiation, whether in the possession of the licensee, registrant, or other person. -Occupational dose does not include dose received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with RH-8420., from voluntary participation in medical research programs, or as a member of the ~~general~~ public.

Particle accelerator - Any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 megaelectron volt.- For purposes of this definition, ''accelerator'' is an equivalent term.

~~RH-1100. (Cont'd)~~

Person -

1. Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency of this state, political subdivision of this state, any other state or political subdivision or agency thereof; and

2. Any legal successor, representative, agent, or agency of the foregoing, but not including United States Government agencies.

Pharmacist - An individual registered by this State to compound and dispense drugs, prescriptions and poisons.

Physician - A doctor of medicine or doctor of osteopathy licensed by the Arkansas State Medical Board to prescribe drugs in the practice of medicine.

Planned special exposure - An infrequent exposure to radiation, separate from and in addition to the annual dose limits.

Positive pressure respirator - a respirator in which the pressure inside the respiratory inlet covering exceeds the ambient air pressure outside the respirator.

Powered air-purifying respirator (PADR) – an air-purifying respirator that uses a blower to force the ambient air through air-purifying elements to the inlet covering.

Pressure demand respirator - a positive pressure atmosphere-supplying respirator that admits breathing air to the facepiece when the positive pressure is reduced inside the facepiece by inhalation.

Protective apron – An apron made of radiation attenuating materials used to reduce radiation exposure.

Public dose - The dose received by a member of the public from exposure to radiation or radioactive material released by a licensee, or to any other source of radiation under the control of a licensee or registrant. –Public dose does not

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include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with RH-8420, or from voluntary participation in medical research programs.

Qualitative fit test (QLFT) - A pass/fail fit test to assess the adequacy of respirator fit that relies on the individual's response to the test agent.

Quality Factor (Q) - The modifying factor (listed in Tables 1 and 2 of RH-1102.) that is used to derive dose equivalent from absorbed dose.

~~RH-1100. (Cont'd)~~

Quantitative fit test (QNFT) – An assessment of the adequacy of respirator fit by numerically measuring the leakage into the respirator.

Quarter - A period of time equal to one-fourth of the year observed by the licensee (approximately 13 consecutive weeks), providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

Rad - See RH-1102., "Units of Radiation Dose."

Radiation (ionizing radiation) - Alpha particles, beta particles, gamma rays, x-rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. ~~-~~Radiation, as used in this Part, does not include non-ionizing radiation, such as radio- or microwaves, or visible, infrared, or ultraviolet light.

Radiation area - An area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.005 rem (0.05 mSv) in one (1) hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates.

Radiation machine - Any device emitting or capable of producing radiation, but excluding devices which ~~produce radiation only by the use of~~ with radioactive material as the

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only source of radiation and devices exempted by these Rules.

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Radioactive material - Any material (solid, liquid or gas) which emits radiation spontaneously including any natural radioactive material such as radium.

Radioactivity - The transformation of unstable atomic nuclei by the emission of radiation.

Reference man - A hypothetical aggregation of human physical and physiological characteristics arrived at by international consensus. These characteristics may be used by researchers and public health workers to standardize results of experiments and to relate biological insult to a common base.

Rem - See RH-1102., "Units of Radiation Dose."

Residual radioactivity - Radioactivity in structures, materials, soils, groundwater, and other media at a site resulting from activities under the licensee's control. -This includes radioactivity from all licensed and unlicensed sources used by the licensee, but excludes background radiation.- It also includes radioactive materials remaining at the site as a result of routine or accidental releases of radioactive material at the site and previous burials at the site, even if

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those burials were made in accordance with the provisions of Part E, "Waste Disposal."

Respiratory protective device - An apparatus, such as a respirator, used to reduce the individual's intake of airborne radioactive materials.

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Restricted area - An area, access to which is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation ~~and radioactive materials~~. -Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

Sanitary sewerage - A system of public sewers for carrying off waste water and refuse, but excluding sewage treatment

facilities, septic tanks, and leach fields owned or operated by the licensee.

Self-contained breathing apparatus (SCBA) - An atmosphere-supplying respirator for which the breathing air source is designed to be carried by the user.

Shallow-dose equivalent (H_s) - (which applies to the external exposure of the skin of the whole body or the skin of an extremity) - The dose equivalent at a tissue depth of 0.007 centimeter (7 mg/cm^2).

Sievert - See RH-1102.,- "Units of Radiation Dose."

Site boundary - That line beyond which the land or property is not owned, leased, or otherwise controlled by the licensee.

Source material -

1. Uranium or thorium or any combination of uranium and thorium in any physical or chemical form; or

2. Ores that contain, by weight, one-twentieth of one percent (0.05%), or more, of uranium, thorium, or any combination of uranium and thorium. Source material does not include special nuclear material.

Source of radiation - Any radioactive material ~~or any radiation machine~~ or device or equipment emitting or capable of producing radiation.

Special nuclear material -

1. Plutonium, uranium-233, uranium enriched in the isotope 233 or in the isotope 235, and any other material that the U.S. Nuclear Regulatory Commission, pursuant to the provisions of Section 51 of the Atomic

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Energy Act of 1954, as amended, determines to be special nuclear material, but does not include source material, or

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2. Any material artificially enriched by any of the foregoing but does not include source material.

Storage container - A device in which sealed sources are transported or stored.

Stochastic effects - Health effects that occur randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. -Hereditary effects and cancer incidence are examples of stochastic effects.

Supplied-air respirator (SAR) or airline respirator - an atmosphere-supplying respirator for which the source of breathing air is not designed to be carried by the user.

Survey - An evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation. -When appropriate, such an evaluation includes a physical survey of the location of radioactive material and measurements or calculations of levels of radiation, or concentrations or quantities of radioactive material present.

Temporary jobsite - A location to which radioactive materials or x-ray equipment have been dispatched to perform one (1) or more of the following service operations:

1. Moisture/density measurements;
2. Level measurements;
3. Any portable devices containing radioactive materials; ~~and/or~~ or
4. Consulting services included, but not limited to:
   - A. Calibration of instruments;
   - B. Repair of devices or sources;
   - C. Sealed source installation ~~and/or~~or exchange;
   - D. Decommissioning of sealed sources.

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Tight-fitting facepiece - A respiratory inlet covering that forms a complete seal with the face.

Total Effective Dose Equivalent (TEDE) - The sum of the effective-dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

Uncontrolled area or unrestricted area - Any area to which access is not controlled by the licensee or registrant for the purposes of protection of individuals from exposure to radiation and radioactive materials and any area used for residential quarters.

Uranium fuel cycle - The operations of milling of uranium ore, chemical conversion of uranium, isotopic enrichment of uranium, fabrication of uranium fuel, generation of electricity by a light-water-cooled nuclear power plant using uranium fuel, and reprocessing of spent uranium fuel to the extent that these activities directly support the production of electrical power for public use. -Uranium fuel cycle does not include mining operations, operations at waste disposal sites, transportation of radioactive material in support of these operations, and the reuse of recovered non-uranium special nuclear and byproduct materials from the cycle.

User seal check (fit check) - An action conducted by the respirator user to determine if the respirator is properly seated to the face.- Examples include negative pressure check, positive pressure, irritant smoke check, or isoamyl acetate check.

Very high radiation area - An area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of 500 rads (5 grays) in one (1) hour at one (1) meter from a radiation source or from any surface that the radiation penetrates.

Note: At very high doses received at high dose rates, units of absorbed dose (e.g., rads and grays) are appropriate, rather than units of dose equivalent (e.g., rems and sieverts).

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Waste - Those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in paragraphs 2., 3., and 4. of the definition of byproduct material set forth in this section.

Week - Seven (7) consecutive days starting on Sunday.

~~RH 1100. (Cont'd)~~

Weighting factor (w_T) - For an organ or tissue (T) is the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective equivalent, the values of w_T are:

ORGAN DOSE WEIGHTING FACTORS

Organ or Tissue	w_T
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30[a]
Whole Body	1.00[b]

[a] 0.30 results from 0.06 for each of 5 "remainder" organs (excluding the skin and the lens of the eye) that receive the highest doses.

[b] For the purpose of weighting the external whole body dose (for adding it to the internal dose), a single weighting factor, $w_T = 1.0$,

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has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

[a] 0.30 results from 0.06 for each of 5 "remainder" organs (excluding the skin and the lens of the eye) that receive the highest doses.

[b] For the purpose of weighting the external whole body dose (for adding it to the internal dose), a single weighting factor, $w_T = 1.0$, has been specified. The use of other weighting factors for external exposure will be approved on a case-by-case basis until such time as specific guidance is issued.

Whole body - For purposes of external exposure, head, trunk (including male gonads), arms above the elbow, or legs above the knee.

Worker - An individual engaged in work under a license or registration issued by the Department and controlled by a licensee or registrant.

Working level (WL) - Any combination of short-lived radon daughters (for radon-222: polonium-218, lead-214, bismuth-214, and polonium-214; and for radon-220: polonium-216, lead-212, bismuth-212, and polonium-212) in one liter of air that will result in the ultimate emission of 1.3×10^5 MeV of potential alpha particle energy.

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Working level month (WLM) - An exposure to one working level for 170 hours (2,000 working hours per year/12 months per year = approximately 170 hours per month).

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Year - The period of time beginning in January used to determine compliance with the provisions of this Section. The licensee may change the starting date of the year used to determine compliance by the licensee provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

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RH-1102. **Units of Radiation Dose**.

As used in this Section, the units of radiation dose are:

a. **Exposure rate** - The exposure per unit of time, such as roentgen per minute and milliroentgen per hour.

b. **Gray** (Gy) - The SI unit of absorbed dose.– One gray is equal to an absorbed dose of one (1) joule/kilogram (100 rads).

c. **Rad** - The special unit of absorbed dose. –One rad is equal to an absorbed dose of 100 ergs/gram or 0.01 joule/kilogram (0.01 gray).

d. **Rem** - The special unit of any of the quantities expressed as dose equivalent. –The dose equivalent in rems is equal to the absorbed dose in rads multiplied by the quality factor (1 rem = 0.01 sievert).

e. **Roentgen** - The special unit of exposure.– One roentgen (R) equals 2.58 X 10^{-4} coulombs/kilogram of air (See "Exposure" in RH-1100).

f. **Sievert** (Sv) - The SI unit of any of the quantities expressed as dose equivalent. –The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1 Sv = 100 rems).

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g. As used in this Section, the quality factors for converting absorbed dose to dose equivalent are shown in Table I to RH-1102.

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TABLE I TO RH-1102.
QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

Type of Radiation	Quality Factor (Q)	Absorbed Dose Equal to a Unit Dose Equivalent[a]
X-, gamma, or beta radiation	1	1
Alpha particles, multiple-charged particles, fission fragments, and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

[a] Absorbed dose in rad equal to 1 rem or the absorbed dose in gray equal to 1 sievert.

h. If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in rems per hour or sieverts per hour, as provided in RH-1102.g. of this section, 1 rem (0.01 Sv) of neutron radiation of unknown energies may, for purposes of the rules in this Section, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. -If sufficient information exists to estimate the approximate energy distribution of the neutrons, the licensee may use the fluence rate per unit dose equivalent or the appropriate Q value from Table II to RH-1102. to convert a measured tissue dose in rads to dose equivalent in rems.

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TABLE II TO RH-1102.
MEAN QUALITY FACTORS, Q, AND FLUENCE PER UNIT DOSE EQUIVALENT FOR MONOENERGETIC NEUTRONS

	Neutron Energy (MeV)	Quality Factor[a] (Q)	Fluence per Unit Dose Equivalent[b] (neutrons cm^{-2} rem^{-1})
(thermal)……	2.5×10^{-8}	2	980×10^{6}
	1×10^{-7}	2	980×10^{6}
	1×10^{-6}	2	810×10^{6}
	1×10^{-5}	2	810×10^{6}
	1×10^{-4}	2	840×10^{6}
	1×10^{-3}	2	980×10^{6}
	1×10^{-2}	2.5	1010×10^{6}
	1×10^{-1}	7.5	170×10^{6}
	5×10^{-1}	11	39×10^{6}
	1	11	27×10^{6}
	2.5	9	29×10^{6}
	5	8	23×10^{6}
	7	7	24×10^{6}
	10	6.5	24×10^{6}
	14	7.5	17×10^{6}
	20	8	16×10^{6}
	40	7	14×10^{6}
	60	5.5	16×10^{6}
	1×10^{2}	4	20×10^{6}
	2×10^{2}	3.5	19×10^{6}
	3×10^{2}	3.5	16×10^{6}
	4×10^{2}	3.5	14×10^{6}

[a] Value of quality factor (Q) at the point where the dose equivalent is maximum in a 30 cm diameter cylinder tissue-equivalent phantom.

[b] Monoenergetic neutrons incident normally on a 30 cm diameter cylinder tissue-equivalent phantom.

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RH-1103. **Units of Radioactivity**.

For the purposes of this Part, activity is expressed in the special unit of curies (Ci) or in the SI unit of becquerels (Bq), or their multiples, or disintegrations (transformations) per unit of time.

a. One becquerel = 1 disintegration per second (s^{-1}).

~~RH-1103. (Cont'd)~~

b. One curie = 3.7 x 10^{10} disintegrations per second = 3.7 x 10^{10} becquerels = 2.22 x 10^{12} disintegrations per minute.

RH-1104. **Interpretations**.

Except as specifically authorized by the Department in writing, no interpretations of the meaning of the rules in this Section by an officer or employee of the Department other than a written interpretation by the Department Director or designee will be recognized as binding upon the Department.

RH-1105. **Implementation**.

a. The applicable section of RH-1000. through RH-2110. must be used in lieu of requirements in the standards for protection against radiation in effect prior to January 1, 1994 that are cited in license conditions except as specified in RH-1105.c. through RH-1105.e. of this section. If the requirements of this Section are more restrictive than the existing license condition, then the licensee shall comply with this Section unless exempted by RH-1105.d. of this section.

b. Any existing license condition that is more restrictive than a requirement in RH-1000. through RH-2110. remains in force until there is a license amendment or license renewal.

c. If a license condition exempted a licensee from a requirement in the standards for protection against radiation in effect prior to January 1, 1994, it continues to exempt a licensee from the corresponding provision of RH-1000. through RH-2110.

d. If a license condition cites provisions in requirements in the standards for protection against radiation in effect prior to January 1, 1994 and there are no corresponding provisions in RH-1000. through RH-2110., the license condition remains in force until there is a license amendment or license renewal that modifies or removes this condition.

e. Any existing license condition that is more restrictive than a requirement in RH-1000. through RH-2110. remains in force until there is a technical specification change, license amendment, or license renewal.

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f. If a license condition exempts a licensee from a provision of this Section in RH-1. through RH-602., it also exempts the licensee from the corresponding provision in RH-1000. through RH-2110.

~~RH-1105. (Cont'd)~~

g. If a license condition cites provisions in the former Part M of Section 3 (currently Appendices A, B, E-H, and J of Section 3 and Appendix A of Section 4) and there are no corresponding provisions in RH-1000. through RH-2110., then the license condition remains in force until there is a license amendment or license renewal that modifies or removes this condition.

RH-1106- RH-1199. Reserved.

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PART C.
PERMISSIBLE DOSES, LEVELS, AND CONCENTRATIONS

RH-1200. **Occupational Dose Limits for Adults**.

a. The licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures under RH-1205, to the following dose limits.

1. An annual limit, which is the more limiting of:

A. The total effective dose equivalent being equal to 5 rems (0.05 Sv), or

B. The sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rems (0.5 Sv).

2. The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities which are:

A. A~~n~~ lens dose equivalent of 15 rems (0.15 Sv), and

B. A shallow-dose equivalent of 50 rems (0.50 Sv) to the skin of the whole body or to skin of any extremity.

b. Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, must be subtracted from the limits for planned special exposures that the individual may receive during the current year (See RH-1205.e.1.) and during the individual's lifetime (See RH-1205.e.2.).

~~RH-1200. (Cont'd)~~

c. When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the Department. The assigned deep-dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow-dose equivalent must be the dose averaged over the contiguous ten (10) square centimeters of skin receiving the highest exposure. The deep-dose equivalent, lens-dose equivalent, and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of

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demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

d. When a protective apron is worn while working with medical fluoroscopic equipment and monitoring is conducted as specified in RH-1302.a.5., the effective dose equivalent for external radiation shall be determined as follows:

1. When only one individual monitoring device is used and it is located at the neck (collar) outside the protective apron, the reported deep dose equivalent shall be the effective dose equivalent for external radiation; or

2. When only one individual monitoring device is used and it is located at the neck (collar) outside the protective apron, and the reported dose exceeds 25 percent (25%) of the limit specified in RH-1200.a., the reported deep dose equivalent value multiplied by 0.3 shall be the effective dose equivalent for external radiation; or

3. When individual monitoring devices are worn, both under the protective apron at the waist and outside the protective apron at the neck, the effective dose equivalent for external radiation shall be assigned the value of the sum of the deep dose equivalent reported for the individual monitoring device located at the waist under the protective apron multiplied by 1.5 and the deep dose equivalent reported for the individual monitoring device located at the neck outside the protective apron multiplied by 0.04.

~~d~~e. Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in Table I of Appendix G to Section 3 and may be used to determine the individual's dose (See RH-1500.f.) and to demonstrate compliance with the occupational dose limits.

~~e~~f. In addition to the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity. (See footnote c of Appendix G to Section 3.)

~~f~~g. The licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person (see RH-1500.d.5.).

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RH-1201. **Compliance with Requirements for Summation of External and Internal Doses**.

a. If the licensee is required to monitor under both RH-1302.a. and b., the licensee shall demonstrate compliance with the dose limits by summing external and internal doses. If the licensee is required to monitor only under RH-1302.a. or only under RH-1302.b., then summation is not required to demonstrate compliance with the dose limits. The licensee may demonstrate compliance with the requirements for summation of external and internal doses by meeting one of the conditions specified in RH-1201.b. and the conditions in RH-1201.c. and RH-1201.d.

NOTE: The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits.

~~RH-1201. (Cont'd)~~

b. **Intake by inhalation**. If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep-dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:

1. The sum of the fractions of the inhalation ALI for each radionuclide, or

2. The total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000, or

3. The sum of the calculated committed effective dose equivalents to all significantly irradiated[1/] organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit.

c. **Intake by oral ingestion**. If the occupationally exposed individual also receives an intake of radionuclides by oral ingestion greater than ten percent (10%) of the applicable oral ALI, the licensee shall account for this intake and include it in demonstrating compliance with the limits.

d. **Intake through wounds or absorption through skin**. The licensee shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption.

NOTE: The intake through intact skin has been included in the calculation of DAC for hydrogen-3 and does not need to be further evaluated.

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RH-1202. **Determination of External Dose From Airborne Radioactive Material**.

Licensees shall, when determining the dose from airborne radioactive material, include the contribution to the deep-dose equivalent, eye dose equivalent, and shallow-dose equivalent from external exposure to the radioactive cloud. (See Appendix G to Section 3, footnotes a and b.)

NOTE: **Airborne radioactivity measurements and DAC values should not be used as the primary means to assess the deep-dose equivalent when the airborne radioactive material includes radionuclides other than noble gases or if the cloud of airborne radioactive material is not relatively uniform. The determination of the deep-dose equivalent to an individual should be based upon measurements using instruments or individual monitoring devices.**

RH-1203. **Determination of Internal Exposure**.

a. For purposes of assessing dose used to determine compliance with occupational dose equivalent limits, the licensee shall, when required under RH-1302., take suitable and timely measurements of:

1. Concentrations of radioactive materials in air in work areas; or
2. Quantities of radionuclides in the body; or
3. Quantities of radionuclides excreted from the body; or
4. Combinations of these measurements.

b. Unless respiratory protective equipment is used, as provided in RH-1303.f.5., or the assessment of intake is based on bioassays, the licensee shall assume that an individual inhales radioactive material at the airborne concentration in which the individual is present.

c. When specific information on the physical and biochemical properties of the radionuclides taken into the body or the behavior or the material in an individual is known, the licensee may:

1. Use that information to calculate the committed effective dose equivalent, and, if used, the licensee shall document that information in the individual's record;

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2. Upon prior approval of the Department, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material (e.g., aerosol size distribution or density); and

3. Separately assess the contribution of fractional intakes of Class D, W, or Y compounds of given radionuclide (See Appendix G to Section 3.) to the committed effective dose equivalent.

d. If the licensee chooses to assess intakes of Class Y material using the measurements given in RH-1203.a.2. or 3., the licensee may delay the recording and reporting of the assessments for periods up to seven (7) months, unless otherwise required by RH-1502. or RH-1504., in order to permit the licensee to make additional measurements basic to the assessments.

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~~RH-1203. (Cont'd)~~

e. If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours must be either:

1. The sum of the ratios of the concentration to the appropriate DAC value (e.g., D, W, Y) from Appendix G to Section 3 for each radionuclide in the mixture; or

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2. The ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.

f. If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture must be the most restrictive DAC of any radionuclide in the mixture.

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g. When a mixture of radionuclides in air exists, licensees may disregard certain radionuclides in the mixture if:

1. The licensee uses the total activity of the mixture in demonstrating compliance with the dose limits in RH-1200. and in complying with the monitoring requirements in RH-1302.b.;

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2. The concentration of any radionuclide disregarded is less than ten percent (10%) of its DAC; and

3. The sum of these percentages for all of the radionuclides disregarded in the mixture does not exceed 30 percent (30%).

h. 1. In order to calculate the committed effective dose equivalent, the licensee may assume that the inhalation of one ALI, or an exposure of 2,000 DAC-hours, results in a committed effective dose equivalent of 5 rems (0.05 Sv) for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent.

~~RH-1203.h. (Cont'd)~~

2. When the ALI (and the associated DAC) is determined by the nonstochastic organ dose limit of 50 rems (0.5 Sv), the intake of radionuclides that would result in a committed effective dose equivalent of 5 rems (0.05 Sv) (the stochastic ALI) is listed in parentheses in Table I of Appendix G to Section 3.

In this case, the licensee may, as a simplifying assumption, use the stochastic ALIs to determine committed effective dose equivalent. However, if the licensee uses the stochastic ALIs, the licensee must also demonstrate that the limit in RH-1200.a.1.B. is met.

RH-1204. Reserved.

RH-1205. **Planned Special Exposures**.

A licensee or registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in RH-1200. provided that each of the following conditions is satisfied:

a. The licensee or registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the dose estimated to result from the planned special exposure are unavailable or impractical.

b. The licensee or registrant (and employer if the employer is not the licensee) specifically authorizes the planned special exposure, in writing, before the exposure occurs.

c. Before a planned special exposure, the licensee or registrant ensures that the individuals involved are:

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1. Informed of the purpose of the planned operation;

2. Informed of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and

3. Instructed in the measures to be taken to keep the dose ALARA considering other risks that may be present.

~~RH-1205. (Cont'd)~~

d. Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant ascertains prior doses as required by RH-1500.d. during the lifetime of the individual for each individual involved.

e. Subject to RH-1200.b., the licensee or registrant does not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:

1. The numerical values of any of the dose limits in RH-1200.a., in any year; and

2. Five (5) times the annual dose limits in RH-1200.a. during the individual's lifetime.

f. The licensee or registrant maintains records of the conduct of a planned special exposure in accordance with RH-1500.e. and submits a written report in accordance with RH-1504.

g. The licensee or registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within thirty (30) days from the date of the planned special exposure. The dose from planned special exposures is not to be considered in controlling future occupational dose of the individual under RH-1200.a. but is to be included in evaluations required by RH-1205.d. and e.

RH-1206. **Occupational Dose Limits for Minors**.

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The annual occupational dose limits for minors are ten percent (10%) of the annual dose limits specified for adult workers in RH-1200.

RH-1207. **Dose Equivalent to an Embryo/Fetus**.

a. The licensee or registrant shall ensure that the dose equivalent to the embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). (For recordkeeping requirements, see RH-1500.f.)

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~~RH-1207. (Cont'd)~~

b. The licensee or registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in paragraph a of this section.

c. The dose equivalent to the embryo/fetus is the sum of:

1. The deep-dose equivalent to the declared pregnant woman; and

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2. The dose equivalent to the embryo/fetus resulting from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

d. If the dose equivalent to the embryo/fetus is found to have exceeded 0.5 rem (5 mSv), or is within 0.05 rem (0.5 mSv) of this dose, by the time the woman declares the pregnancy to the licensee or registrant, the licensee or registrant shall be deemed to be in compliance with RH-1207.a. if the additional dose to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.

RH-1208. **Dose Limits for Individual Members of the Public**.

a. Each licensee or registrant shall conduct operations so that:

1. The total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed 0.1 rem (1 millisievert) in a year, exclusive of the dose contribution from the background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with RH-8420., from voluntary participation in

medical research program, and from licensee's disposal of radioactive material into sanitary sewerage in accordance with RH-1402.; and

2. The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with RH-8420., does not exceed 0.002 rem (0.02 millisievert) in any one hour.

~~RH-1208. (Cont'd)~~

b. If the licensee or registrant permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.

c. Notwithstanding RH-1208.a.1. of this section, a licensee may permit visitors to an individual who cannot be released, under RH-8420., to receive a radiation dose greater than 0.1 rem (1 mSv) if:

1. The radiation dose received does not exceed 0.5 rem (5 mSv);

2. The authorized user, as defined in Section 9, has determined before the visit that it is appropriate; and

3. Documentation shall be maintained by the licensee.

d. A licensee ~~or license applicant~~ or registrant, or an applicant for a license or registration may apply for prior Department authorization to operate up to an annual dose limit for an individual member of the public of 0.5 rem (5 mSv). ~~The~~ This ~~licensee or license applicant or registrant~~ application shall include the following information ~~in this application~~:

1. Demonstration of the need for and the expected duration of operations in excess of the limit in RH-1208.a. of this section;

2. The licensee's or registrant's program to assess and control dose within the 0.5 rem (5 mSv) annual limit; and

3. The procedures to be followed to maintain the dose as low as is reasonably achievable.

e. In addition to the requirements of this Section, a licensee subject to the provisions of EPA's generally applicable environmental radiation standards in 40 CFR Part 190 shall comply with those standards.

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f. The Department may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee may release in effluents in order to restrict the collective dose.

RH-1209. **Compliance with Dose Limits for Individual Members of the Public**.

a. The licensee or registrant shall make or cause to be made, as appropriate, surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in RH-1208.

b. A licensee or registrant shall show compliance with the annual dose limit in RH-1208. by:

1. Demonstrating by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed or registered operation does not exceed the annual dose limit; or

2. Demonstrating that:

A. The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table II of Appendix G to Section 3; and

B. If an individual were continually present in an unrestricted area, the dose from external sources would not exceed 0.002 rem (0.02 mSv) in an hour and 0.05 rem (0.5 mSv) in a year.

c. Upon approval from the Department, the licensee may adjust the effluent concentration values in Table II of Appendix G to Section 3 for members of the public, to take into account the actual physical and chemical characteristics of the effluents (e.g., aerosol size distribution, solubility, density, radioactive decay equilibrium, chemical form).

RH-1210. Deleted.

RH-1211. **Orders Requiring Furnishing of Bioassay Services**.

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Where necessary or desirable in order to aid in determining the extent of an individual's exposure to concentrations of radioactive material, the Department may require a licensee to make available to the individual appropriate bioassay services and to furnish a copy of the reports of such services to the Department.

RH-1212. **Testing for Leakage ~~and/or~~ or Contamination of Sealed Sources**.

a. A licensee possessing any sealed radioactive source under the provisions of a specific license, except as specified in paragraph b. of this section, shall assure that:

1. Each sealed source is tested for leakage ~~and/or~~or contamination and the test results are received before the sealed source is put into use unless the licensee has a certificate from the transferor indicating that the sealed source was tested within the interval listed in the Sealed Source and Device Registry prior to transfer to the licensee;

2. Each sealed source that is not designed to emit alpha particles is tested for leakage ~~and/or~~ or contamination at intervals not to exceed those listed in the Sealed Source and Device Registry;

3. Each sealed source that is designed to emit alpha particles is tested for leakage ~~and/or~~aor contamination at intervals not to exceed three (3) months.

4. Each sealed source for which there is reason to suspect might have been damaged or might be leaking is tested for leakage ~~and/or~~or contamination before further use.

5. Tests for leakage ~~and/or~~ or contamination shall be capable of detecting the presence of 0.005 microcuries (185 Bq) of radioactive material on the test sample.

6. Test samples shall be collected at the most accessible area where contamination would accumulate if the sealed source were leaking.

b. A licensee need not perform tests for leakage ~~and/or~~or contamination on the following sources:

1. Sealed sources containing only radioactive material with a half-life of less than 30 days;

2. Sealed sources containing only radioactive material as a gas;

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3. Sealed sources containing 100 microcuries (3.7 MBq) or less of beta- ~~and/or~~or photon-emitting material or 10 microcuries (370 kBq) or less of alpha-emitting material;

4. Sealed sources containing only hydrogen-3;

5. Seeds of iridium-192 encased in nylon ribbon; and

~~RH-1212.b. (Cont'd)~~

6. Sealed sources, except for alpha sources, which are stored, not being used and are identified as being in storage. ~~-~~The licensee shall, however, test each such sealed source for leakage ~~and/or~~ or contamination and receive the test results before any use or transfer unless it has been tested for leakage ~~and/or~~or contamination within the required leak test interval before the date of use or transfer. ~~-~~No sealed source shall be stored for a period of more than 3 years without being tested for leakage ~~and/or~~ or contamination.

c. Tests for leakage ~~and/or~~ or contamination, including sample collection and analysis, shall be performed by persons specifically authorized by the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State to perform such services.

d. Records of test results for leakage ~~and/or~~ or contamination shall be made in accordance with RH-1500.j.

e. Any test conducted pursuant to RH-1212. which reveals the presence of 0.005 microcuries (185 Bq) or more of removable contamination shall be considered evidence that the sealed source is leaking.~~-~~ The licensee shall immediately withdraw the sealed source from use and shall take action to prevent the spread of contamination. The leaking sealed source shall be repaired or disposed of in accordance with these Rules.

f. Reports of test results indicating a leaking sealed source shall be made to the Department in accordance with RH-1508.

RH-1213. Deleted.

RH-1214. Deleted.

RH-1215. **General Provisions and Scope – Radiological Criteria for License Termination.**

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a. Any person licensed to receive, possess, own, acquire, use, process, transfer, or dispose of radioactive material is subject to RH-1215. through RH-1220.

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~~RH-1215. (Cont'd)~~

b. After a site has been decommissioned and the license terminated in accordance with the criteria in RH-1215. through RH-1220., the Department will require additional cleanup only if, based on new information, it determines that the criteria in RH-1215. through RH-1220. were not met and residual radioactivity remaining at the site could result in significant threat to public health and safety.

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c. When calculating TEDE to the average member of the critical group, the licensee shall determine the peak annual TEDE dose expected within the first 1000 years after decommissioning.

RH-1216. **Radiological Criteria for Unrestricted Use**.

A site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a TEDE to an average member of the critical group that does not exceed 25 mrem (0.25 mSv) per year, including that from groundwater sources of drinking water, and the residual radioactivity has been reduced to levels that are as low as reasonably achievable (ALARA). Determination of the levels which are ALARA must take into account consideration of any detriments, such as deaths from transportation accidents, expected to potentially result from decontamination and waste disposal.

RH-1217. **Criteria for License Termination Under Restricted Conditions**.

A site will be considered acceptable for license termination under restricted conditions if:

a. The licensee can demonstrate that further reductions in residual radioactivity necessary to comply with the provisions of RH-1217 would result in net public or environmental harm or were not being made because the residual levels associated with restricted conditions are ALARA. Determination of the levels which are ALARA must take into account consideration of any detriments, such as traffic accidents, expected to potentially result from decontamination and waste disposal;

b. The licensee has made provisions for legally enforceable institutional controls that provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group will not exceed 25 mrem (0.25 mSv) per year;

~~RH-1217. (Cont'd)~~

c. The licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site. Acceptable financial assurance mechanisms are:

1. Funds placed into a trust segregated from the licensee's assets and outside the licensee's administrative control, and in which the adequacy of the trust funds is to be assessed based on an assumed annual one percent (1%) real rate of return on investment;

2. A statement of intent in the case of State or local Government licensees, as described in RH-409.h.6.D.; or

3. When a government entity is assuming custody and ownership of a site, an arrangement that is deemed acceptable by such governmental entity.

d. The licensee has submitted a decommissioning plan or License Termination Plan (LTP) to the Department indicating the licensee's intent to decommission in accordance with RH-410.d. and specifying that the licensee intends to decommission by restricting use of the site. The licensee shall document in the LTP or decommissioning plan how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and incorporated, as appropriate, following analysis of that advice.

1. Licensees proposing to decommission by restricting use of the site shall seek advice from such affected parties regarding the following matters concerning the proposed decommissioning:

A. Whether provisions for institutional controls proposed by the licensee:

i. Will provide reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical

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group will not exceed 25 mrem (0.25 mSv) TEDE per year;

ii. Will be enforceable; and

iii. Will not impose undue burdens on the local community or other affected parties.

~~RH-1217.d.1. (Cont'd)~~

B. Whether the licensee has provided sufficient financial assurance to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site.

2. In seeking advice on the issues identified in RH-1217.d.1., the licensee shall provide for:

A. Participation by representatives of a broad cross section of community interest who may be affected by the decommissioning:

B. An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

C. A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues; and

e. Residual radioactivity at the site has been reduced so that if the institutional controls were no longer in effect, there is reasonable assurance that the TEDE from residual radioactivity distinguishable from background to the average member of the critical group is as low as reasonably achievable and would not exceed either:

1. 100 mrem (1mSv) per year; or

2. 500 mrem (1mSv) per year provided the licensee

A. Demonstrates that further reductions in residual radioactivity necessary to comply with the 100 mrem/y (1mSv/y) value of RH-1217.e.1. are not technically

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achievable, would be prohibitively expensive, or would result in net public or environmental harm;

B. Makes provisions for durable institutional controls; and

~~RH-1217.e.2. (Cont'd)~~

C. Provides sufficient financial assurance to enable a responsible government entity or independent third party, including a governmental custodian of a site, both to carry out periodic rechecks of the site no less frequently than every five (5) years to assure that the institutional controls remain in place as necessary to meet the criteria of RH-1217.b. and to assume and carry out responsibilities for any necessary control and maintenance of those controls. Acceptable financial assurance mechanisms are those in RH-1217.c.

RH-1218. **Alternate Criteria for License Termination**.

a. The Department may terminate a license using alternate criteria greater than the dose criterion of RH-1216., RH-1217.b., and RH-1217.d.1.A.i., if the licensee:

1. Provides assurance that public health and safety would continue to be protected, and that it is unlikely that the dose from all man-made sources combined, other than medical, would be more than the 100 mrem/y (1 mSv/y) limit of Part C of Section 3, by submitting an analysis of possible sources of exposure;

2. Has employed to the extent practical restrictions on site use according to the provisions of RH-1217. in minimizing exposures at the site; and

3. Reduces doses to ALARA levels, taking into consideration any detriments such as traffic accidents expected to potentially result from decontamination and waste disposal.

4. Has submitted a decommissioning plan or License Termination Plan (LTP) to the Department indicating the licensee's intent to decommission in accordance with RH-410.d. and specifying that the licensee proposes to decommission by use of alternate criteria. The licensee shall document in the decommissioning plan or LTP

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how the advice of individuals and institutions in the community who may be affected by the decommissioning has been sought and addressed, as appropriate, following analysis of that advice. In seeking such advice, the licensee shall provide for:

~~RH-1218.a.4. (Cont'd)~~

A. Participation by representatives of a broad cross section of community interests who may be affected by the decommissioning;

B. An opportunity for a comprehensive, collective discussion on the issues by the participants represented; and

C. A publicly available summary of the results of all such discussions, including a description of the individual viewpoints of the participants on the issues and the extent of agreement and disagreement among the participants on the issues.

5. Has provided sufficient financial assurance in the form of a trust fund to enable an independent third party, including a governmental custodian of a site, to assume and carry out responsibilities for any necessary control and maintenance of the site.

b. The use of alternate criteria to terminate a license requires the approval of the Department after consideration of the Department's staff recommendations that will address any comments provided by the U.S. Environmental Protection Agency, any other State Governmental organization, and any public comments submitted pursuant to RH-1219.

RH-1219. **Public Notification and Public Participation**.

Upon the receipt of an LTP or decommissioning plan from the licensee, or a proposal by the licensee for release of a site pursuant to RH-1217. or RH-1218., or whenever the Department deems such notice to be in the public interest, the Department shall:

a. Notify and solicit comments from:

1. Local and State government organizations in the vicinity of the site and any Indian Nation or any other indigenous people that have treaty of statutory rights that could be affected by the decommissioning; and

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2. ~~2.~~ The Environmental Protection Agency (EPA) for cases where the licensee proposes to release a site pursuant to RH-1218.

~~RH-1219. (Cont'd)~~

b. Publish a notice in a forum, such as local newspapers, letters to State or local organizations, or other appropriate forum, that is readily accessible to individuals in the vicinity of the site, and solicit comments from affected parties.

RH-1220. **Minimization of Contamination**.

a. Applicants for licenses, other than renewals, shall describe in the application how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

b. Licensees shall, to the extent practical, conduct operations to minimize the introduction of residual radioactivity into the site, including the subsurface, in accordance with the existing radiation protection requirements in Part A of Section 3 and radiological criteria for license termination in RH-1215. through RH-1220.

RH-1221. Deleted. See RH-409.i.

RH-1222.- RH-1299. Reserved.

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PART D.
PRECAUTIONARY PROCEDURES

RH-1300. **Surveys**.

a. Each licensee or registrant shall make or cause to be made, surveys of areas, including the subsurface, that:

1. May be necessary for the licensee or registrant to comply with the rules in this Section; and

2. Are reasonable under the circumstances to evaluate:

A. The magnitude and extent of radiation levels,

B. Concentrations or quantities of residual radioactivity, and

C. The potential radiological hazards of the radiation levels and residual radioactivity detected.

b. Notwithstanding RH-1500.c.1., records from surveys describing the location and amount of subsurface residual radioactivity identified at the site must be kept with records important for decommissioning, and such records must be retained in accordance with RH-409.h.7., as applicable.

c. The licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements (e.g., dose rate and effluent monitoring) are calibrated at intervals recommended by the manufacturer or approved by the Department for the radiation measured. However, a more frequent interval may be required in another applicable Part of these Rules.

RH-1301. **Personnel Monitoring**.

a. All personnel dosimeters (except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to the extremities) that require processing to determine the radiation dose and that are used by licensees or registrants to comply with RH-1200., with other applicable provisions of these Rules, or with conditions specified in a license or a registration must be processed and evaluated by a dosimetry processor:

1. Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

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~~RH-1301.a. (Cont'd)~~

2. Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

RH-1302. **Conditions Requiring Individual Monitoring of External and Internal Occupational Dose**.

Each licensee or registrant shall monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of this Section.~~-~~ As a minimum:

a. Each licensee or registrant shall monitor occupational exposure to radiation from licensed and unlicensed, registered and unregistered, radiation sources under the control of the licensee or registrant and shall supply and require the use of individual monitoring devices by:

1. Adults likely to receive, in one (1) year from sources external to the body, a dose in excess of ten percent (10%) of the limits in RH-1200.a;

2. Minors likely to receive, in one (1) year, from sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv), a lens dose equivalent in excess of 0.15 rem (1.5 mSv), or a shallow dose equivalent to the skin or to the extremities in excess of 0.5 rem (5 mSv);~~ and~~

3. Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv);~~ and~~

NOTE: All of the occupational doses in RH-1200. continue to be applicable to the declared pregnant worker as long as the embryo/fetus dose limit is not exceeded.

4. Individuals entering a high or very high radiation area~~.~~; and

5. Individuals working with medical fluoroscopic equipment.

A. An individual monitoring device used for the dose to an embryo/fetus of a declared pregnant woman, pursuant to RH-1207.a., shall be located under the protective apron at the waist~~.~~;

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~~RH-1302.a.5. (Cont'd)~~

B. An individual monitoring device used for lens dose equivalent shall be located at the neck (collar), or an unshielded location closer to the eye, outside the protective apron;~~. If leaded eyewear is worn, the device should be clipped to the eyewear.~~ and

C. When only one (1) individual monitoring device is used to determine the effective dose equivalent for external radiation, it shall be located at the neck (collar) outside the protective apron. ~~-~~When a second individual monitoring device is used for the same purpose, it shall be located under the protective apron at the waist.~~-~~ The second individual monitoring device is required for a declared pregnant woman.

b. Each licensee ~~or registrant~~ shall monitor, to determine compliance with RH-1203., the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

1. Adults likely to receive, in one (1) year, an intake in excess of ten percent (10%) of the applicable ALI(s) in Table I, Columns 1 and 2, of Appendix G to Section 3; and

2. Minors likely to receive, in one (1) year, a committed effective dose equivalent in excess of 0.1 rem (1 mSv).

3. Declared pregnant women likely to receive, during the entire pregnancy, a committed dose equivalent in excess of 0.1 rem (1 mSv).

RH-1303. **Caution Signs, Labels, and Signals. Control of Exposure from External Sources in Restricted Areas. Respiratory Protection and Controls**

a. **Symbol**.

1. ~~Except as~~ Unless otherwise authorized by the Department, the symbols prescribed by this Section shall use the ~~conventional radiation caution~~ colors (magenta, or purple, or black, on yellow background).

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2. The symbol prescribed by this Section is the ~~conventional~~ three-bladed design. The cross-hatched area shall be magenta, or purple, or black and the background shall be yellow.

~~RH-1303.a. (Cont'd)~~

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3. Notwithstanding the requirements of ~~RH-1303.a.~~ paragraph a. of this section, licensees or registrants are authorized to label sources, source holders, or device components containing sources of ~~licensed materials~~ radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

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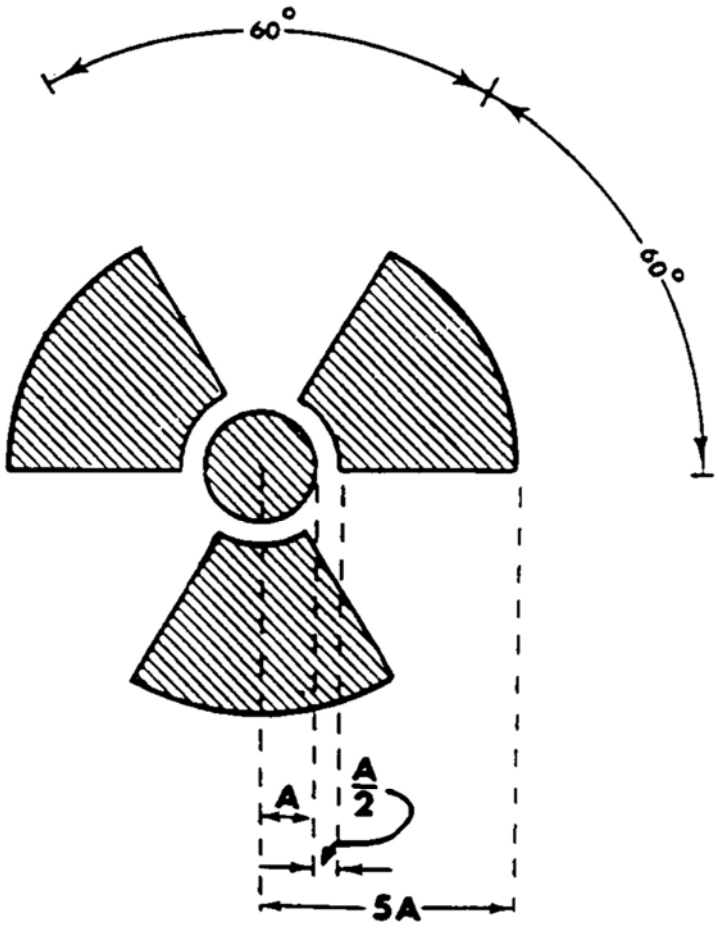
4. In addition to the contents of signs and labels prescribed in this Section, a licensee or registrant may provide on or near ~~such~~ the required signs and labels, ~~any~~ additional information, ~~which may be~~ as appropriate, ~~in aiding~~ to make individuals aware of potential radiation exposures and to minimize the exposures ~~to radiation~~.

~~RH-1303.a. (Cont'd)~~



RADIATION SYMBOL

~~RH-1303. (Cont'd)~~

b. **Posting requirements**.

1. **Posting of Radiation Areas.**

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The licensee or registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words

"CAUTION, RADIATION AREA."

2. **Posting of High Radiation Areas.**

The licensee or registrant shall post each high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words

"CAUTION, HIGH RADIATION AREA" or "DANGER, HIGH RADIATION AREA."

3. **Posting of Very High Radiation Areas.**

The licensee or registrant shall post each very high radiation area with a conspicuous sign or signs bearing the radiation symbol and the words

"GRAVE DANGER, VERY HIGH RADIATION AREA."

4. **Posting of Airborne Radioactivity Area.**

The licensee shall post each airborne radioactivity area with a conspicuous sign or signs bearing the radiation symbol and the words

"CAUTION, AIRBORNE RADIOACTIVITY AREA" or "DANGER, AIRBORNE RADIOACTIVITY AREA."

5. **Posting of Areas or Rooms in which Licensed Material is Used or Stored.**

The licensee shall post each area or room in which there is used or stored an amount of licensed material exceeding ten (10) times the quantity of such material specified in Appendix H to Section 3 with a conspicuous sign or signs bearing the radiation symbol and the words

"CAUTION, RADIOACTIVE MATERIAL(S)" or "DANGER, RADIOACTIVE MATERIAL(S)."

c. **Control of access to ~~H~~high radiation areas**.

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~~RH-1303.c. (Cont'd)~~

2. The licensee or registrant shall ensure that each entrance or access point to a high radiation area has one or more of the following features:

   A. A control device that, upon entry into the area, causes the level of radiation to be reduced below that level at which an individual might receive a deep-dose equivalent of 0.1 rem (1 mSv) in one (1) hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates;

   B. A control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or

   C. Entryways that are locked, except during periods when access to the areas is required, with positive control over each individual entry.

3. In place of the controls required by ~~RH-1303.~~Paragraph c.2. of this section for a high radiation area, the licensee or registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

4. A licensee or registrant may apply to the Department for approval of alternative methods for controlling access to high radiation areas.

5. The licensee or registrant shall establish the controls required by ~~RH-1303 .~~paragraph c.2 and ~~RH-1303.~~paragraph c.4 of this section in a way that does not prevent individuals from leaving a high radiation area.

6. Control is not required for each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with the regulations of the Department of Transportation provided that:

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A. The packages do not remain in the area longer than three (3) days; and

B. The dose rate at one (1) meter from the external surface of any package does not exceed 0.01 rem (0.1 mSv) per hour.

~~RH-1303.c. (Cont'd)~~

7. Control of entrance or access to rooms or other areas in hospitals is not required solely because of the presence of patients containing radioactive material, provided that there are personnel in attendance who will take the necessary precautions to prevent the exposure of individuals to radiation or radioactive material in excess of the limits established in this Section and to operate within the ALARA provisions of the licensee's radiation protection program.

8. The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a high radiation area as described in paragraph c. of this section if the registrant has met all the specific requirements for access and control specified in other applicable parts of these Rules, such as Part I of Section 3 for industrial radiography, Section 10 for non-therapeutic use of machine-produced radiation in the healing arts and veterinary medicine, and Section 13 for non-healing arts use of machine-produced radiation.

d. ~~1.~~ **Control of access to ~~V~~very high radiation areas**.

1. In addition to the requirements in RH-1303.c., the licensee or registrant shall institute additional measures to ensure that an individual is not able to gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 500 rads (5 grays) or more in one (1) hour at one (1) meter from a ~~radiation~~ source of radiation or any surface through which the radiation penetrates. This requirement does not apply to non-self-shielded irradiators.

2. ~~Deleted. See RH-1303.b.~~The registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a very high radiation area as described in paragraph d. of this section if the registrant has met all the specific requirements for access and control specified in other applicable parts of these Rules, such as Part I of Section 3 for industrial radiography, Section 10 for non-therapeutic use of machine-produced radiation in the healing arts and veterinary

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medicine, and Section 13 for non-healing arts use of machine-produced radiation.

e. **Control of access to ~~V~~very high radiation areas - irradiators.**

1. RH-1303.e. applies to licensees or registrants with sources of radiation in non-self-shielded irradiators. Paragraph e. does not apply to sources of radiation that are used in teletherapy, in industrial radiography, or in completely self-shielded irradiators in which the source of radiation is both stored and operated within the same shielding radiation barrier and, in the designed configuration of the irradiator, is always physically inaccessible to any individual and cannot create high levels of radiation in an area that is accessible to any individual.

~~1~~2. Each area in which there may exist radiation levels in excess of 500 rads (5 grays) in one (1) hour at one (1) meter from a source of radiation ~~a sealed radioactive source~~[2/] that is used to irradiate materials ~~must~~ shall meet the following requirements.

A. Each entrance or access point ~~must~~shall be equipped with entry control devices which:

i. Function automatically to prevent any individual from inadvertently entering ~~the area when~~ a very high radiation ~~levels exist~~area;

ii. Permit deliberate entry into the area only after a control device is actuated that causes the radiation level within the area, from the ~~sealed~~ source of radiation, to be reduced below that at which it would be possible for an individual to receive a deep-dose equivalent in excess of ~~-~~ 0.1 rem (1 mSv) in one (1) hour; and

~~RH-1303.e.1.A. (Cont'd)~~

iii. Prevent operation of the source of radiation if ~~the source~~ it would produce radiation levels in the area that could result in a deep-dose equivalent to an individual in excess of 0.1 rem (1 mSv) in one (1) hour.

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B. Additional control devices must be provided so that upon failure of the entry control devices to function as required by ~~RH-1303.e.1.A.~~paragraph e.2.A. of this section:

i. The radiation level within the area, from the ~~sealed~~ source of radiation, is reduced below that at which it would be possible for an individual to receive a deep-dose equivalent in excess of 0.1 rem (1 mSv) in one (1) hour; and

ii. Conspicuous visible and audible alarm signals are generated to make an individual attempting to enter the area aware of the hazard and at least one other authorized individual, who is physically present, familiar with the activity and prepared to render or summon assistance, aware of the failure of the entry control devices.

C. The licensee or registrant shall provide control devices so that, upon failure or removal of physical radiation barriers other than the sealed source's shielded storage container:

i. The radiation level from the source is reduced below that at which it would be possible for an individual to receive a deep-dose equivalent in excess of 0.1 rem (1 mSv) in one (1) hour; and

ii. Conspicuous visible and audible alarm signals are generated to make potentially affected individuals aware of the hazard and the licensee or registrant or at least one other individual, who is familiar with the activity and prepared to render or summon assistance, aware of the failure or removal of the physical barrier.

D. When the shield for ~~the~~ stored sealed source is a liquid, the licensee shall provide means to monitor the integrity of the shield and to signal, automatically, loss of adequate shielding.

~~RH-1303.e.1. (Cont'd)~~

E. Physical radiation barriers that comprise permanent structural components, such as walls, that have no credible probability of failure or removal in ordinary circumstances

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need not meet the requirements of paragraphs e.2.C. and e.2.D. of this ~~paragraph~~ section.

F. Each area ~~must~~shall be equipped with devices that will automatically generate conspicuous visible and audible alarm signals to alert personnel in the area before the source of radiation can be put into operation and in sufficient time for any individual in the area to operate a clearly identified control device, which must be installed in the area and which can prevent the source from being put into operation.

G. Each area ~~must~~ shall be controlled by use of such administrative procedures and such devices as are necessary to ensure that the area is cleared of personnel prior to each use of the source of radiation.

H. Each area ~~must~~ shall be checked by a radiation measurement to ensure that, prior to the first individual's entry into the area after any use of the source of radiation, the radiation level from the source in the area is below that at which it would be possible for an individual to receive a deep-dose equivalent in excess of 0.1 rem (1 mSv) in one (1) hour.

I. The entry control devices required in RH-1303.e.1.A. ~~must~~ shall be tested for proper functioning. ~~-~~ (See RH-1500.i. for recordkeeping requirements.)

i. Testing ~~must~~shall be conducted prior to initial operation with the source of radiation on any day, ~~(~~unless operations were continued uninterrupted from the previous day~~)~~;

ii. Testing ~~must~~ shall be conducted prior to resumption of operation of the source of radiation after any unintended interruption; and

iii. The licensee or registrant shall submit and adhere to a schedule for periodic tests of the entry control and warning systems.

~~RH-1303.e.1. (Cont'd)~~

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J. The licensee or registrant ~~may~~ shall not conduct operations, other than those necessary to place the source of radiation in safe condition or to effect repairs on controls, unless control devices are functioning properly.

K. Entry and exit portals that are used in transporting materials to and from the irradiation area, and that are not intended for use by individuals, ~~must~~ shall be controlled by such devices and administrative procedures as are necessary to physically protect and warn against inadvertent entry by any individual through these portals. ~~-~~Exit portals for ~~processed~~ irradiated materials ~~must~~ shall be equipped to detect and signal the presence of any loose ~~radiation sources~~ radioactive material that ~~are~~is carried toward such an exit and ~~to~~ automatically to prevent loose ~~radiation sources~~ radioactive material from being carried out of the area.

~~2~~3. ~~Persons holding licenses~~ Licensees, registrants, or applicants for licenses or registrations for sources of radiation ~~sources~~ that are within the purview of ~~RH-1303.e.1.~~ paragraph e.2 of this section and that will be used in a variety of positions or in locations, such as open fields or forests, that make it impracticable to comply with certain requirements of ~~RH-1303.e.1.,~~ paragraph e.2 of this section, such as those for the automatic control of radiation levels, may apply to the Radiation Control Section Chief for approval of ~~the use of~~ alternative safety measures. ~~Any a~~Alternative safety measures ~~must~~ shall provide ~~a degree of~~ personnel protection at least equivalent to those specified in ~~RH-1303.e.1~~paragraph e.2 of this section. ~~-~~At least one of the alternative measures ~~must~~ shall include an entry-preventing interlock control based on a measurement of the radiation that ensures the absence of high radiation levels before an individual can gain access to the area where such sources of radiation ~~sources~~ are used.

~~3~~4. The entry control devices required by ~~RH-1303.e.1. and 2.~~ Paragraphs e.2 and e.3 of this section must be established in such a way that no individual will be prevented from leaving the area.

f. **~~Airborne radioactivity area.~~Respiratory protection and controls to restrict internal exposure in restricted areas.**

1. Deleted.~~-~~ Airborne radioactivity area is defined in RH-1100.

2. Deleted.~~-~~ See RH-1303.b.

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3. **Use of process or other engineering controls**.

The licensee shall use, to the extent practical, process or other engineering controls (e.g., containment, decontamination, or ventilation) to control the concentration of radioactive material in air.

4. **Use of other controls**.

A. When it is not practicable to apply process or other engineering controls to control the concentrations of radioactive material in air to values below those that define an airborne radioactivity area, the licensee shall, consistent with maintaining the total effective dose equivalent ALARA, increase monitoring and limit intakes by one or more of the following means:

i. Control of access;

ii. Limitation of exposure times;

iii. Use of respiratory protection equipment; or

iv. Other controls.

B. If the licensee performs an ALARA analysis to determine whether or not respirators should be used, the licensee may consider safety factors other than radiological factors. The licensee should also consider the impact of respirator use on workers' industrial health and safety.

5. **Use of individual respiratory protection equipment**.

A. If the licensee assigns or permits the use of respiratory protection equipment to limit the intake of radioactive material,

i. The licensee shall use only respiratory protection equipment that is tested and certified or had certification extended by the National Institute for Occupational Safety and Health (NIOSH) except as otherwise noted in this Section.

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ii. If the licensee wishes to use equipment that has not been tested or certified by NIOSH, or for which there is no schedule for testing or certification, the licensee shall submit an application for authorized use of this equipment, except as provided in this Section. The application must include evidence that the material and performance characteristics of the equipment are capable of providing the proposed degree of protection under anticipated conditions of use. This must be demonstrated either by licensee testing or on the basis of reliable test information.

iii. The licensee shall implement and maintain a respiratory protection program that includes:

(a). Air sampling sufficient to identify the potential hazard, permit proper equipment selection, and estimate doses;

(b). Surveys and bioassays, as necessary, to evaluate actual intakes;

(c). Testing of respirators for operability (user seal check for face sealing devices and functional check for others) immediately prior to each use;

(d). Written procedures regarding:

(1). Monitoring, including air sampling and bioassays;

(2). Supervision and training of respirator users;

(3). Fit testing;

(4). Respirator selection;

(5). Breathing air quality;

(6). Inventory and control;

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~~RH-1303.f.5.A.iii.(d). (Cont'd)~~

(7). Storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment;

(8). Recordkeeping; and

(9). Limitations on periods of respirator use and relief from respirator use;

(e). Determination by a physician that the individual user is medically fit to use respiratory protection equipment; before

(1). The initial fitting of a face sealing respirator;

(2). Before the first field use of a non-face sealing respirator; and

(3). Either every twelve (12) months thereafter, or periodically at a frequency determined by a physician.

(f). Fit testing, with fit factor greater than or equal to 10 times the APF for negative pressure devices, and a fit factor greater than or equal to 500 for any positive pressure, continuous flow, and pressure-demand devices, before the first field use of tight fitting, face-sealing respirators and periodically thereafter at a frequency not to exceed one (1) year. -Fit testing must be performed with the facepiece operating in the negative pressure mode.

iv. The licensee shall advise each respirator user that the user may leave the area at any time for relief from respirator use in the event of equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other conditions that might require such relief.

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v. The licensee shall also consider limitations appropriate to the type and mode of use. When selecting respiratory devices, the licensee shall provide for vision correction, adequate communication, low temperature work environments, and the concurrent use of other safety or radiological protection equipment. The licensee shall use equipment in such a way as not to interfere with the proper operation of the respirator.

vi. Standby rescue persons are required whenever one-piece atmosphere-supplying suits, or any combination of supplied air respiratory protection device and personnel protective equipment are used from which an unaided individual would have difficulty extricating himself or herself. The standby persons must be equipped with respiratory protection devices or other apparatus appropriate for the potential hazards. The standby rescue persons shall observe or otherwise maintain continuous communication with the workers (visual, voice, signal line, telephone, radio, or other suitable means), and be immediately available to assist them in case of a failure of the air supply or for any other reason that requires relief from distress.
A sufficient number of standby rescue persons must be immediately available to assist all users of this type of equipment and to provide effective emergency rescue if needed.

vii. Atmosphere-supplying respirators must be supplied with respirable air of grade D quality or better as defined by the Compressed Gas Association in publication G-7.1, "Commodity Specification for Air," 1997 and included in the regulations of the Occupational Safety and Health Administration (29 CFR 1910.134(i)(1)(ii)(A) through (E). Grade D quality air criteria include:

(a). Oxygen content (v/v) of 19.5-23.5%;

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(b). Hydrocarbon (condensed) content of five (5) milligrams per cubic meter of air or less;

~~RH-1303.f.5.A.vii. (Cont'd)~~

(c). Carbon monoxide (CO) content of ten (10) ppm or less;

(d). Carbon dioxide content of 1,000 ppm or less; and

(e). Lack of noticeable odor.

viii. The licensee shall ensure that no objects, materials or substances, such as facial hair, or any conditions that interfere with the face-facepiece seal or valve function, and that are under the control of the respirator wearer, are present between the skin of the wearer's face and the sealing surface of a tight-fitting respirator facepiece.

ix. In estimating the dose to individuals from intake of airborne radioactive materials, the concentration of radioactive material in the air that is inhaled when respirators are worn is initially assumed to be the ambient concentration in air without respiratory protection, divided by the assigned protection factor. If the dose is later found to be greater than the estimated dose, the corrected value must be used. If the dose is later found to be less than the estimated dose, the corrected value may be used.

B. The licensee shall notify, in writing, the Radiation Control Section Chief at least thirty (30) days before the date that respiratory protection equipment is first used under the provisions of RH-1303.f.5.A.

6. **Further restrictions on the use of respiratory protection equipment**.

The Department may impose restrictions in addition to those in RH-1303.f.4. and RH-1303.f.5. and Appendix E to Section 3 to:

A. Ensure that the respiratory protection program of the licensee is adequate to limit doses to individuals from

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intakes of airborne radioactive materials consistent with maintaining total effective dose equivalent ALARA; and

~~RH-1303.f.6. (Cont'd)~~

B. Limit the extent to which a licensee may use respiratory protection equipment instead of process or other engineering controls.

7. **Application for use of higher assigned protection factors**.

The licensee shall obtain authorization from the Department before using assigned protection factors in excess of those specified in Appendix E to Section 3. The Department may authorize a licensee to use higher assigned protection factors on receipt of an application that:

A. Describes the situation for which a need exists for higher protection factors; and

B. Demonstrates that the respiratory protection equipment provides these protection factors under the proposed conditions of use.

g. Deleted. See RH-1303.b.

h. Deleted. (See RH-1309. and RH-1310.)

~~i. Each licensee shall, prior to disposal of an empty uncontaminated container to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive material.~~

~~j. All devices and equipment capable of producing radiation when operated shall be appropriately labeled so as to caution individuals that such devices or equipment produce radiation when operated.~~

~~k. Each radiation machine, except radiographic and fluoroscopic x-ray machines used solely in the healing arts, which is capable of producing, in any area accessible to individuals, a dose rate in excess of ten (10) millirems per hour shall be provided with a warning signal or light. Such a signal or light shall be so connected as to be activated automatically when the machine is "on" in order to provide adequate warning against entering the area.~~

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RH-1304. **Exceptions ~~From~~ to Posting Requirements**.

Notwithstanding the provisions of RH-1303.:

a. A room or area is not required to be posted with a caution sign because of the presence of a sealed source, provided the radiation level twelve (12) inches (30 centimeters) from the surface of the source container or housing does not exceed five (5) millirems (0.05 mSv) per hour.

b. Rooms or other areas in hospitals that are occupied by patients are not required to be posted with caution signs provided that the patient could be released from licensee control pursuant to RH-8420.

c. ~~Caution signs are not required to be posted~~ A licensee or registrant is not required to post caution signs in areas or rooms containing ~~radioactive materials~~sources of radiation for periods of less than eight (8) hours provided that:

   1. The ~~materials~~ sources of radiation are constantly attended during such periods by an individual who shall take the precautions necessary to prevent the exposure of ~~any~~ individuals to sources of radiation ~~or radioactive materials~~ in excess of the limits established in this Section; and

   2. Such area or room is subject to the licensee's or registrant's control.

~~d. A room or other area is not required to be posted with a caution sign, and control is not required for each entrance or access point to a room or other area which is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled in accordance with regulations of the Department of Transportation.~~

RH-1305. **Instruction of Personnel; Posting of Notice to Employees**.

Instructions required for individuals working in or frequenting any portion of a restricted area are specified in Part N of this Section.

RH-1306. **~~Storage~~ Security and Control of Sources of Radiation**.

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a. The licensee ~~or registrant~~ shall secure ~~sources of radiation~~ licensed material from unauthorized removal or access.

b. The licensee shall maintain constant surveillance and use devices or administrative procedures to prevent unauthorized use of licensed material that is in a controlled or unrestricted area and that is not in storage.

~~b~~c. ~~Sources of radiation~~ Licensed material shall not be stored in residential areas.

d. The registrant shall secure radiation machines from unauthorized removal.

e. The registrant shall use devices or administrative procedures to prevent unauthorized use of radiation machines.

RH-1307. **Procedures for Receiving and Opening Packages**.

a. Each licensee who expects to receive a package containing quantities of radioactive material in excess of a "Type A" quantity, as defined in RH-3100. and Appendix A to Section 4, shall make arrangements:

1. To receive the package when the carrier offers it for delivery; or

2. To receive notification of the arrival of the package at the carrier's terminal and take possession of the package expeditiously.

b. Each licensee shall:

1. Monitor the external surfaces of a labeled[4/] package for radioactive contamination unless the package contains only radioactive material in the form of a gas or in special form as defined in RH-3100.

2. Monitor the external surfaces of a labeled[4/] package for radiation levels unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity as defined in RH-3100. and Appendix A to Section 4; and

3. Monitor all packages known to contain radioactive material for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged.

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c. The licensee shall perform the monitoring required by paragraph b. of this section as soon as practical after receipt of the package, but not later than three (3) hours after the package is received at the licensee's facility if it is received during the licensee's normal working hours, or not later than three (3) hours from the beginning of the next working day if it is received after working hours.

d. The licensee shall immediately notify the final delivery carrier and the Department by telephone at 1-800-633-1735, when:

1. Removable radioactive surface contamination exceeds the limits of RH-3503.i.; or

2. External radiation levels exceed the limits of RH-3400.

~~RH-1307. (Cont'd)~~

e. Each licensee shall:

1. Establish, maintain, and retain written procedures for safely opening packages in which radioactive material is received; and

2. Ensure that the procedures are followed and that due consideration is given to special instructions for the type of package being opened.

f. Licensees transferring special form sources in licensee-owned or licensee-operated vehicles to and from a work site are exempt from the contamination monitoring requirements of paragraph b. of this section, but are not exempt from the survey requirement in paragraph b. of this section for measuring radiation levels that is required to ensure that the source is still properly lodged in its shield.

RH-1308. ~~Control of Material Not in Storage.~~Deleted

~~The licensee shall control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.~~

RH-1309. **Labeling Containers and Radiation Machines**.

a. The licensee shall ensure that each container of licensed material bears a durable, clearly visible label bearing the radiation symbol and the words:

CAUTION **DANGER**
or
RADIOACTIVE MATERIAL **RADIOACTIVE MATERIAL**

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The label must also provide sufficient information (such as the radionuclide(s) present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, radiation levels, kinds of materials, and mass enrichment) to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

b. Each licensee shall, prior to removal or disposal of empty uncontaminated containers to unrestricted areas, remove or deface the radioactive material label or otherwise clearly indicate that the container no longer contains radioactive materials.

c. Each registrant shall ensure that each radiation machine is labeled in a conspicuous manner that cautions individuals that radiation is produced when it is energized.

RH-1310. **Exemptions to Labeling Requirements**.

A licensee is not required to label:

a. Containers holding licensed material in quantities less than the quantities listed in Appendix H to Section 3 entitled "Quantities of Licensed Material Requiring Labeling"; or

b. Containers holding licensed material in concentrations less than those specified in Table 3 of Appendix G entitled "ALIs and DACs of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage."

c. Containers attended by an individual who takes the precautions necessary to prevent the exposure of individuals in excess of the limits established by this Section; or

d. Containers when they are in transport and packaged and labeled in accordance with the regulations of the Department of Transportation.[5/]

e. Containers that are accessible only to individuals authorized to handle or use them, or to work in the vicinity of the containers, if the contents are identified to these individuals by a readily available written record (examples of containers of this type are containers in locations such as water-filled canals, storage vaults, or hot cells). The record must be retained as long as the containers are in use for the purpose indicated on the record; or

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f. Installed manufacturing or process equipment, such as reactor components, piping, and tanks; or

g. Containers holding licensed material (other than sealed sources that are either specifically or generally licensed) at a facility licensed by the U.S. Nuclear Regulatory Commission (NRC) Part 50 (Domestic Licensing of Production and Utilization Facilities) or Part 52 (Licenses, Certifications, and Approvals for Nuclear Power Plants), not including non-power reactors, that are within an area posted under the requirements in RH-1303. if the containers are:

1. ~~1.~~ Conspicuously marked (such as by providing a system of color coding of containers) commensurate with the radiological hazard;

~~RH-1310.g. (Cont'd)~~

2. ~~2.~~ Accessible only to individuals who have sufficient instruction to minimize radiation exposure while handling or working in the vicinity of the containers; and

~~3.~~ Subject to plant procedures to ensure they are appropriately labeled, as specified in RH-1309. before being removed from the
3. posted area.

RH-1311. **Location of Individual Monitoring Devices**.

Each licensee or registrant shall ensure that individuals who are required to monitor occupational doses in accordance with RH-1302.a. wear individual monitoring devices as follows:

a. An individual monitoring device used for monitoring the dose to the whole body shall be worn at the unshielded location of the whole body likely to receive the highest exposure. When a protective apron is worn, the location of the individual monitoring device is typically at the neck (collar);

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b. An individual monitoring device used for monitoring the dose to an embryo/fetus of a declared pregnant woman, pursuant to RH-1207.a., shall be located at the waist under any protective apron being worn by the woman;

c. An individual monitoring device used for monitoring the lens dose equivalent, to demonstrate compliance with RH-1200.a.2.A., shall be located at the neck (collar), outside any protective apron being worn by the monitored individual, or at an unshielded location closer to the eye. ~~If leaded eyewear is worn, the device should be clipped to the eyewear~~; and

d. An individual monitoring device used for monitoring the dose to the extremities, to demonstrate compliance with RH-1200.a.2.B., shall be worn on the extremity likely to receive the highest exposure. Each individual monitoring device shall be oriented to measure the highest dose to the extremity being monitored.

RH-1312.- RH-1399. Reserved.

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PART E.
WASTE DISPOSAL

RH-1400. **General Requirements**.

A licensee shall dispose of licensed material only:

a. By transfer to an authorized recipient as provided in RH-1406. or in Section 2, or to the Department of Energy; or

b. By decay in storage; or

c. By release in effluents within the limits in RH-1208.; or

d. As authorized under RH-1401., RH-1402., RH-1404., RH-1405., or RH-1408.

e. A person must be specifically licensed to receive waste containing licensed material from other persons for:

1. Treatment prior to disposal; or

2. Treatment or disposal by incineration; or

3. Decay in storage; or

4. Storage until transferred to a storage or disposal facility authorized to receive the waste.

RH-1401. **Method for Obtaining Approval of Proposed Disposal Procedures**.

A licensee or applicant for a license may apply to the Department for approval of proposed procedures, not otherwise authorized in these Rules, to dispose of licensed material generated in the licensee's activities. Each application shall include:

a. A description of the waste containing licensed material to be disposed of, including the physical and chemical properties important to risk evaluation, and the proposed manner and conditions of waste disposal;

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b. An analysis and evaluation of pertinent information on the nature of the environment;

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c. The nature and location of other potentially affected licensed and unlicensed facilities; and

d. Analyses and procedures to ensure that doses are maintained ALARA and within the dose limits in this Section.

RH-1402. **Disposal by Release Into Sanitary Sewerage**.

a. A licensee may discharge licensed material into sanitary sewerage if each of the following conditions is satisfied:

1. The material is readily soluble (or is readily dispersible biological material) in water;

2. The quantity of licensed or other radioactive material that the licensee releases into the sewer in one month divided by the average monthly volume of water released into the sewer by the licensee does not exceed the concentration listed in Table III of Appendix G to Section 3; and

3. If more than one (1) radionuclide is released, the following conditions must also be satisfied:

A. The licensee shall determine the fraction of the limit in Table III of Appendix G to Section 3 represented by discharges into sanitary sewerage by dividing the actual monthly average concentration of each radionuclide released by the licensee into the sewer by the concentration of that radionuclide listed in Table III of Appendix G to Section 3; and

B. The sum of the fractions for each radionuclide required by paragraph a.3.A. of this section does not exceed unity; and

4. The total quantity of licensed and other radioactive material that the licensee releases into the sanitary sewerage system in a year does not exceed five (5) Curies (185 GBq) of hydrogen-3, one (1) Curie (37 GBq) of carbon-14, and one (1) Curie (37 GBq) of all other radioactive materials combined.

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b. Excreta from individuals undergoing medical diagnosis or therapy with radioactive material is not subject to the limitations contained in paragraph a of this section.

RH-1403. Deleted.

RH-1404. **Treatment or Disposal by Incineration**.

A licensee may treat or dispose of licensed material by incineration only in the amounts and forms specified in RH-1405. or as specifically approved by the Department pursuant to RH-1401.

RH-1405. **Disposal of Specific Wastes**.

a. Any licensee may dispose of the following licensed material without regard to its radioactivity:

1. 0.05 microcuries (1.85 kBq), or less, of hydrogen-3 or carbon-14 per gram of medium used for liquid scintillation counting; and

2. 0.05 microcuries (1.85 kBq), or less, of hydrogen-3 or carbon-14 per gram of animal tissue, averaged over the weight of the entire animal.

b. A licensee may not dispose of tissue under paragraph a.2. of this section in a manner that would permit its use either as food for humans or as animal feed.

c. The licensee shall maintain records in accordance with RH-1500.h.

RH-1406. **Transfer for Disposal and Manifests**.

a. The requirements of this section and Appendix G to 10 CFR Part 20 are designed to:

1. Control transfers of low-level radioactive waste (LLW) by any waste generator, waste collector, or waste processor licensee, as defined in Section 2, who ships low-level waste either directly, or indirectly through a waste collector or waste processor, to a licensed low-level waste land disposal facility as defined in Section 2;

2. Establish a manifest tracking system; and

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3. Supplement existing requirements concerning transfers and recordkeeping for those wastes.

~~RH-1406. (Cont'd)~~

b. Any licensee shipping radioactive waste intended for ultimate disposal at a licensed land disposal facility must document the information required on the U.S. Nuclear Regulatory Commission's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with Appendix G to 10 CFR Part 20.

c. Each shipment manifest must include a certification by the waste generator as specified in Section II of Appendix G to 10 CFR Part 20.

d. Each person involved in the transfer for disposal and disposal of waste, including the waste generator, waste collector, waste processor, and disposal facility operator, shall comply with the requirements specified in Section III of Appendix G to 10 CFR Part 20.

e. Any licensee shipping byproduct material as defined in paragraphs 3. and 4. of the definition of byproduct material set forth in RH-1100. intended for ultimate disposal at a land disposal facility licensed under RH-407. must document the information required on the NRC's Uniform Low-Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with Appendix G to 10 CFR Part 20.

RH-1407. **Compliance with Environmental and Health Protection Regulations**.

Nothing in this Part relieves the licensee from complying with other applicable Federal, State, and local regulations governing any other toxic or hazardous properties of materials that may be disposed of under this Part.

RH-1408. **Disposal of Certain Byproduct Material**.

a. Licensed material as defined in paragraphs 3. and 4. of the definition of byproduct material set forth in RH-1100. may be disposed of in accordance with RH-407. of this chapter, even though it is not defined as low level radioactive waste. Therefore, any licensed byproduct material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed under RH-407., must meet the requirements of RH-1406.

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b. A licensee may dispose of byproduct material, as defined in paragraphs 3. and 4. of the definition of byproduct material set forth in RH-1100., at a disposal facility authorized to dispose of such material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005.

RH-1409.- RH-1499. Reserved.

PART F.
RECORDS, REPORTS, NOTIFICATIONS, AND TESTS

RH-1500. **Records**.

a. **General provisions**.

1. Each licensee or registrant shall use the units: curie, rad, rem, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this Section.

2. In the records required by this Section, the licensee or registrant may record quantities in the International System of Units (SI) units in parentheses following each of the units specified in paragraph a.1. of this section. However, all quantities must be recorded as stated in paragraph a.1. of this section.

3. Notwithstanding the requirements of paragraph a.1. of this section, when recording information on shipment manifests, as required in RH-1406.b., information must be recorded in the International System of Units (SI) or in SI and units as specified in paragraph a.1. of this section.

4. The licensee or registrant shall make a clear distinction among the quantities entered on the records required by this Section (e.g., total effective dose equivalent, shallow-dose equivalent, lens dose equivalent, deep-dose equivalent, committed effective dose equivalent).

b. **Records of radiation protection programs**.

1. Each licensee or registrant shall maintain records of the radiation protection program, including:

A. The provisions of the program; and

B. Audits and other reviews of program content and implementation.

2. The licensee or registrant shall retain the records required by paragraph b.1.A. of this section until the Department terminates each pertinent license or registration requiring the record. The

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licensee or registrant shall retain the records required by paragraph b.1.B. of this section for three (3) years after the record is made.

c. **Records of surveys**.

1. Each licensee or registrant shall maintain records showing the results of surveys and calibrations required by RH-1300. and RH-1307. The licensee or registrant shall retain these records for three (3) years after the record is made.

2. The licensee or registrant shall retain each of the following records until the Department terminates each pertinent license or registration requiring the record:

A. Records of the results of surveys to determine the dose from external sources and used, in the absence of or in combination with individual monitoring data, in the assessment of individual dose equivalents;

B. Records of the results of measurements and calculations used to determine individual intakes of radioactive material and used in the assessment of internal dose;

C. Records showing the results of air sampling, surveys, and bioassays required pursuant to RH-1303.f.5.A.iii.; and

D. Records of the results of measurements and calculations used to evaluate the release of radioactive effluents to the environment.

d. **Determination of prior occupational dose**.

1. For each individual who is likely to receive an annual occupational dose requiring monitoring pursuant to RH-1302., the licensee or registrant shall determine the occupational radiation dose received during the current year.

2. Prior to permitting an individual to participate in a planned special exposure, the licensee or registrant shall determine:

A. The internal and external doses from all previous planned special exposures; and

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B. All doses in excess of the limits (including doses received during accidents and emergencies) received during the lifetime of the individual.

~~RH 1500.d. (Cont'd)~~

3. In complying with the requirements of paragraphs d.1.and d.2. of this section, a licensee or registrant may:

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A. Accept, as a record of the occupational dose that the individual received during the current year, a written signed statement from the individual, or from the individual's most recent employer for work involving radiation exposure, that discloses the nature and the amount of any occupational dose that the individual may have received during the current year;

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B. Accept, as the record of cumulative radiation dose, an up-to-date RC FORM 111, "Cumulative Occupational Dose History," or equivalent, signed by the individual and counter-signed by an appropriate official of the most recent employer for work involving radiation exposure, or the individual's current employer (if the individual is not employed by the licensee or registrant); and

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C. Obtain reports of the individual's dose equivalent(s) from the most recent employer for work involving radiation exposure, or the individual's current employer (if the individual is not employed by the licensee or registrant) by telephone, telegram, electronic media, or letter. The licensee or registrant shall request a written verification of the dose data if the authenticity of the transmitted report cannot be established.

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4. The licensee or registrant shall record the exposure history, as required by paragraphs d.1. and d.2. of this section, on an up-to-date RC FORM 111, or other clear and legible record, including all of the information required on that form[6/]. The form or record must show each period in which the individual received occupational exposure to radiation or radioactive material and must be signed by the individual who received the exposure. For each period for which the licensee or registrant obtains reports, the licensee or registrant shall use the dose shown in the report in preparing RC FORM 111, or equivalent. For any period in which the licensee or registrant does not obtain a report, the licensee or

registrant shall place a notation on RC FORM 111, or equivalent, indicating the periods of time for which data are not available.

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~~RH-1500.d. (Cont'd)~~

5. If the licensee or registrant is unable to obtain a complete record of an individual's current and previously accumulated occupational dose, the licensee or registrant shall assume:

   A. In establishing administrative controls under RH-1200.f. for the current year, that the allowable dose limit for the individual is reduced by 1.25 rems (12.5 mSv) for each quarter for which records were unavailable and the individual was engaged in activities that could have resulted in occupational radiation exposure; and

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   B. That the individual is not available for planned special exposures.

6. The licensee or registrant shall retain the records on RC FORM 111, or equivalent, until the Department terminates each pertinent license or registration requiring this record. The licensee or registrant shall retain records used in preparing RC FORM 111, or equivalent, for three (3) years after the record is made.

e. **Records of planned special exposures**.

1. For each use of the provisions of RH-1205. for planned special exposures, the licensee or registrant shall maintain records that describe:

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   A. The exceptional circumstances requiring the use of a planned special exposure;

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   B. The name of the management official who authorized the planned special exposure and a copy of the signed authorization;

   C. What actions were necessary;

   D. Why the actions were necessary;

   E. How doses were maintained ALARA; and

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F. What individual and collective doses were expected to result and the doses actually received in the planned special exposure.

~~RH-1500.e. (Cont'd)~~

2. The licensee or registrant shall retain the records until the Department terminates each pertinent license or registration requiring these records.

f. **Records of individual monitoring results**.

1. **Recordkeeping requirement**.

Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to RH-1302., and records of doses received during planned special exposures, accidents, and emergency conditions. These records[7/] must include, when applicable:

A. The deep-dose equivalent to the whole body, lens dose equivalent, shallow-dose equivalent to the skin, and shallow-dose equivalent to the extremities;

B. The estimated intake of radionuclides (See RH-1201.);

C. The committed effective dose equivalent assigned to the intake of radionuclides;

D. The specific information used to calculate the committed effective dose equivalent pursuant to RH-1203.a. and RH-1203.c. and when required by RH-1302.;

E. The total effective dose equivalent when required by RH-1201.; and

F. The total of the deep-dose equivalent and the committed dose to the organ receiving the highest total dose.

2. **Recordkeeping frequency**.

The licensee or registrant shall make entries of the records specified in paragraph f.1. of this section at least annually.

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~~RH-1500.f. (Cont'd)~~

3. **Recordkeeping format**.

The licensee or registrant shall maintain the records specified in paragraph f.1. of this section on an up-to-date RC FORM 110, "Occupational Dose Record for a Monitoring Period," in accordance with the instructions for RC FORM 110, or in clear and legible records containing all the information required by that form.

4. **Privacy protection**.

The records required under this section should be protected from public disclosure because of their personal privacy nature.

5. The licensee or registrant shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman.- The declaration of pregnancy, including the estimated date of conception, shall also be kept on file but may be maintained separately from the dose records.

6. The licensee or registrant shall retain each required form or record until the Department terminates each pertinent license or registration requiring the record.

g. **Records of dose to individual members of the public**.

1. Each licensee or registrant shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public (See RH-1208.).

2. The licensee or registrant shall retain the records required by paragraph g.1. of this section until the Department terminates each pertinent license or registration requiring the record.

h. **Records of waste disposal**.

1. Each licensee shall maintain records of the disposal of licensed materials made under RH-1401., RH-1402., a previous RH-1403. that authorized certain burials[8/], RH-1404., RH-1405., and RH-1408.

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2. The licensee shall retain the records required by paragraph h.1. of this section until the Department terminates each pertinent license requiring the record. ~~-~~Requirements for disposition of these records, prior to license termination, are located in RH-600.

i. **Records of testing entry control devices for very high radiation areas**.

1. Each licensee or registrant shall maintain records of tests made under RH-1303.e.1.I. on entry control devices for very high radiation areas.~~-~~ These records must include the date, time, and results of each such test of function.

2. The licensee or registrant shall retain the records required by paragraph i.1. of this section for three (3) years after the record is made.

j. **Records of tests for leakage ~~and/or~~ or contamination of sealed sources.**

1. Each licensee shall maintain records of tests for leakage ~~and/or~~or contamination of sealed sources required by RH-1212.a. ~~-~~These records must include identification of the source such as manufacturer, model number, and serial number; the date the sample was collected; the date the sample was analyzed; and the measured activity of the sample in units of microcuries or becquerels.

2. The licensee shall retain the records required by paragraph j.1. of this section for three (3) years after the record is made.

k. **Records required at temporary jobsites**.

Each licensee or registrant conducting activities as described in the definition for temporary jobsite in RH-1100. shall have the following records available at the temporary jobsite for inspection by the Department:

1. Current copy of appropriate license issued by the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State.

2. A copy of these Rules.

3. Operating and Emergency Procedures.

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4. The latest instrument calibration, if applicable.

~~RH-1500.k. (Cont'd)~~

5. Survey records required pursuant to RH-1803.c. for the period of operation at the jobsite, if applicable.

6. The latest leak test record for the device(s) in use at the jobsite if applicable.~~.~~

7. Daily pocket dosimeter record for the period of operation at the jobsite, if applicable.

l. Reserved.

m. Reserved.

n. 1. **Record retention periods**.

A. Each licensee or registrant shall retain each record that is required by this Section or by license condition for the period specified by the appropriate rule or license condition.~~-~~ If a retention period is not otherwise specified by rule or license condition, the record must be retained until the Department terminates each license or registration that authorizes the activity that is subject to the recordkeeping requirement.

B. If there is a conflict between the Department's rules in this Section, license condition, or other written Department approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the rules in this Section for such records shall apply unless the Department, pursuant to RH-2000., has granted a specific exemption from the record retention requirements specified in the rules in this Section.

~~RH-1500.n. (Cont'd)~~

2. **Record maintenance**.

Each record required by this Section must be legible throughout the specified retention period. ~~-~~The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the

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required retention period. -The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. -Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials, and signatures. -The licensee or registrant shall maintain adequate safeguards against tampering with and loss of records.

RH-1501. **Reports of Lost, Stolen, or Missing Licensed or Registered Sources of Radiation**.

a. **Telephone reports**.

1. Each licensee or registrant shall report to the Department by telephone as follows:

A. Immediately after its occurrence becomes known to the licensee, any lost, stolen, or missing licensed material in an aggregate quantity equal to or greater than 1,000 times the quantity specified in Appendix H to Section 3 under such circumstances that it appears to the licensee that an exposure could result to persons in unrestricted areas; or

B. Within 30 days after the occurrence of any lost, stolen, or missing licensed material becomes known to the licensee, all licensed material in a quantity greater than ten (10) times the quantity specified in Appendix H to Section 3 that is still missing at this time.

C. Immediately after its occurrence becomes known to the registrant, a lost, stolen, or missing radiation machine.

2. Reports must be made as follows:

All licensees or registrants shall make reports to the Department at 1-800-633-1735.

~~RH-1501. (Cont'd)~~

b. **Written reports**.

1. Each licensee or registrant required to make a report under paragraph a. of this section shall, within 30 days after making the telephone report, make a written report to the Department setting forth the following information:

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A. A description of the licensed or registered source of radiation involved, including, for radioactive material, kind, quantity, and chemical and physical form; and, for radiation machines, the manufacturer, model number, serial number, and type and maximum energy of radiation emitted;

B. A description of the circumstances under which the loss or theft occurred;

C. A statement of disposition, or probable disposition, of the licensed or registered source of radiation involved;

D. Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas;

E. Actions that have been taken, or will be taken, to recover the source of radiation; and

F. Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed or registered sources of radiation.

2. Reports must be made as follows:

All licensees or registrants shall make reports to the Arkansas Department of Health, Radiation Control Section Chief, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

c. Subsequent to filing the written report, the licensee or registrant shall also report any additional substantive information on the loss or theft within thirty (30) days after the licensee or registrant learns of such information.

d. The licensee or registrant shall prepare any report filed with the Department pursuant to this section so that names of individuals who may have received exposure to radiation are stated in a separate and detachable part of the report.

RH-1502. **Notification of Incidents**.

a. **Immediate notification**.

Notwithstanding any other requirements for notification, each licensee or registrant shall immediately report to the Department any event involving

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a source of radiation possessed by the licensee or registrant that may have caused or threatens to cause any of the following conditions:

1. An individual to receive:

   A. A total effective dose equivalent of 25 rems (0.25 Sv) or more; or

   B. A lens dose equivalent of 75 rems (0.75 Sv) or more; or

   C. A shallow-dose equivalent to the skin or extremities of 250 rads (2.5 Gy) or more; or

2. The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for twenty-four (24) hours, the individual could have received an intake five (5) times the occupational annual limit on intake. ~~(~~The provisions of this paragraph do not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.)

b. **Twenty-four hour notification**.

Each licensee or registrant shall, within twenty-four (24) hours of discovery of the event, report to the Department any event involving loss of control of a licensed or registered source of radiation possessed by the licensee or registrant that may have caused, or threatens to cause, any of the following conditions:

1. An individual to receive, in a period of twenty-four (24) hours:

   A. A total effective dose equivalent exceeding five (5) rems (0.05 Sv); or

   B. A lens dose equivalent exceeding fifteen (15) rems (0.15 Sv); or

   C. A shallow-dose equivalent to the skin or extremities exceeding fifty (50) rems (0.5 Sv); or

~~RH-1502.b. (Cont'd)~~

2. The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for twenty-four (24) hours, the individual could have received an intake in excess of one occupational annual limit on intake. ~~(~~The provisions of this

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paragraph do not apply to locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures.)

c. Licensees or registrants shall make the reports required by this section by telephone to the Department at 1-800-633-1735 and by confirming letter to the Arkansas Department of Health, Radiation Control Section Chief, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

d. The licensee or registrant shall prepare any report filed with the Department pursuant to this section so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable part of the report.

e. The provisions of this section do not include doses that result from planned special exposures, provided such doses are within the limits for planned special exposures and are reported under RH-1503.

RH-1503. **Reports of Planned Special Exposures.**

The licensee or registrant shall submit a written report to the Department within thirty (30) days following any planned special exposure conducted in accordance with RH-1205., informing the Department that a planned special exposure was conducted and indicating the date the planned special exposure occurred and the information required by RH-1500.e.

RH-1504. **Reports of Exposures, Radiation Levels, and Concentrations of Radioactive Material Exceeding the Constraints or Limits**.

a. **Reportable events**.

In addition to the notification required by RH-1502., each licensee or registrant shall submit a written report within thirty (30) days after learning of any of the following occurrences:

1. Any incident for which notification is required by RH-1502.; or

~~RH-1504.a. (Cont'd)~~

2. Doses in excess of any of the following:

A. The occupational dose limits for adults in RH-1200.; or

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B. The occupational dose limits for a minor in RH-1206.; or

C. The limits for an embryo/fetus of a declared pregnant woman in RH-1207.; or

D. The limits for an individual member of the public in RH-1208.; or

E. Any applicable limit in the license; or

F. The ALARA constraints for air emissions established under RH-1004.d.; or

3. Levels of radiation or concentrations of radioactive material in:

A. A restricted area in excess of any applicable limit in the license; or

B. An unrestricted area in excess of ten (10) times any applicable limit set forth in this Section or in the license (whether or not involving exposure of any individual in excess of the limits in RH-1208.); or

4. For licensees subject to the provisions of EPA's generally applicable environmental radiation standards in 40 CFR Part 190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.

b. **Contents of reports**.

1. Each report required by paragraph a. of this section must describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:

A. Estimates of each individual's dose;

B. The levels of radiation and concentrations of radioactive material involved;

~~RH-1504.b.1. (Cont'd)~~

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C. The cause of the elevated exposures, dose rates, or concentrations; and

D. Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints, generally applicable environmental standards, and associated license conditions.

2. Each report filed pursuant to paragraph a. of this section must include for each occupationally overexposed[9/] individual: the name, social security number, or other unique identifier, and date of birth. The report must be prepared so that this information is stated in a separate and detachable part of the report.

3. The licensee or registrant shall prepare any report filed with the Department pursuant to this section so that names of individuals who have received exposure to sources of radiation are stated in a separate and detachable part of the report.

c. Licensees or registrants who make reports pursuant to paragraph a. of this section shall submit the report in writing to the Arkansas Department of Health, Radiation Control Section Chief, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

RH-1505. **Notifications and Reports to Individuals**.

~~a.~~ Requirements for notification and reports to individuals of exposure to radiation or radioactive material are specified in Part N of this Section (RH-2804).

a. **Reports to individuals of exceeding dose limits**.

When a licensee or registrant is required pursuant to RH-1503. or RH-1504. to report to the Department any exposure of an identified occupationally exposed individual, or an identified member of the public, to radiation or radioactive material, the licensee or registrant shall also provide the individual a report on his or her exposure data included in the report to the Department. The report must be transmitted no later than the transmittal to the Department.

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RH-1506. **Notification of Intent to Vacate Premises.**

Each specific licensee shall, no less than thirty (30) days before vacating or relinquishing possession or control of premises which may have been contaminated with radioactive material as a result of the activities, notify the Department in writing of intent to vacate. ~~-~~When deemed necessary by the Department, the licensee shall decontaminate the premises in such a manner as the Department may specify.

RH-1507. Deleted. Refer to RH-8703. and RH-8800.

RH-1508. **Reports of Leaking Sealed Sources.**

A licensee shall file a report with the Department within five (5) days if a test for leakage ~~and/or~~ or contamination required by RH-1212. reveals the presence of 0.005 microcuries (185 Bq) or more of removable contamination. ~~-~~The written report must include the results of the test; the date the test results were received; identification of the source such as manufacturer, model number, and serial number; the radionuclide and its estimated activity; any equipment involved; any contamination which resulted from the leaking source; and the corrective actions taken.

RH-1509. **Reports of Individual Monitoring**.

a. This section applies to each person licensed by the Department to:

1. Possess or use radioactive material for purposes of radiography pursuant to Part I of Section 3; or

~~RH-1509.a. (Cont'd)~~

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2. Possess or use at any time, for processing or manufacturing for distribution pursuant to Section 2 or 9, radioactive material in quantities exceeding any one of the following quantities:

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TABLE TO RH-1509.a.2.

Radionuclide	Activity[a]	
	Ci	GBq
Cesium-137	1	37
Cobalt-60	1	37
Gold-198	100	3,700

Iodine-131	1	37
Iridium-192	10	370
Krypton-85	1,000	37,000
Promethium-147	10	370
Technetium-99m	1,000	37,000

[a] The Department may require as a license condition, or by rule or order pursuant to RH-2001., reports from licensees who are licensed to use radionuclides not on this list, in quantities sufficient to cause comparable radiation levels.

b. Each licensee in a category listed in paragraph a. of this section shall complete an annual report of the results of individual monitoring carried out by the licensee for each individual for whom monitoring was required by RH-1302. during that year. The licensee may include additional data for individuals for whom monitoring was provided but not required. The licensee shall use an up-to-date RC FORM 110 or equivalent containing all the information required by RC FORM 110.

c. The licensee shall complete the report required by paragraph b. of this section, covering the preceding year, on or before May 31 of each year. The licensee shall retain the report and submit it, if requested, to the Arkansas Department of Health, Radiation Control Section Chief, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

RH-1510. Deleted. Refer to RH-8308., RH-8703., and RH-8800.

RH-1511. Deleted. Refer to RH-107.

RH-1512. Deleted. Refer to RH-1500.k.

RH-1513. **Reports of Transactions Involving Nationally Tracked Sources**.

Each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report as specified in paragraphs a. through e. of this section for each type of transaction. See Appendix D to Section 3, "Nationally Tracked Source Thresholds."

a. Each licensee who manufactures a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

1. The name, address, and license number of the reporting licensee;

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2. The name of the individual preparing the report;

3. The manufacturer, model, and serial number of the source;

4. The radioactive material in the source;

5. The initial source strength in becquerels (curies) at the time of manufacture; and

6. The manufacture date of the source.

b. Each licensee that transfers a nationally tracked source to another person shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

1. The name, address, and license number of the reporting licensee;

2. The name of the individual preparing the report;

3. The name and license number of the recipient facility and the shipping address;

4. The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

5. The radioactive material in the source;

6. The initial or current source strength in becquerels (curies);

7. The date for which the source strength is reported;

~~RH 1513.b. (Cont'd)~~

8. The shipping date;

9. The estimated arrival date; and

10. For nationally tracked sources transferred as waste under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification of the container with the nationally tracked source.

c. Each licensee that receives a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

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1. The name, address, and license number of the reporting licensee;

2. The name of the individual preparing the report;

3. The name, address, and license number of the person that provided the source;

4. The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

5. The radioactive material in the source;

6. The initial or current source strength in becquerels (curies);

7. The date for which the source strength is reported;

8. The date of receipt; and

9. For material received under a Uniform Low-Level Radioactive Waste Manifest, the waste manifest number and the container identification with the nationally tracked source.

d. Each licensee that disassembles a nationally tracked source shall complete and submit a National Source Tracking Transaction Report. The report must include the following information:

1. The name, address, and license number of the reporting licensee;

2. The name of the individual preparing the report;

~~RH 1513.d. (Cont'd)~~

3. The manufacturer, model, and serial number of the source or, if not available, other information to uniquely identify the source;

4. The radioactive material in the source;

5. The initial or current source strength in becquerels (curies);

6. The date for which the source strength is reported; and

7. The disassemble date of the source.

e. Each licensee who disposes of a nationally tracked source shall complete and submit a National Source Tracking Transaction Report.

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The report must include the following information:

1. The name, address, and license number of the reporting licensee;

2. The name of the individual preparing the report;

3. The waste manifest number;

4. The container identification with the nationally tracked source;

5. The date of disposal; and

6. The method of disposal.

f. The reports discussed in paragraphs a. through e. of this section must be submitted by the close of the next business day after the transaction. A single report may be submitted for multiple sources and transactions. The reports must be submitted to the National Source Tracking System by using:

1. The on-line National Source Tracking System;

2. Electronically using a computer-readable format;

3. By facsimile;

4. By mail to the address on the National Source Tracking Transaction Report Form (NRC Form 748); or

~~RH-1513.f. (Cont'd)~~

5. By telephone with follow-up by facsimile or mail.

g. Each licensee shall correct any error in previously filed reports or file a new report for any missed transaction within five (5) business days of the discovery of the error or missed transaction. Such errors may be detected by a variety of methods such as administrative reviews or by physical inventories required by rule. In addition, each licensee shall reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System. The reconciliation must be conducted during the month of January in each year. The reconciliation process must include resolving any discrepancies

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between the National Source Tracking System and the actual inventory by filing the reports identified by paragraphs a. through e. of this section. By January 31 of each year, each licensee must submit to the National Source Tracking System confirmation that the data in the National Source Tracking System is correct.

RH-1514. - RH-1519. – Reserved.

RH-1520. **Tests**.

Upon instruction from the Department, each licensee and registrant shall perform or cause to have performed, and shall permit the Department to perform, such reasonable tests as the Department deems appropriate or necessary, including, but not limited to, tests of:

a. Sources of radiation;

b. Facilities wherein sources of radiation are used or stored;

c. Radiation detection and monitoring instruments; and

d. Other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

RH-1521. - RH-1599. – Reserved.

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PART G.

~~SPECIAL REQUIREMENTS FOR THE USE OF X-RAYS IN THE HEALING ARTS~~

[RESERVED]

~~RH-1600. **Scope**.~~

~~This Part establishes requirements, for which a registrant (or licensee) is responsible, for use of x-ray equipment by or under the supervision of an individual authorized by and licensed in accordance with state statutes to engage in the healing arts or veterinary medicine. The provisions of this Part are in addition to and not in substitution for, other applicable provisions of these Rules.~~

~~RH-1601. **Definitions**.~~

~~**Accessible surface** - The external surface of the enclosure or housing provided by the manufacturer.~~

~~**Added filtration** - Any filtration which is in addition to the inherent filtration~~

~~**Aluminum equivalent** - The thickness of type 1100 aluminum alloy[11/] affording the same attenuation, under specified conditions, as the material in question.~~

~~**Assembler** - Any person engaged in the business of assembling, replacing or installing one or more components into an x-ray system or subsystem.~~

~~**Attenuation block** - A block or stack, having dimensions 20 centimeters by 20 centimeters by 3.8 centimeters, of type 1100 aluminum alloy[11/] or other materials having equivalent attenuation.~~

~~**Automatic exposure control** - A device which automatically controls one or more technique factors in order to obtain at a pre-selected location(s) a required quantity of radiation. (See also "Phototimer.")~~

~~**Barrier** - See "Protective barrier."~~

~~**Beam axis** - A line from the source through the centers of the x-ray fields.~~

~~**Beam-limiting device** - A device which provides a means to restrict the dimensions of the x-ray field.~~

~~**Beam monitoring system** - A system designed to detect and measure the radiation present in the useful beam.~~

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Commented [AO55]: RH-1600.- RH-1611., RH-1613. Deleted. See Section 10.
Schedule A to Section 3. Deleted. See Appendix C to Section 1.
RH-1612. Deleted. See Section 13.

RH-1601. (Cont'd)

Calibration - The determination of (1) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument or (2) the strength of a source of radiation relative to a standard.

Cephalometric device - A device intended for the radiographic visualization and measurement of the dimensions of the human head.

Certified components - Components of x-ray systems which are subject to regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968.

Certified system - Any x-ray system which has one or more certified component(s).

Changeable filters - Any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical or physical process.

Coefficient of variation or "C" - The ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}}\left[\frac{\sum_{i=1}^{n}\left(x_i - \bar{x}\right)^2}{n-1}\right]^{\frac{1}{2}}$$

where:

s = Estimated standard deviation of the population;

$\bar{x}$ = Mean value of observations in sample;

x_i = i^{th} observation in sample; and

n = Number of observations in sample.

Contact therapy system - An x-ray system used for therapy with the x-ray tube port placed in contact with or within five (5) centimeters of the surface being treated.

Control panel - That part of the x-ray control upon which are mounted the switches, knobs, push buttons, and other hardware necessary for manually setting the technique factors.

Commented [AO56]: RH-1601 Images to be removed unable to strike through

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RH-1601. (Cont'd)

Cooling curve - The graphical relationship between heat units stored and cooling time.

Dead-man switch - A switch constructed that a circuit closing contact can be maintained only by continuous pressure on the switch by the operator.

Detector - See "Radiation detector."

Diagnostic source assembly - The tube housing assembly with a beam-limiting device attached.

Diagnostic x-ray system - An x-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization.

Direct scattered radiation - The scattered radiation which has been deviated in direction only by materials irradiated by the useful beam. (See "Scattered radiation.")

Entrance exposure - The roentgens per unit time at the point where the center of the useful beam enters the patient.

Equipment - See "X-ray equipment."

Exposure - The quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass dm are completely stopped in air. (The special unit of exposure is the roentgen [R]).

Field emission equipment - Equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

Filter - Material placed in the useful beam to absorb preferentially selected radiations.

Fluoroscopic imaging assembly - A subsystem in which x-ray photons produce a fluoroscopic image. It includes the image receptor(s) such as the image intensifier and spot-film device, electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

Focal spot - The area projected on the anode of the x-ray tube by the electrons accelerated from the cathode and from which the useful beam originates.

RH-1601. (Cont'd)

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Full beam detector - A radiation detector of such size that the total cross section of the maximum size useful beam is intercepted.

General purpose radiographic x-ray system - Any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

Gonad shield - A protective barrier for the testes or ovaries.

Half-value layer - The thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

Healing arts screening - The testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.

Heat unit - A unit of energy equal to the product of the peak kilovoltage, milliamperes and seconds, i.e., kVp x mA x second.

HVL - See "Half-value layer."

Image intensifier - A device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher energy density.

Image receptor - Any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.

Image receptor support - For mammographic systems, that part of the system designed to support the image receptor in a horizontal plane during a mammographic examination.

Inherent filtration - The filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

Interlock - A device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

RH-1601. (Cont'd)

Irradiation - The exposure of matter to ionizing radiation.

Kilovolts peak - See "Peak tube potential."

kV - Kilovolts.

kVp - See "Peak tube potential."

kWs - Kilowatt second. It is equivalent to 10^3 kV·mA·sec, i.e.,

$$(A)\text{kWs} = (X)\text{kV} \cdot (Y)\text{mA} \cdot (Z)\text{sec} \cdot \frac{\text{kWs}}{10^3\text{kV} \cdot \text{mA} \cdot \text{sec}} = \frac{XYZ\ \text{kWs}}{10^3}$$

Lead equivalent - The thickness of lead affording the same attenuation, under specified conditions, as the material in question.

Leakage radiation - Radiation emanating from the diagnostic or therapeutic source assembly except for:

1. the useful beam, and

2. radiation produced when the exposure switch or timer is not activated.

Leakage technique factors - The technique factors associated with the tube housing assembly which are used in measuring leakage radiation. They are defined as follows:

1. For capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being 10 millicoulombs, i.e., 10 milliampere seconds or the minimum obtainable from the unit, whichever is larger.

2. For field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential.

3. For all other equipment, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

RH-1601. (Cont'd)

Light field - That area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the focus of points at which the illumination is one-fourth of the maximum in the intersection.

Line-voltage regulation - The difference between the no-load and the load line potentials expressed as a percentage of the load line potential. It is calculated using the following equation:

Percent line-voltage regulation = $100(V_n-V_l)/V_l$

where:

V_n = No-load line potential; and

V_l = Load line potential.

mA - Milliampere.

mAs - Milliampere second.

Maximum line current - The root-mean-square current in the supply line of an x-ray machine operating at its maximum rating.

Mobile equipment - See "X-ray equipment."

Patient - An individual subjected to healing arts examination, diagnosis or treatment.

Peak tube potential - The maximum value of the potential difference across the x-ray tube during an exposure.

Phantom - A volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation.

Phototimer - A method for controlling radiation exposures to image receptors by the amount of radiation which reaches a radiation monitoring device(s). The radiation monitoring device(s) is part of an electronic circuit which controls the duration of time the tube is activated. (See "Automatic exposure control.")

PID - See "Position indicating device."

Position indicating device - A device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

RH-1601. (Cont'd)

Primary dose monitoring system - A system which will monitor the useful beam during irradiation and which will terminate irradiation when the pre-selected number of dose monitor units have been acquired.

Primary protective barrier - See "Protective barrier."

Protective apron - An apron made of radiation attenuating materials used to reduce radiation exposure.

Protective barrier - A barrier of radiation attenuating material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

1. Primary protective barrier - The material, excluding filters, placed in the useful beam, for protection purposes, to reduce the radiation exposure.

2. Secondary protective barrier - A barrier sufficient to attenuate the stray radiation to the required degree.

Protective glove - A glove made of radiation attenuating materials used to reduce radiation exposure.

Qualified expert - An individual who has demonstrated to the satisfaction of the Department that such individual possesses the knowledge and training to measure ionizing radiation, to evaluate safety techniques and to advise regarding radiation protection needs.

Radiation detector - A device which in the presence of radiation provides by either direct or indirect means, a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

Radiation therapy simulation system - A radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

Radiograph - An image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

Radiograph imaging system - Any system whereby a permanent or semi-permanent image is recorded on an image receptor by the action of ionizing radiation.

Rating - The operating limits as specified by the component manufacturer.

RH-1601. (Cont'd)

Recording - Producing a permanent form of an image resulting from x-ray photons (e.g., film, video tape).

Response time - The time required for an instrument system to reach 90 percent (90%) of its final reading when the radiation-sensitive volume of the instrument system is exposed to a step change in radiation flux from zero sufficient to provide a steady state mid scale reading.

Scattered radiation - Radiation that, during passage through matter, has been deviated in direction. (See "Direct scattered radiation.")

Secondary dose monitoring system - A system which will terminate irradiation in the event of failure of the primary system.

Secondary protective barrier - See "Protective barrier."

Shutter - A device attached to the tube housing assembly which can totally intercept the useful beam and which as a lead equivalency not less than that of the tube housing assembly.

SID - See "Source-image receptor distance."

Source - The focal spot of the x-ray tube.

Source-image receptor distance - The distance from the source to the center of the input surface of the image receptor.

Spot check - A procedure which is performed to assure that a previous calibration continues to be valid.

Spot film - A radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

Spot-film device - A device intended to transport and/or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of an image intensifier for the purpose of making a radiograph.

SSD - The distance between the source and the skin of the patient.

Stationary equipment - See "X-ray equipment."

Stray radiation - The sum of leakage and scattered radiation.

RH-1601. (Cont'd)

Technique factors - The conditions of operation. They are specified as follows:

1. For capacitor energy storage equipment, peak tube potential in kV and quantity of charge in mAs.

2. For field emission equipment rated for pulsed operation, peak tube potential in kV and number of x-ray pulses.

3. For all other equipment, peak tube potential in kV and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs.

Termination of irradiation - The stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

Traceable to a national standard - A quantity or a measurement that has been compared to a NIST* (National Institute of Standards and Technology) standard directly or indirectly through one or more intermediate steps and that all comparisons have been documented.

Therapeutic-type housing -

1. For x-ray therapy equipment not capable of operating at 500 kVp or above, the following definition applies: An x-ray tube housing so constructed that the leakage radiation averaged over any 100 cm^2 area at a distance of one meter from the source does not exceed one roentgen in an hour when the tube is operated at its maximum rated continuous current for the maximum rated tube potential.

2. For x-ray therapy equipment capable of operation at 500 kVp or above, the following definition applies: An x-ray tube housing so constructed that leakage radiation averaged over any 100 cm^2 area at a distance of one meter from the source does not exceed 0.1 percent of the useful beam dose rate at one meter from the source for any of its operating conditions.

Therapeutic x-ray and/or electron system - A system designed for irradiation of any part of the human body for the purpose of treatment or alleviation of symptoms of disease.

Tube - An x-ray tube, unless otherwise specified.

*formerly NBS (National Bureau of Standards)

RH-1601. (Cont'd)

Tube housing assembly - The tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

Tube rating chart - The set of curves which specify the rated limits of operation of the tube in terms of the technique factors.

Useful beam - The radiation which passes through the tube housing port and the aperture of the beam-limiting device when the exposure switch or timer is activated.

Variable-aperture beam-limiting device - A beam-limiting device which has capacity for stepless adjustment of the x-ray field size at a given SID.

Visible area - That portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

Wedge filter - An added filter effecting continuous progressive attenuation on all or part of the useful beam.

X-ray control - A device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers and similar devices, which control the technique factors of an x-ray exposure.

X-ray equipment - An x-ray system, subsystem or component thereof. Types of x-ray equipment are as follows:

1. Mobile x-ray equipment: X-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.

2. Portable x-ray equipment: X-ray equipment designed to be hand-carried.

3. Stationary x-ray equipment: X-ray equipment which is installed in a fixed location.

X-ray field - The area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

RH-1601. (Cont'd)

X-ray high-voltage generator - A device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices and other appropriate elements.

X-ray system - An assemblage of components for the controlled production of x-rays. It includes an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

X-ray subsystem - Any combination of two or more components of an x-ray system.

X-ray tube - Any electron tube which is designed to be used primarily for the production of x-rays.

RH-1602. **General Requirements. Administrative Controls.**

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a. **Registrant.**

The registrant shall be responsible for directing the operation of the x-ray systems which have been registered with the Department. The registrant or the registrant's agent shall assure that the requirements of RH-1602.a. are met in the operation of the x-ray system(s).

1. An x-ray system which does not meet the provisions of these Rules shall not be operated for diagnostic or therapeutic purposes.

2. Individuals who will be operating the x-ray systems shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment.

3. A chart shall be provided in the vicinity of the diagnostic x-ray system's control panel which specifies, for all examinations performed with that system, the following information:

A. Patient's anatomical size versus technique factors to be utilized;

B. Type and size of the film or film-screen combination to be used;

RH-1602.a.3. (Cont'd)

C. Type and focal distance of the grid to be used, if any;

D. Source to image receptor distance to be used; and

E. Type and location of placement of gonad shielding to be used.

F. For mammography, indication of kVp/target/filter combination.

4. Written safety procedures and rules shall be provided to each individual operating x-ray equipment, including any restrictions of the operating technique required for the safe operation of the particular x-ray system. The operator shall be able to demonstrate familiarity with these rules.

5. Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:

A. All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by 0.5 millimeter lead equivalent.

B. Staff and ancillary personnel shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent.

C. Patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of 0.25 millimeter lead equivalent or shall be so positioned that the nearest portion of the body is at least two meters from both the tube head and the nearest edge of the image receptor.

6. New gonad shielding of not less than 0.5 millimeter lead equivalent material shall be used for human patients, who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

Commented [AO57]: RH-1602.a.6 Gonadal shielding removed; see position statements from : National Council on Radiation Protection and Measurements (NCRP); American Association of Physicists in Medicine (AAPM)

RH-1602.a. (Cont'd)

7. Individuals shall not be exposed to the useful beam except for healing arts purposes and such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

   A. Exposure of an individual for training, demonstration or other non-healing-arts purposes; and

   B. Exposure of an individual for the purpose of healing arts screening except as authorized by RH-1602.a.11.

8. When a patient or film must be provided with auxiliary support during a radiation exposure:

   A. Mechanical holding devices shall be used when the technique permits.

   B. If a human holder must be utilized:

      i. Written safety procedures, as required by RH-1602.a.4., shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

      ii. The human holder shall be protected as required by RH-1602.a.5.;

      iii. No individual shall be used routinely to hold film or patients;

      iv. Such holding shall be permitted only in very unusual and rare situations;

      v. In those cases where the patient must hold the film, except during intra-oral examinations, any portion of the body, other than the area of clinical interest, struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material; and

RH-1602.a.8.B. (Cont'd)

vi. Each facility shall have leaded aprons and gloves available in sufficient numbers to provide protection to all personnel who are involved with x-ray operations and who are otherwise not shielded.

9. Procedures and auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized. This is interpreted to include but not limited to:

A. The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations.

B. The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality.

C. Portable or mobile equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary radiographic installation.

D. X-ray systems subject to RH-1604. shall not be utilized in procedures where the source to patient distance is less than thirty (30) centimeters.

i. X-ray systems shall not be utilized in procedures where the source to patient distance is less than thirty (30) centimeters, except for veterinary systems.

ii. If grids are used between the patient and the image receptor to decrease scatter to the film and improve contrast, the grid shall:

(a) Be positioned properly, i.e., tube side facing the right direction, and grid centered to the central ray;

(b). If of the focused type, be of the proper focal distance for the SIDs being used.

RH-1602.a.9.D. (Cont'd)

10. All individuals who are associated with the operation of an x-ray system are subject to the requirements of RH-1200.

A. When protective clothing or devices are worn on portions of the body and a monitoring device(s) is required, at least one such monitoring device shall be utilized as follows:

i. When an apron is worn, the monitoring device shall be worn at the collar outside of the apron.

ii. The dose to the whole body based on the maximum dose attributed to the most critical organ shall be recorded in the reports required by Part F of Section 3. If more than one device is used and a record is made of the data, each dose shall be identified with the area where the device was worn on the body.

B. Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited.

11. **Healing arts screening**.

Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the Department. When requesting such approval, that person shall submit the information as deemed necessary by the Department. If any information submitted to the Department becomes invalid or out-dated, the Department will be notified in writing within thirty (30) days.

12. **Information and maintenance record and associated information**.

The registrant shall maintain the following information for each x-ray system for inspection by the Department:

A. Maximum rating of technique factors;

B. Model and serial numbers of all certifiable components;

C. Aluminum equivalent filtration of the useful beam, including any routine variation;

D. Tube rating charts and cooling curves;

RH-1602.a. (Cont'd)

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E. Records of surveys, calibrations, maintenance and modifications performed on the X-ray system(s) after July 1, 1983 with the names of persons who performed such services;

F. A scale drawing of the room in which a stationary x-ray system is located with such drawing indicating the use of areas adjacent to the room and an estimation of the extent of occupancy by an individual in such areas. In addition, the drawing shall include:

i. The results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions; or

ii. The type and thickness of materials or lead equivalency, of each protective barrier; and

G. A copy of all correspondence with the Department regarding that x-ray system.

13. **X-ray log.**

Each facility shall maintain an x-ray log containing the patient I.D., the type of examinations and the dates the examinations were performed. When the patient or film must be provided with human auxiliary support, the name of the human holder shall be recorded.

b. **General requirements for all diagnostic x-ray systems.**

In addition to other requirements of this Part, all diagnostic x-ray systems shall meet the following requirements:

1. **Warning label.**

The control panel containing the main power switch shall bear the warning statement or its equivalent, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

RH-1602. (Cont'd)

2. **Battery charge indicator.**

On battery-powered x-ray generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

3. **Leakage radiation from the diagnostic source assembly.**

The leakage radiation from the diagnostic source assembly measured at a distance of one (1) meter in any direction from the source shall not exceed 100 milliroentgens in one (1) hour when the x-ray tube is operated at its leakage technique factors. Compliance shall be determined

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by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

4. **Radiation from components other than the diagnostic source assembly.**

The radiation emitted by a component other than the diagnostic source assembly shall not exceed two (2) milliroentgens in one (1) hour at five (5) centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than twenty (20) centimeters.

5. **Beam quality.**

A. **Half-value layer.**

i. The half-value layer of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table I to RH-1602. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made.

RH-1602.b. (Cont'd)

TABLE I TO RH-1602.

Design Operating Range (Kilovolts peak)	Measured Potential (Kilovolts peak)	Half-value Layer (millimeters of aluminum)
----Below 50----	30	0.3
	40	0.4
	49	0.5
----50 to 70----	50	1.2
	60	1.3
	70	1.5
----Above 70----	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

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ii. The requirements of RH-1602.b.5.A.i. will be considered to have been met if it can be demonstrated that the aluminum equivalent of the total filtration in the primary beam is not less than that shown in Table II to RH-1602.

RH-1602.b.5.A. (Cont'd)

TABLE II TO RH-1602.

Filtration Required vs. Operating Voltage	
Operating Voltage (kVp)	**Total Filtration (inherent plus added) (millimeters aluminum equivalent)**
Below 50	0.5
50 to 70	1.5
Above 70	2.5

iii. Beryllium window tubes shall have a minimum of 0.5 millimeter aluminum equivalent filtration permanently installed in the useful beam.

iv. For capacitor energy storage equipment, compliance with the requirements of RH-1602.b.5. shall be determined with the maximum quantity of charge per exposure.

v. The required minimal aluminum equivalent filtration shall include the filtration contributed by all materials which are always present between the source and the patient.

B. **Filtration controls**.

For x-ray systems which have variable kVp and variable filtration for the useful beam, a device shall link the kVp selector with the filter(s) and shall prevent an exposure unless the minimum amount of filtration required by RH-1602.b.5.A.i. or ii. is in the useful beam for the given kVp which has been selected.

6. **Multiple tubes**.

Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control panel and at or near the tube housing assembly which has been selected.

RH-1602.b. (Cont'd)

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7. **Mechanical support of tube head.**

The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the x-ray system.

c. **Other requirements**.

1. Pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from boxes, and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.

2. The darkroom shall be light tight and use proper safelighting such that any film type in use exposed in a cassette to x-radiation sufficient to produce an optical density for one (1) to two (2) when processed shall not suffer an increase in density greater than 0.1 (0.05 mammography) when exposed in the darkroom for two (2) minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film.

3. Darkrooms typically used by more than one individual shall be provided a method to prevent accidental entry while undeveloped films are being handled or processed.

4. Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.

5. Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary to best assure radiographs of good diagnostic quality.

6. Outdated x-ray film shall not be used for diagnostic radiographs, unless the film has been stored in accordance with manufacturer's recommendations and a sample of the film passes a sensitometric test for normal ranges of base plus fog and speed.

7. Film developing solutions shall be prepared in accordance with the directions given by the manufacturer, and shall be maintained in strength by replenishment or renewal so that full development is accomplished within the time specified by the manufacturer.

A. The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated. The requirement may be permanent markings on

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equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

B. The requirement may be permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

8. **Maintaining Compliance**.

Diagnostic x-ray systems and their associated components used on humans and certified pursuant to the Federal X-Ray Equipment Performance Standard (21 CFR Part 1020) shall be maintained in compliance with applicable requirements of that standard.

9. **Locks.**

All position locking, holding, and centering devices on x-ray system components and systems shall function as intended.

RH-1603. **Fluoroscopic X-Ray Systems**.

All fluoroscopic x-ray systems shall meet the following requirements:

a. **Limitation of useful beam**.

1. **Primary barrier**.

A. The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any Source Image Distance (SID). RH-1603.a.1. (Cont'd)

A. The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam.

2. **Fluoroscopic beam limitation**.

A. For certified fluoroscopic systems with or without a spot film device, neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than three percent (3%) of the SID. The sum of the excess length and the excess width shall be no greater than four percent (4%) of the SID.

B. For uncertified fluoroscopic systems with a spot film device, the x-ray beam with the shutter fully opened (during fluoroscopy or spot filming) shall be no larger than the largest spot film size for which the device is designed. Measurements shall be made at the maximum SID available but at no less than twenty (20) centimeters from the tabletop to the film plane distance.

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C. For uncertified fluoroscopic systems without a spot film device, the requirements of RH-1603. apply.

D. **Other requirements for fluoroscopic beam limitation**:

i. Means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID or a visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the x-ray field;

ii. All equipment with a fixed SID and a visible area of 300 square centimeters or less shall be provided either with stepless adjustment of the x-ray field or with means to further limit the x-ray field size at the plane of the image receptor to 125 square centimeters or less;

RH-1603.a.2.D. (Cont'd)

iii. If provided, stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum attainable to a field size of five (5) centimeters by five (5) centimeters or less;

iv. For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor;

v. For noncircular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

3. **Spot-film beam limitation**.

Spot-film devices shall meet the following requirements:

A. Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the film to the size of that portion of the film which has been selected on the spot film automatically accomplished except when the x-ray field size in the plane of the film is smaller than that of the selected portion of the film. For spot-film devices manufactured after June 21, 1979, if the x-ray field size is less than the size of the selected portion of the film, the means for adjustment of the field size shall be only at the operator's option;

B. Neither the length nor the width of the x-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than three percent (3%) of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed four percent (4%) of the SID;

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~~RH-1603.a.3. (Cont'd)~~

~~C. It shall be possible to adjust the x-ray field size in the plane of the film to a size smaller than the selected portion of the film. The minimum field size at the greatest SID shall be equal to, or less than, five (5) centimeters by five (5) centimeters;~~

~~D. The center of the x-ray field in the plane of the film shall be aligned with the center of the selected portion of the film to within two percent (2%) of the SID; and~~

~~E. On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.~~

~~4. **Override.**~~

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~~If a means exists to override any of the automatic x-ray field size adjustments required, that means:~~

~~A. Shall be designed for use only in the event of system failure;~~

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~~B. Shall incorporate a signal visible at the fluoroscopist's position which will indicate whenever the automatic field size adjustment is overridden; and~~

~~C. Shall have a clear and durable label as follows:~~

~~i. For x-ray fields.~~

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~~ii. Limitation system failure.~~

~~iii. Activation of the fluoroscopic tube.~~

~~RH-1603.a.4.C. (Cont'd)~~

iv. X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the fluoroscopist for the entire time of any exposure. When recording serial fluoroscopic images, the fluoroscopist shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

b. **Exposure rate limits**.

1. **Entrance exposure rate allowable limits**.

A. Fluoroscopic equipment that is provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of ten (10) roentgens (2.6 mC/kg) per minute at the point where the center of the useful beam enters the patient, except:

i. During recording of fluoroscopic images; or

ii. When an optional high level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of five (5) roentgens (1.3 mC/kg) per minute at the point where the center of the useful beam enters the patient unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

RH-1603.b.1. (Cont'd)

B. Fluoroscopic equipment which is not provided with automatic exposure rate control shall not be operable at any combination of tube potential and current which will result in an exposure rate in excess of five (5) roentgens (1.3 mC/kg) per minute at the point where the center of the useful beam enters the patient, except:

i. During recording of fluoroscopic images; or

ii. When the mode or modes have an optional high level control, in which case the mode or modes shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of 5 roentgens (1.3 mC/kg) per minute at the point where the center of the useful beam enters the patient, unless the high level control is activated. Special means of activation of high level controls shall be required. The high level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high level control is being employed.

C. Compliance with the requirements of RH-1603. shall be determined as follows:

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i. Movable grids and compression devices shall be removed from the useful beam during the measurement;

ii. If the source is below the table, exposure rate shall be measured one (1) centimeter above the table top or cradle;

iii. If the source is above the table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement;

RH-1603.b.1.C. (Cont'd)

iv. All C-arm fluoroscopes, both stationary and mobile, shall meet the entrance exposure rate limits at 30 centimeters from the input surface of the fluoroscopic imaging assembly with the source positioned at any available SID provided that the end of the spacer assembly or beam-limiting device is not closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly.

v. For a lateral type fluoroscope, the exposure rate shall be measured at a point 15 centimeters from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters to the centerline of the x-ray table.

D. Fluoroscopic equipment which is provided with both automatic exposure rate control mode and a manual mode shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of ten (10) roentgens (2.6 mC/kg) per minute in either mode at the point where the center of the useful beam enters the patient, except:

i. During recording of fluoroscopic images; or

ii. When the mode or modes have an optional high-level control, in which case the mode or modes shall not be operable at any combination of tube potential and current which shall result in an exposure rate in excess of five (5) roentgens (1.3 mC/kg) per minute at the point where the center of the useful beam enters the patient, unless the high-level control is activated. Special means of activation of high-level controls shall be required. The high-level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

RH-1603.b.1. (Cont'd)

E. Any fluoroscopic equipment manufactured after May 19, 1995, which can exceed five (5) roentgens (1.3 mC/kg) per minute shall be equipped with an automatic exposure rate control. All entrance exposure rate limits shall be ten (10) roentgens (2.6 mC/kg) per minute with an upper limit of 20 roentgens (5.2 mC/kg) per minute when the high-level control is activated.

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F. Conditions of periodic measurement of maximum entrance exposure rate are as follows:

i. The measurement shall be made under the conditions that satisfy the requirements;

ii. The kVp, mA, or other selectable parameters shall be adjusted to those settings which give the maximum entrance exposure rate;

iii. The x-ray system(s) that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce either a milliamperage or kilovoltage or both to satisfy the conditions of RH-1603.

e. **Barrier transmitted radiation rate limits**.

1. The exposure rate due to transmission through the primary protective barrier with the attenuation block in the useful beam, combined with radiation from the image intensifier, if provided, shall not exceed two (2) milliroentgens (0.516 μC/kg) per hour at ten (10) centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor for each roentgen per minute of entrance exposure rate.

2. **Measuring compliance of barrier transmission**.

A. The exposure rate due to transmission through the primary protective barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

RH-1603.e.2. (Cont'd)

B. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop.

C. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters.

D. Movable grids and compression devices shall be removed from the useful beam during the measurement.

3. **Indication of potential and current**.

During fluoroscopy and cinefluorography, the kV and the mA shall be continuously indicated.

d. **Source-to-skin distance**.

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~~The SSD shall not be less than:~~

~~1. 38 centimeters on stationary fluoroscopes installed on or after August 1, 1974;~~

~~2. 35.5 centimeters on stationary fluoroscopes which were in operation prior to August 1, 1974; 30 centimeters on all mobile fluoroscopes;~~

~~3. 20 centimeters for mobile fluoroscopes used for specific surgical application;~~

~~4. The written safety procedures must provide precautionary measures to be adhered to during the use of this device in addition to the procedures provided in RH-1603.~~

~~e. **Fluoroscopic timer**.~~

~~1. Means shall be provided to preset the cumulative on-time of the fluoroscopic x-ray tube. The maximum cumulative time of the timing device shall not exceed five (5) minutes without resetting.~~

~~RH-1603.e. (Cont'd)~~

~~2. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x-rays are produced until the timing device is reset.~~

~~f. **Control of scattered radiation**.~~

~~1. Fluoroscopic table designs when combined with procedures utilized shall be such that no unprotected part of any staff or ancillary individual's body shall be exposed to un-attenuated scattered radiation which originates from under the table. The attenuation required shall be not less than 0.25 millimeter lead equivalent.~~

~~2. Equipment configuration when combined with procedures shall be such that no portion of any staff or ancillary individual's body, except the extremities, shall be exposed to the un-attenuated scattered radiation emanating from above the tabletop unless that individual:~~

~~A. Is at least 120 centimeters from the center of the useful beam, or~~

~~B. The radiation has passed through not less than 0.25 millimeter lead equivalent material including, but not limited to, drapes, Bucky-slot cover panel, or self-supporting curtains, in addition to any lead equivalency provided by the protective apron referred to in RH-1603.~~

~~3. The Department may grant exemptions where a sterile field will not permit the use of the normal protective barriers. Where the use of prefitted sterilized covers for the barriers is practical, the Department shall not permit such exemption.~~

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~~RH-1603. (Cont'd)~~

~~g. **Spot-film exposure reproducibility.**~~

~~Fluoroscopic systems equipped with spot-film (radiographic) mode shall meet the exposure reproducibility requirements when operating in the spot-film mode.~~

~~1. Radiation therapy simulation systems shall be exempt from all the requirements provided that:~~

~~A. Such systems are designed and used in such a manner that no individual other than the patient is in the x-ray room during periods of time when the system is producing x-rays; and~~

~~B. Systems which do not meet the requirements are provided with a means of indicating the cumulative time that an individual patient has been exposed to x-rays. Procedures shall require in such cases that the timer be reset between examinations.~~

~~h. **Special procedures estimated patient exposure documentation.**~~

~~1. Each facility using fluoroscopic equipment for procedures including, but not limited to:~~

~~A. Pacemaker implantation;~~

~~B. Diagnostic cardiac procedures (catheterization); and~~

~~C. Therapeutic cardiac procedures:~~

~~i. Angioplasty balloon;~~

~~ii. Stent;~~

~~iii. Directional coronary atherectomy;~~

~~D. Radio frequency ablation;~~

~~E. Intravascular brachytherapy;~~

~~F. All neurointerventional procedures including:~~

~~i. Embolizations;~~

~~RH-1603.h.1.F. (Cont'd)~~

~~ii. Interventional radiology procedures such as:~~

~~(a). TIPS;~~

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(b). Vascular embolizations;

(c). Stents; and

(d). Angioplasty;

G. Infusion drug procedures:

i. Complex biliary cases;

ii. Complex gastrointestinal cases; and

iii. Complex genitourinary procedures.

shall include in a log for Department review the estimated patient radiation exposure received per procedure. Estimated adult skin doses that exceed 300 rad and estimated skin doses for children (under the age of 18) that exceed 100 rad must be reviewed by the facility's radiation safety committee.

The review must document the reason why an estimated skin dose exceeded 300 rad for adults or 100 rad for children, and the reason must be documented in the committee's minutes. If a facility does not have a radiation safety committee, the facility must provide the Department, within thirty (30) days of the event, documentation stating why the patient's estimated dose exceeded 300 rad for adults or 100 rad for children.

i. **Equipment operation**.

1. All imaging formed by the use of fluoroscopic x-ray systems shall be directly viewed and interpreted by a licensed practitioner of the healing arts.

2. Overhead fluoroscopy shall not be used as a positioning tool for general purpose radiographic examinations.

RH-1603.i. (Cont'd)

3. Facilities that use fluoroscopic x-ray systems shall maintain a record of cumulative fluoroscopic exposure time used and the number of spot films for each examination. This record shall indicate patient identification, type of examination, date of examination, and operator's name.

j. **Periodic measurements**.

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1. Periodic measurement of entrance exposure rate shall be performed by a qualified expert for both typical and maximum values as follows:

A. Such measurements shall be made annually or after any maintenance of the system which might affect the exposure rate.

B. Results of these measurements shall be available where any fluoroscopist may have ready access to such results while using the fluoroscope. The measurement results shall be stated in coulombs per kilogram or mR/hr and include the technique factors used in measurements. The date the measurements were performed shall also be included in the results.

C. Conditions of periodic measurement of typical entrance exposure rate are as follows:

i. The measurement shall be made under the conditions that satisfy the requirements;

ii. The kVp, mA, and/or other selectable parameters shall be adjusted to those settings typical of clinical use on a 23 cm thick abdominal patient;

iii. The x-ray system that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce a milliamperage and/or kilovoltage to satisfy the conditions.

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D. Conditions of periodic measurement of maximum entrance exposure rate are as follows:

i. The measurements shall be made under the conditions that satisfy the requirements;

ii. The kVp, mA and/or other selectable parameters shall be adjusted to those settings which give the maximum entrance exposure rate;

iii. The x-ray system(s) that incorporates automatic exposure rate control shall have sufficient attenuative material placed in the useful beam to produce the maximum entrance exposure rate of the system.

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RH-1604. **Radiographic Systems Other than Fluoroscopic, Dental Intraoral, Veterinarian, or Computed Tomography Systems**.

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a. **Beam limitation**.

1. The useful beam shall be limited to the area of clinical interest. This shall be considered met if a positive beam-limiting device meeting manufacturer's specifications has been properly used or if evidence of collimation is shown on at least three sides or three corners of the film (for example, projections from the shutters of the collimator, cone cutting at the corners, or borders at the film's edge.)

2. **General purpose stationary and mobile x-ray systems and veterinarian systems (other than portable) installed after July 1, 1998**.

A. Only x-ray systems provided with means for independent stepless adjustment of at least two (2) dimensions of the x-ray field shall be used.

B. A method shall be provided for visually defining the perimeter of the x-ray field.

i. Illuminance shall be greater than 7.5 foot-candles or 80.3 LUX at 100 centimeters or maximum SID whichever is less.

ii. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed two percent (2%) of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

iii. The Department may grant an exemption on non-certified x-ray provided the registrant makes a written application for such exemption and in that application demonstrates it is impractical to comply and the purpose will be met by other methods.

3. **Additional requirements for stationary general purpose x-ray systems.**

In addition to the requirements for stationary general purpose x-ray systems, both certified and non-certified systems shall also meet the following requirements:

A. Method shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within two percent (2%) of the SID, and to indicate the SID to within two percent (2%);

B. The beam-limiting device shall indicate numerically the field size in the plane of the image receptor to which it is adjusted; and

C. Indication of field size dimensions and SIDs shall be specified in inches or centimeters, and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within two percent (2%) of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor.

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4. Reserved.

RH-1604.a. (Cont'd)

5. **X-ray systems designed for one (1) image receptor size**.

Radiographic equipment designed for only one (1) image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within two percent (2%) of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

6. **Other x-ray systems and veterinary systems installed prior to July 1, 1998, and all portable veterinary x-ray systems**.

A. Means shall be provided to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than two percent (2%) of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

B. Means shall be provided to align the center of the x-ray field with the center of the image receptor to within two percent (2%) of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. Compliance shall be determined with the axis of the x-ray beam perpendicular to the plane of the image receptor.

C. Alignment requirements may be met with either:

i. An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed with each such device having clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

RH-1604.a.6.C. (Cont'd)

ii. A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

b. **Radiation exposure control devices.**

1. **Timers.**

A. Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action.

B. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition, it shall not be possible to make an exposure when the timer is set to a "**zero**" or "**off**" position if either position is provided. Except for dental panoramic systems, termination of an exposure shall cause automatic resetting of the timer to its initial setting or to "**zero**."

2. **X-ray control. Manual exposure control.**

A. An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time except for exposure of one-half second or less, or during serial radiography when means shall be provided to permit completion of any single exposure of the series in process.

RH-1604.b.2. (Cont'd)

B. Each x-ray control shall be located in such a way as to meet the following requirements:

i. Stationary x-ray systems (except dental, podiatry and veterinary units) shall be required to have the x-ray exposure switch permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure and so that the operator can view the patient while making any exposures;

ii. Mobile and portable x-ray systems which are:

(a.) Used for greater than one (1) week in the same location, i.e., a room or suite; or

(b). Used for greater than one (1) hour and less than one (1) week at the same location, i.e., a room or suite; or

(c). In a clinical setting for routine extremities only, or where moving the x-ray system from room to room is impractical;

(d). Shall meet the requirement of the above paragraph RH-1604.b.2.B.i., or one of the following must be met.

(1). Equipment installed or relocated after January 1, 2006 is placed at least nine (9) feet (2.7 meters) from the tube housing assembly.

(2). Equipment installed before January 1, 2006 is placed at least six (6) feet (1.8 meters) from the tube housing assembly.

C. Written procedures must instruct the operator to remain in the protected area during the entire exposure.

RH-1604.b.2.C. (Cont'd)

iii. (a). Stationary podiatric systems installed or relocated after January 1, 2006, which do not meet the above requirements, shall be

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provided with a nine (9) foot exposure button cord which allows the operator to remain behind a protective barrier during the entire exposure.

(b). Stationary podiatric systems installed before January 1, 2006, which do not meet the above requirements, shall be provided with a six (6) foot exposure button which allows the operator to remain behind a protective barrier during the entire exposure.

(c). If the protective barrier is moveable, written procedures must be on file at the facility, which dictate that the operator will remain behind the barrier during the entire exposure.

C. The x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

3. **Automatic exposure controls**.

When an automatic exposure control is provided:

A. Indication shall be made on the control panel when this mode of operation is selected;

B. If the x-ray tube potential is equal to or greater than 50 kVp, the minimum exposure time for field emission equipment rated for pulsed operation shall be equal to or less than a time interval equivalent to two (2) pulses;

C. The minimum exposure time for all equipment shall be equal to or less than one-sixtieth second or a time interval required to deliver five (5) mAs, whichever is greater;

RH-1604.b.3. (Cont'd)

D. Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kWs per exposure, or the product of x-ray tube current and exposure

time shall be limited to not more than 600 mAs per exposure except that, when the x-ray tube potential is less than 50 kVp, the product of x-ray tube current and exposure time shall be limited to not more than 2000 mAs per exposure; and

E. A visible signal shall indicate when an exposure has been terminated, and manual resetting shall be required before further automatically timed exposures can be made.

4. **Reproducibility**.

With a timer setting of 0.5 seconds or less, the average exposure period (T) shall be greater than or equal to five (5) times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when four timer tests are performed:

$$T > 5\,(T_{max} - T_{min})$$

5. **Exposure duration (timer) linearity**.

For systems having independent selection of exposure time settings, the average ratios (X_1) of exposure to the indicated timer setting, in units of C $kg^{-1}s^{-1}$ (mR/s), obtained at any two clinically used timer settings shall not differ by more than 0.10 times their sum. This is written as:

$$(X_1 - X_2) < 0.1\,(X_1 + X_2)$$

where X_1 and X_2 are the average C $kg^{-1}s^{-1}$ (mR/s) values.

e. **Source-to-skin distance**.

All mobile or portable radiographic systems shall be provided with means to limit the source-to-skin distance to equal to or greater than thirty (30) centimeters except for veterinary systems.

RH-1604. (Cont'd)

d. **Exposure reproducibility**.

When all technique factors are held constant, including control panel selections associated with automatic exposure control systems, the coefficient of variation of exposure for both manual and automatic exposure control systems shall not exceed 0.05. This requirement applies to clinically used techniques.

e. **Radiation from capacitor energy storage equipment in standby status**.

Radiation emitted from the x-ray tube when the system is fully charged and the exposure switch or timer is not activated shall not exceed a rate of two (2) milliroentgens (0.516 μC/kg) per hour at five (5) centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open.

f. **Accuracy**.

Deviation of measured technique factors from indicated values of kVp and exposure time shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed ten percent (10%) of the indicated value for kVp and twenty percent (20%) for time mA/mAs linearity.

g. The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of forty percent (40%) to one hundred percent (100%) of the maximum rated:

1. **Equipment having independent selection of x-ray tube current (mA).**

The average ratios (X_1) of exposure to the indicated milliampere-seconds product ($C\ kg^{-1}mAs^{-1}$ (or mR/mAs)) obtained at any two (2) consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 < 0.10\ (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at each of two (2) consecutive tube current settings, or at two settings differing by no more than a factor of two (2) where the tube current selection is continuous.

RH-1604.g. (Cont'd)

2. **Equipment having a combined x-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector.**

The average ratios (X_1) of exposure to the indicated milliampere-seconds product, in units of mR/mAs (or C kg^{-1}mAs^{-1}), obtained at any two consecutive mAs selector settings shall not differ by more than 0.10 times their sum:

$$X_1 - X_2 < 0.10 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at any two (2) consecutive mAs selector settings, or at two (2) settings differing by no more than a factor of two (2) where the mAs selector provides continuous selection.

3. **Measuring compliance.**

Determination of compliance shall be based on ten (10) exposures taken within a time period of one (1) hour, at each of the two (2) settings. These two (2) settings may include any two focal spot sizes except where one is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the x-ray tube manufacturer.

h. **Additional requirements applicable to certified systems only.**

Diagnostic x-ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirement(s) which relate to that certified component(s).

i. **Beam limitation for stationary and mobile general purpose x-ray systems.**

1. There shall be provided a means of stepless adjustment of the x-ray field. The minimum field size at an SID of 100 centimeters shall be equal to or less than five (5) centimeters by five (5) centimeters.

RH-1604.i. (Cont'd)

2. When a light localizer is used to define the x-ray field, it shall provide an average illumination of not less than 160 lux or 15 foot-candles at 100 centimeters or at the maximum SID, whichever is less. The average illumination shall be based upon measurements made in the approximate center of each quadrant of the light field.

Radiation therapy simulation systems manufactured on and after May 27, 1980, are exempt from this requirement.

3. The edge of the light field at 100 centimeters or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than four (4) in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than three (3) in the case of beam-limiting devices designed for use on mobile equipment. The contrast ratio is defined as I_1/I_2 where I_1 is the illumination three (3) millimeters from the edge of the light field toward the center of the field; and I_2 is the illumination three (3) millimeters from the edge of the light field away from the center of the field.

4. Compliance shall be determined with a measuring instrument aperture of one (1) millimeter in diameter.

j. **Beam limitation and alignment on stationary general purpose x-ray systems equipped with Positive Beam Limitation (PBL).**

If PBL is being used, the following requirements shall be met:

1. PBL shall prevent the production of x-rays when:

A. Either the length or width of the x-ray field in the plane of the image receptor differs from the corresponding image receptor dimensions by more than three percent (3%) of the SID; or

B. The sum of the length and width differences, without regard to sign exceeds four percent (4%) of the SID;

C. Compliance shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor. Compliance shall be determined no sooner than five (5) seconds after insertion of the image receptor;

RH-1604.j.1. (Cont'd)

D. The PBL system shall be capable of operation, at the discretion of the operator, such that the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. The minimum

field size at an SID of 100 centimeters shall be equal to or less than five (5) centimeters by five (5) centimeters;

E. The PBL system shall be designed such that if a change in image receptor does not cause an automatic return to PBL function, then any change of image receptor size or SID must cause the automatic return.

2. **Beam limitation for portable x-ray systems**.

Beam limitation for portable x-ray systems shall meet the beam limitation requirements.

3. **Tube stands for portable x-ray systems**.

A tube stand or other mechanical support shall be used for portable x-ray systems, so that the x-ray tube housing assembly need not be handheld during exposures.

k. Systems used in a clinical (non-surgical) setting shall be restricted to one room within a location or suite which meets the requirements.

RH-1605. Reserved.

RH-1606. **Intraoral Dental Radiographic Systems**.

The requirements for general x-ray tubes apply to the intraoral dental machines.

a. **Source-to-skin distance**.

X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance to not less than:

1. 18 centimeters if operable above 50 kVp, or

2. 10 centimeters if not operable above 50 kVp.

RH-1606. (Cont'd)

b. **Beam limitation**.

Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the X-ray beam such that:

1. If the minimum source-to-skin distance (SSD) is 18 centimeters or more, the x-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than seven (7) centimeters; and

2. If the minimum SSD is less than 18 centimeters, the x-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than six (6) centimeters.

3. The position indicating device shall be shielded and open-ended. The shielding shall be equivalent to the requirements.

c. **Exposure control. Exposure initiation**.

A. Means shall be provided to initiate the radiation exposure by deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action; and

B. It shall not be possible to make an exposure when the timer is set to a "**zero**" or "**off**" position if either position is provided.

d. **Exposure indication**.

Means shall be provided for visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated except in x-ray systems that cannot be altered to meet this requirement.

e. **Exposure termination**.

1. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition:

A. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to "**zero**."

RH-1606.e.1. (Cont'd)

B. An x-ray control shall be incorporated into each x-ray system such that an exposure can be terminated by the operator at any time, except for exposures of one-half (½) second or less.

2. **Exposure duration (timer) linearity.**

For systems having independent selection of exposure time settings, the average ratios (X_1) of exposure to the indicated timer setting, in units of C $kg^{-1}s^{-1}$ (mR/s), obtained at any two clinically used timer settings shall not differ by more than 0.10 times their sum. This is written as:

$$(X_1 - X_2) < 0.1\ (X_1 + X_2)$$

where X_1 and X_2 are the average values.

3. Each x-ray exposure switch shall be located in such a way as to meet the following requirements:

A. Stationary x-ray systems shall be required to have the x-ray exposure switch located in a protected area or have an exposure switch cord of sufficient length to permit the operator to activate the unit while in a protected area, e.g., corridor outside the operatory. The procedures must instruct the operator to remain in the protected area during the entire exposure.

B. Mobile and portable x-ray systems which are:

i. Used for greater than one (1) week in the same location, i.e., a room or suite, shall meet the other requirements.

RH-1606.e.3.B. (Cont'd)

ii. Used for greater than one (1) hour and less than one (1) week at the same location, i.e., a room or suite, shall meet the requirements of the above paragraph or be provided with a 6.5 foot (1.98 meters) high protective barrier or means to allow the operator to be at least nine (9) feet (2.7 meters) from the tube housing assembly while making exposure if the equipment has been installed or relocated after January 1, 2006.

For equipment installed before January 1, 2006, there must exist a means to allow the operator to be at least six (6) feet (1.8 meters) from the tube housing assembly while making exposure.

4. **Reproducibility**.

When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific combination of selected technique factors.

f. **mA/mS linearity**.

The following requirements apply when the equipment is operated on a power supply as specified by the manufacturer for any fixed x-ray tube potential within the range of forty percent (40%) to one hundred percent (100%) of the maximum rated:

1. Equipment having independent selection of x-ray tube current (mA). The average ratios (X_1) of exposure to the indicated milliampere-seconds product, in units of C $kg^{-1}mAs^{-1}$ (or mR/mAs), obtained at any two (2) consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$(X_1 - X_2) \leq 0.1 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at each of two (2) consecutive tube current settings, or at two settings differing by no more than a factor of two (2) where the tube current selection is continuous.

2. Equipment having a combined x-ray tube current-exposure time product (mAs) selector, but not a separate tube current (mA) selector. The average ratios (X_1) of exposure to the indicated milliampere-seconds product, in units of C $kg^{-1}mAs^{-1}$ (or mR/mAs), obtained at any two (2) consecutive mAs selector settings shall not differ by more than 0.10 times their sum:

$$(X_1 - X_2) \leq 0.1 (X_1 + X_2)$$

where X_1 and X_2 are the average values obtained at any two (2) mAs selector settings, or at two (2) settings differing by no more than a factor of two (2) where the mAs selector provides continuous selection.

3. **Measuring compliance.**

Determination of compliance shall be based on ten (10) exposures taken within a time period of one (1) hour, at each of the two (2) settings. These two (2) settings may include any two (2) focal spot sizes except where one (1) is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the nominal focal spot size specified by the x-ray tube manufacturer.

g. **Accuracy**.

Deviation of technique factors from indicated values for kVp and exposure time (if time is independently selectable) shall not exceed the limits specified for that system by its manufacturer. In the absence of manufacturer's specifications, the deviation shall not exceed ten percent (10%).

h. **kVp limitations**.

Dental x-ray machine with a nominal fixed kVp of less than 50 kVp shall not be used to make diagnostic dental radiographs of humans.

i. **Administrative controls**.

1. Patient and film holding devices shall be used when the techniques permit.

2. The tube housing and the Patient Imaging Device (PID) shall not be hand-held during an exposure.

RH-1606.i. (Cont'd)

3. The x-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements.

4. Dental fluoroscopy without image intensification shall not be used.

NOTE: In many cases structural materials of ordinary walls suffice as a protective barrier without addition of special shielding material.

RH-1607. 1608. Deleted. See Section 11, "Therapeutic Radiation Machines."

Commented [AO58]: RH-1607-1609 Deleted. See Section 11, "Therapeutic Radiation Machines."

RH-1609. **Veterinary Medicine**.

a. **Equipment.**

1. The protective tube housing shall be equivalent to general x-ray tube.

2. Diaphragms or cones shall be provided for collimating the useful beam to the area of clinical interest and shall provide the same degree of protection as is required of the housing.

3. The total filtration permanently in the useful beam shall not be less than 0.5 millimeters aluminum equivalent for machines operating up to 50 kVp, 1.5 millimeters aluminum equivalent for machines operating between 50 and 70kVp, and 2.5 millimeters aluminum equivalent for machines operating above 70 kVp.

b. **Operator protection.**

All wall, ceiling, and floor areas shall be equivalent or provided with applicable protective barriers. Stationary, mobile or portable x-ray systems shall be provided with either a two (2) meter (6.5 feet) high protective barrier for operator protections during exposures, or shall be provided with means to allow the operator to be at least 2.7 meters (9 feet) from the tube housing assembly during exposures if the equipment has been installed or relocated after January 1, 2006.

For equipment installed before January 1, 2006, there must exist a means to allow the operator to be at least six (6) feet (1.8 meters) from the tube housing assembly during exposures.

RH-1609. (Cont'd)

c. **Operating procedures.**

1. No individual other than the operator shall be in the x-ray room while exposures are being made unless such individual's assistance is required, and

2. The operator shall stand behind the protective barrier of nine (9) feet from the useful beam and the animal during radiographic exposures, or

3. When an animal must be held in position during radiography, mechanical supporting or restraining devices should be used. If the animal must be held by an individual, that individual shall be protected with appropriate shielding devices, such as protective gloves and apron, and shall be so positioned that no part of the

holder's body will be struck by the useful beam. The exposure of any individual used for this purpose shall be monitored.

RH-1610. **Mammography Systems.**

a. **Definitions**.

Accreditation body or body - An entity that has been approved by FDA accredit mammography facilities.

Action limits or action levels - The minimum and maximum values of a quality assurance measurement that can be interpreted as representing acceptable performance with respect to the parameter being tested. Values less than the minimum or greater than the maximum action limit or level indicate that corrective action must be taken by the facility. Action limits or levels are also sometimes called control limits or levels.

Air kerma - Kerma in a given mass of air. The unit used to measure the quantity of air kerma is the Gray (Gy). For x-rays with energies less than 300 kiloelectronvolts (keV), 1 Gy = 100 rad. In air, 1 Gy of absorbed dose is delivered by 114 roentgens (R) of exposure.

Breast implant - A prosthetic device implanted in the breast.

Calendar quarter - Any one of the following time periods during a given year: January 1 through March 31, April 1 through June 30, July 1 through September 30, or October 1 through December 31.

RH-1610.a. (Cont'd)

Category I - Medical educational activities that have been designated as Category I by the Accreditation Council for Continuing Medical Education (ACCME), the American Osteopathic Association (AOA), a state medical society, or an equivalent organization.

Certificate - The certificate described in the "Mammography Quality Standards Act," Subchapter I to Title 21 of the Code of Federal Regulations, paragraph (a) of Section 900.11.

Certification - The process of approval of a facility by FDA to provide mammography services.

Clinical image - A mammogram.

Commented [AO59]: RH-1610 - Changed and moved to RH-9310.m. 21 CFR Part 900.12 (d)(iii) of the FDA's "Mammography Quality Standards Act." All systems designed for mammography shall comply with the Mammography Quality Standards Act of 1994, 42 USC 263b, as in effect on January 1, 2025

Consumer - An individual who chooses to comment or complain in reference to a mammography examination, including the patient or representative of the patient (e.g., family member or referring physician).

Continuing education unit or continuing education credit - One (1) contact hour of training.

Contact hour - An hour of training received through direct instruction.

Diagnostic Mammography - A problem solving radiographic procedure of higher intensity than screening mammography provided to women who are suspected to have breast pathology. Patients are usually referred for analyses of palpable abnormalities or for further evaluation of mammographically detected abnormalities. All images are immediately reviewed by the physicians interpreting the study, and additional views are obtained as needed. Physical examinations of the breast by the interpreting physician to correlate the radiologic findings is often performed as part of the study.

Direct instruction - Face-to-face interaction between instructor(s) and student(s), as when the instructor provides a lecture, conducts demonstrations, or reviews student performance; or the administration and correction of student examinations by an instructor(s) with subsequent feedback to the student(s).

Direct Supervision of Interpreting Physicians - During joint interpretation of mammograms, the supervising interpreting physician reviews, discusses, and confirms the diagnosis of the physician being supervised and signs the resulting report before it is entered into the patient's records.

RH-1610.a. (Cont'd)

Direct Supervision of Radiologic Technologists - During the performance of a mammography examination or survey of the facility's equipment and quality assurance program, the supervisor is present to observe and correct, as needed, the performance of the individual being supervised who is performing the examination or conducting the survey.

Established operating level - The value of a particular quality assurance parameter that has been established as an acceptable normal level by the facility's quality assurance program.

Facility - A hospital, outpatient department, clinic, radiology practice, mobile unit, office of a physician, or other facility that conducts mammography activities, including the following: operation of equipment to produce a mammogram, processing of the mammogram, initial

interpretation of the mammogram, and maintaining viewing conditions for the interpretation. This term does not include a facility of the Department of Veterans Affairs.

FDA - The Food and Drug Administration.

First allowable time - The earliest time a resident physician is eligible to take the diagnostic radiology boards from an FDA-designated certifying body. The "first allowable time" may vary with the certifying body.

Interim regulations - The regulations entitled "Requirements for Accrediting Bodies of Mammography Facilities" (58 FR 67558-67565), published by FDA on December 21, 1993, and amended on September 30, 1994 (59 FR 49808-49813). These regulations established the standards that had to be met by mammography facilities in order to lawfully operate between October 1, 1994, and April 28, 1999.

Interpreting physician - A licensed physician who interprets mammograms and who meets the requirements set forth in the "Mammography Quality Standards Act," Subchapter I to Title 21 of the Code of Federal Regulations, paragraph (a)(1) of Section 900.12.

Kerma - The sum of the initial energies of all the charged particles liberated by uncharged ionizing particles in a material of given mass.

Laterality - The designation of either the right or left breast.

RH-1610.a. (Cont'd)

Lead interpreting physician - The interpreting physician assigned the general responsibility for ensuring that a facility's quality assurance program meets all of the requirements in 21 CFR Part 16 and the "Mammography Quality Standards Act," Subchapter I to 21 CFR, paragraphs (d) through (f) of Section 900.12. The administrative title and other supervisory responsibilities of the individual, if any, are left to the discretion of the facility.

Mammogram - A radiographic image produced through mammography.

Mammographic modality - A technology, within the scope of 42 U.S.C. 263b, for radiography of the breast. Examples are screen-film mammography and digital mammography.

Mammography - Radiography of the breast, but for the purposes of this part, does not include: radiography of the breast performed during invasive interventions for localization or biopsy procedures; or radiography of the breast performed with an investigational mammography device as part of a scientific study conducted in accordance with FDA's investigational device exemption regulations.

Mammography equipment evaluation - An onsite assessment of mammography unit or image processor performance by a medical physicist for the purpose of making a preliminary determination as to whether the equipment meets all of the applicable standards set forth in the "Mammography Quality Standards Act," Subchapter I to Title 21 of the Code of Federal Regulations, paragraphs (b) and (e) of Section 900.12.

Mammography medical outcomes audit - A systematic collection of mammography results and the comparison of those results with outcomes data.

Mammography unit or units - An assemblage of components for the production of x-rays for use during mammography, including, at a minimum: an x-ray generator, and x-ray control, a tube housing assembly, a beam limiting device, and the supporting structures for these components.

Mean optical density - The average of the optical densities measured using phantom thickness of two (2), four (4), and six (6) centimeters with values of kilovolt peak (kVp) clinically appropriate for those thicknesses.

RH-1610.a. (Cont'd)

Medical physicist - A person trained in evaluating the performance of mammography equipment and facility quality assurance programs and who meets the qualifications for a medical physicist set forth in the "Mammography Quality Standards Act," Subchapter I to Title 21 of the Code of Federal Regulations, paragraph (a)(3) of Section 900.12.

MQSA - The Mammography Quality Standards Act.

Multi-reading - Two (2) or more physicians, at least one (1) of whom is an interpreting physician, interpreting the same mammogram.

Patient - Any individual who undergoes a mammography evaluation in a facility, regardless of whether the person is referred by a physician or is self-referred.

Phantom - A test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer.

Phantom image - A radiographic image of a phantom.

Physical science - Physics, chemistry, radiation science (including medical physics and health physics), and engineering.

Positive mammogram - A mammogram that has an overall assessment of findings that are either "suspicious" or "highly suggestive of malignancy."

Provisional certificate - The provisional certificate described in 21 CFR Section 900.11(b)(2).

Qualified instructor - An individual whose training and experience adequately prepares him or her to carry out specified training assignments. Interpreting physicians, radiologic technologists, or medical physicists who meet the requirements of 21 CFR Section 900.12(a) would be considered qualified instructors in their respective areas of mammography. Other examples of individuals who may be qualified instructors for the purpose of providing training to meet the regulations of this part include, but are not limited to, instructors in a post-high school training institution and manufacturer's representatives.

Quality control technologist - An individual meeting the requirements of 21 CFR Section 900.12(a)(2) who is responsible for those quality assurance responsibilities not assigned to the lead interpreting physician or to the medical physicist.

RH-1610.a. (Cont'd)

Radiographic equipment - X-ray equipment used for the production of static x-ray images.

Radiologic technologist - An individual specifically trained in the use of radiographic equipment and the positioning of patients for radiographic examinations and who meets the requirements set forth in 21 CFR Section 900.12(a)(2).

Review physician - A physician who, by meeting the requirements set out in 21 CFR Section 900.4(c)(5), is qualified to review clinical images on behalf of the accreditation body.

Screening mammography - Radiographic procedure provided to a woman, who has no signs or symptoms of breast cancer, for the purpose of

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~~early detection of breast cancer. The procedure entails two views of each breast and includes a physician's interpretation of the results of the procedure.~~

~~**Serious adverse event** - An adverse event that may significantly compromise clinical outcomes, or an adverse event for which a facility fails to take appropriate corrective action in a timely manner.~~

~~**Serious compliant** - A report of a serious adverse event.~~

~~**Standard breast** - A 4.2 centimeter (cm) thick compressed breast consisting of fifty percent (50%) glandular and fifty percent (50%) adipose tissue.~~

~~**Survey** - An on-site physics consultation and evaluation of a facility quality assurance program performed by a medical physicist.~~

~~**Time cycle** - The film development time.~~

~~**Traceable to a national standard** - An instrument is calibrated at either the National Institute of Standards and Technology (NIST) or at a calibration laboratory that participates in a proficiency program with NIST at least once every two (2) years and the results of the proficiency test conducted within 24 months of calibration show agreement within plus or minus three percent (± 3%) of the national standard in the mammography energy range.~~

~~RH-1610. (Cont'd)~~

~~b. **Accreditation.**~~

~~1. All facilities performing screening or diagnostic mammography shall be accredited every three (3) years by the Arkansas Department of Health or the American College of Radiology. Such accreditation shall be in accordance with the Food and Drug Administration (FDA) 21 CFR Part 16 and the "Mammography Quality Standards Act," Subchapter I to Chapter I of 21 CFR.~~

~~2. No mammography shall be performed in an unaccredited facility after January 1, 1990. The owners of any unaccredited facility where in mammography is performed after January 1, 1990 shall be subject to a civil penalty imposed by the Arkansas Department of Health in an amount not to exceed one hundred dollars ($100)~~

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for each day the facility operates without accreditation by the Department.

e. **Quality standards.**

1. **Personnel.**

The following requirements apply to personnel involved in any aspect of mammography, including production, processing, and interpretation of mammograms and related quality assurance activities.

A. **Interpreting physicians.**

Interpreting physicians shall meet the minimum requirements of 21 CFR Part 900.12(a)(1) of the Food and Drug Administration's "Mammography Quality Standards Act."

B. **Radiological technologist.**

i. Radiological technologists shall meet the minimum requirements of 21 CFR Part 900.12.(a)(2) of the Food and Drug Administration's "Mammography Quality Standards Act."

ii. Licensed by the State of Arkansas as a Registered Radiologic Technologist.

RH-1610.c.1. (Cont'd)

C. **Mammography imaging medical physicist.**

i. Mammography imaging medical physicists shall meet the minimum requirements of 21 CFR Part 900.12.(a)(3) of the Food and Drug Administration's "Mammography Quality Standards Act."

ii. All mammography imaging medical physicists must be registered with the State as a vendor as required by RH-34.

2. **Medical physicist's survey requirements.**

A. Medical physicist's surveys must be performed at least annually.

B. A mammography medical physicist who meets the qualification requirements of RH-1610.c.1.C. must sign all physicist survey reports.

C. Mammography medical physicists who sign a facility survey report must have been present in that facility during the survey.

D. Medical physicist's surveys must meet the requirements of 21 CFR Part 900.12(e)(9) of the Food and Drug Administration (FDA).

3. **Obtaining and preserving records**.

All reasonable efforts must be made to obtain any of the beneficiary's previous mammogram records, including original images and films, copies of written reports prepared by interpreting physicians, and other relevant information pertinent to previous mammograms that might be available from others, for comparison with current mammogram records. All reporting and record keeping must meet the requirements of 21 CFR Part 900.12(e) of the Food and Drug Administration (FDA).

RH-1610.c. (Cont'd)

4. **Equipment**.

The equipment used to perform mammography should be specifically designed for mammography and must meet the following standards:

A. **Food and Drug Administration (FDA), Subchapter I entitled "Mammography Quality Standards Act."**

21 CFR Part 900.12(b).

B. **Food and Drug Administration (FDA), Subchapter J entitled "Radiological Health."**

Certified equipment must meet the FDA performance standards for diagnostic x-ray systems and their major

components at 21 CFR 1020.30 and FDA's standards for radiographic equipment at 21 CFR 1020.31.

C. **Focal spot size.**

The measured focal spot size of the x-ray tube should not exceed 0.7 mm.

D. **Control panel indicators**.

The equipment must have a control panel that includes a device (usually a milliammeter) or means for an audible signal to give positive indication of the production of x-rays whenever the x-ray tube is energized. The control panel must include appropriate indicators (labeled control settings of meters that show the physical factors such as kilovoltage potential [kVp], milliampere seconds [mAs], exposure time, or whether timing is automatic) used for exposure.

E. All mammography units must be registered with the State of Arkansas as required by RH-21.

RH-1610.c.4. (Cont'd)

F. **Mammography equipment evaluations**.

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All variable parameters of the equipment must be evaluated and adjusted as needed to comply with 21 CFR Part 900.12(e)(10) of the FDA's "Mammography Quality Standards Act." This includes but is not limited to the following:

i. When the equipment is installed;

ii. After any major changes or replacement of parts;

iii. When quality assurance tests indicate that calibration or other maintenance is needed;

iv. When equipment is disassembled and reassembled.

5 **Safety standards**.

Mammograms must be conducted using equipment and operating procedures free of unnecessary hazards and providing minimum radiation exposure to patients, personnel, and other persons in the immediate environment.

A. **Safety precautions.**

Proper safety precautions must be maintained. This includes adequate shielding for patients, personnel, and facilities. The equipment must be operable only from a shielded position.

B. **Exposure badges.**

Personnel operating the equipment must be monitored in accordance with RH-1301. and RH-1302.

C. **Equipment inspection.**

Periodic inspection of equipment and shielding must be made by a staff or consultant medical physicist or by a physicist approved by an appropriate State or local government agency as meeting the qualification requirements of RH-1610. Identified hazards must be promptly corrected.

RH-1610.c.5. (Cont'd)

D. **Protection against electrical hazards.**

All equipment must be shockproof and grounded.

6. **Quality assurance.**

Each facility must establish and maintain a quality assurance program that meets the requirements of 21 CFR Part 900.12(d) of the FDA's "Mammography Quality Standards Act."

A. **Responsibilities for the lead interpreting physician.**

The lead interpreting physician has the following responsibility:

i. Ensuring that the facility's quality assurance program meets all the requirements of 21 CFR Part 900.12(d) of the FDA's "Mammography Quality Standards Act."

B. **Responsibilities for the mammography medical physicist.**

The person furnishing medical physics support has the overall responsibility for establishing and conducting the ongoing equipment quality assurance program. That individual's specific duties must include:

i. The duties outlined in 21 CFR Part 900.12 (d)(iii) of the FDA's "Mammography Quality Standards Act."

ii. Conducting or training others to conduct equipment performance monitoring functions;

iii. Analyzing the monitoring results to determine if there are any problems requiring correction; and

iv. Carrying out or arranging for the necessary corrective actions as well as for the calibrations and other preventive maintenance.

RH-1610.c.6.B. (Cont'd)

v. Conduct an annual survey of the facility's equipment quality assurance program as required by 21 CFR Part 900.12(e)(9) of the FDA's "Mammography Quality Standards Act."

vi. Submit a written report describing the results of the survey as required by 21 CFR Part 900.12(e)(9)(iii) of the FDA's "Mammography Quality Standards Act."

C. **Responsibilities of the quality control technologist.**

The quality control technologist must perform the tasks within the quality assurance program that are not assigned to the lead interpreting physician or the medical physicist.

D. **Quality assurance**.

~~The facility must ensure the quality of mammography by maintaining a quality assurance program that meets the requirements found in 21 CFR Part 900.12(e) of the FDA's "Mammography Quality Standards Act" and verifying that the action limits described in Part 900.12(e) have been met. These tests and their frequencies are as follows:~~

~~i. **Daily**.~~

~~Processor performance tests, which includes assessment of base plus fog density, mid-density, and density difference.~~

~~ii. **Weekly**.~~

~~Image quality evaluation test using an FDA-approved phantom.~~

~~iii. **Quarterly**.~~

~~Fixer retention in film test, repeat film analysis.~~

~~iv. **Semi-annually**.~~

~~Dark room fog evaluation, screen film contact test and compression device evaluation.~~

~~RH-1610.c.6.D. (Cont'd)~~

~~v. **Annual testing**.~~

~~Automatic exposure control performance, kilovoltage peak (kVp) accuracy and reproducibility, focal spot condition, breast entrance air kerma and AEC reproducibility, dosimetry, x-ray field/light field/image receptor/compression paddle alignment, uniformity of screen speed, radiation output, system artifacts, and decompression.~~

~~vi. **Mobile units**.~~

~~The facility shall verify that mammography units used to produce mammograms at more than one location meet the requirements in paragraphs (e)(1) through (e)(6) of 21 CFR Part 900.12. In addition, at each examination location, before any~~

examinations are conducted, the facility shall verify satisfactory performance of such units using a test method that establishes the adequacy of the image quality produced by the unit.

vii. **Quality control tests - other modalities**.

For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in the FDA 21 CFR Part 900.12 (e)(5)(vi).

viii. The facility shall establish and implement adequate protocols for maintaining darkroom, screen, and view box cleanliness and shall document that all cleaning procedures are performed at the frequencies specified in the protocols.

RH-1610.c.6.D. (Cont'd)

ix. **Infection control**.

Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. This system shall specify the methods for documenting facility compliance with the infection control procedures established and shall comply with the requirements in the FDA 21 CFR Part 900.12(e)(13).

E. **Evaluation of monitoring results**.

Quality assurance test results must be evaluated in a timely manner by the individual that is responsible for performing the test to ensue compliance with 21 CFR Part 900.12(e)(8) of the FDA "Mammography Quality Standards Act." The

responsible individuals are limited to the lead interpreting physician, the medical physicist and the quality control technologist.

F. **Medical outcomes audit**.

Each facility must establish and maintain a medical outcomes audit program to follow-up positive mammographic assessments and to correlate pathology results to the interpreting physician's findings. This program must comply with 21 CFR Part 900.12(f) of the FDA "Mammography Quality Standards Act."

G. **Procedures and techniques for mammography of patients with breast implants**.

Each facility must have procedures, which specify techniques, and procedures for imaging patients with breast implants. These procedures must comply with 21 CFR Part 900.12(g) of the FDA "Mammography Quality Standards Act."

RH-1610.c.6. (Cont'd)

H. **Consumer complaint mechanism**.

Each facility must have a consumer complaint mechanism. This mechanism must comply with 21 CFR Part 900.12(h) of the FDA "Mammography Quality Standards Act."

7. **Standards for diagnostic mammography**.

Facilities who wish to be accredited for diagnostic mammography shall, in addition to meeting all of the requirements for mammography also:

A. Have the interpreting physician as defined in RH-1610.c.1.A. present during all diagnostic mammography for direct supervision of the exam and film interpretation.

B. Have mammography systems with cone down compression and magnification capabilities, to enhance film interpretation.

d. **Applications and fees**.

Applications for accreditation or renewal shall be made on forms supplied by the Department. Evidence of compliance with all of the requirements for performing screening and/or diagnostic mammography and the accreditation fee must be included with the application.

e. **Additional review and patient notification**.

1. When quality assurance tests indicate that calibration is needed, and the Department believes that mammography quality at a facility has been compromised and may present a serious risk to human health, the facility shall provide clinical images and other relevant information, as specified by the Department, for review by the accreditation body. This additional mammography review will help the Department to determine whether the facility is in compliance with RH-1610. and, if not, whether there is a need to notify affected patients, their physicians or the public that the reliability, clarity and accuracy of interpretation of mammograms has been compromised.

RH-1610.e. (Cont'd)

2. If the Department determines that any activity related to the provision of mammography at a facility may present a serious risk to human health such that patient notification is necessary, the facility shall notify patients or their designees, their physicians or the public of action that may be taken to minimize the effects of the risk. Such notification shall occur within a timeframe and in a manner specified and approved by the Department.

f. **Retention of personnel records**.

Facilities shall maintain records to document the qualifications of all personnel who worked at the facility as interpreting physicians, radiologic technologists, or medical physicists. These records must be available for review by the MQSA inspectors. Records of personnel no longer employed by the facility should not be discarded until the next annual inspection has been completed, and FDA has determined that the facility is in compliance with MQSA personnel requirements.

g. **Quality assurance record keeping**.

All quality assurance record keeping shall meet the requirements of 21 CFR Part 900.12(d)(2) of the Food and Drug Administration (FDA) "Mammography Quality Standards Act." The lead interpreting physician, quality control technologist, and medical physicist shall ensure that records concerning mammography technique and procedures, quality control (including monitoring data, problems detected by analysis of that data, corrective actions, and the effectiveness of the corrective actions), safety, protection, and employee qualifications to meet assigned quality assurance tasks, are properly maintained and updated. The quality control records shall be kept for each test specified in paragraphs (e) and (f) of 21 CFR Part 900.12 until the next annual inspection has been completed, and FDA has determined that the facility is in compliance with the quality assurance requirements or until the test has been performed two additional times at the required frequency, whichever is longer.

h. **Clinical image quality**.

Clinical images produced by any certified facility must continue to comply with the standards for clinical image quality established by that facility's accreditation body.

RH-1611. **Bone Densitometry**.

a. Bone densitometry systems shall be:

1. Certified by the U.S. Department of Health and Human Services.

2. Registered in accordance with these Rules; and

3. Maintained and operated in accordance with the manufacturer's specifications.

b. Operators of bone densitometry systems shall be:

1. Licensed, certified, or permitted as a radiologic technologist by the Department; or

2. Licensed as a practitioner of the healing arts; or

3. Permitted or approved by the Department as a bone densitometry operator.

c. During the operation of any bone densitometry system:

1. The operator, ancillary personnel, and members of the general public shall be positioned at least one meter from the patient and bone densitometry system during the examination.

2. The operator shall advise the patient the bone densitometry examination is a type of x-ray procedure.

d. The registrant shall keep maintenance records for bone densitometry systems as prescribed. These records shall be maintained for inspection by the Department recordkeeping timelines as appropriate.

e. Bone densitometry on human patients shall be conducted only:

1. Under a prescription of a licensed practitioner of the healing arts; or

2. Under a screening program approved by the Department.

f. Any person proposing to conduct a bone densitometry screening program shall submit the information outlined in Schedule A to Section 3 with the exception of g, h, i, j, k, and m, and include the name and address of the individual who will interpret the screening results.

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~~**SCHEDULE A TO SECTION 3**~~

~~**INFORMATION TO BE SUBMITTED BY PERSONS PROPOSING TO CONDUCT HEALING ARTS SCREENING**~~

~~Persons requesting that the Department approve a healing arts screening program shall submit the following information and evaluation:~~

~~a. Name and address of the applicant and, where applicable, the names and addresses of agents within this State;~~

~~b. Diseases or conditions for which the x-ray examinations are to be used in diagnoses;~~

~~c. A detailed description of the x-ray examinations proposed in the screening program;~~

~~d. Description of the population to be examined in the screening program, i.e., age, sex, physical condition, and other appropriate information;~~

~~e. An evaluation of any known alternate methods not involving ionizing radiation which could achieve the goals of the screening program and why these methods are not used instead of the x-ray examinations;~~

~~f. An evaluation by a qualified expert of the x-ray system(s) to be used in the screening program. The evaluation by the qualified expert shall show that such system(s) do satisfy all requirements of these Rules. The evaluation shall include a measurement of patient exposures from the x-ray examinations to be performed;~~

~~g. A description of the diagnostic x-ray quality control program;~~

~~h. A copy of the technique chart for the x-ray examination procedures to be used;~~

~~i. The qualifications of each individual who will be operating the x-ray system(s);~~

~~j. The qualifications of the individual who will be supervising the operators of the x-ray system(s). The extent of supervision and the method of work performance evaluation shall be specified;~~

~~k. The name and address of the individual who will interpret the radiograph(s);~~

~~l. A description of the procedures to be used in advising the individual screening procedure and any further medical needs indicated;~~

~~m. A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the x-ray examinations;~~

~~n. An indication of the frequency of screening and the duration of the entire screening program.~~

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RH-1612. **Scope and Purpose – Analytical X-ray Equipment**.

This Part provides special requirements for analytical x-ray equipment. The requirements of this Part are in addition to, and not in substitution for, applicable requirements in other Parts of these Rules.

a. **Definitions**.

Analytical x-ray equipment - X-Ray equipment used for x-ray diffraction fluorescence analysis or spectroscopy.

Analytical x-ray system - A group of local and remote components utilizing x-rays to determine the elemental composition or to examine the microstructure of materials. Local components include those that are struck by x-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors and shielding. Remote components include power supplies, transformers, amplifiers, readout devices, and control panels.

Fail-safe characteristics - A design feature which causes beam port shutters to close or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.

Local components - Part of an analytical x-ray system and include areas exposed to x-rays, such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors and shielding, but does not include power supplies, transformers, amplifiers, readout devices and control panels.

Normal operating procedures - Operating procedures for conditions suitable for analytical purposes with shielding and barriers in place. These do not include maintenance but do include routine alignment procedures. Routine and emergency radiation safety considerations are part of these procedures.

Open-beam configuration - An analytical x-ray system in which an individual could accidentally place some part of his/her body in the primary beam path during normal operation.

Primary beam - Ionizing radiation which passes through an aperture of the source housing by a direct path from the x-ray tube located in the radiation source housing.

RH-1612. (Cont'd)

b. **Equipment Requirements**.

1. **Safety device**.

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~~A device which prevents the entry of any portion of an individual's body into the primary x-ray beam path or which causes the beam to be shut off upon entry into its path shall be provided on all open-beam configurations. A registrant may apply to the Department for an exemption from the requirement of a safety device. Such application shall include:~~

~~A. A description of the various safety devices that have been evaluated;~~

~~B. The reason each of these devices cannot be used; and~~

~~C. A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.~~

~~2. **Warning devices**.~~

~~A. Open-beam configurations shall be provided with a readily discernible indication of:~~

~~i. X-ray tube status **(ON-OFF)** located near the radiation source housing, if the primary beam is controlled in this manner; and/or~~

~~ii. Shutter status **(OPEN-CLOSED)** located near each port on the radiation source housings, if the primary beam is controlled in this manner.~~

~~B. Warning devices shall be labeled so that their purpose is easily identified. On equipment installed after January1, 1979, warning devices shall have fail-safe characteristics.~~

~~3. **Ports**.~~

~~Unused ports on radiation machine source housings shall be secured in the closed position in a manner which will prevent casual opening.~~
~~RH-1612.b. (Cont'd)~~

~~4. **Labeling**.~~

~~All analytical x-ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol and the words:~~

~~A. "**CAUTION - HIGH INTENSITY X-RAY BEAM**," or words having a similar intent, on the x-ray source housing; and~~

~~B. "**CAUTION RADIATION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED**," or words having a similar intent, near any switch that energizes an x-ray tube.~~

~~5. **Shutters**.~~

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~~On open-beam configurations installed after January 1, 1979, each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.~~

~~6. **Warning lights**.~~

~~A. An easily visible warning light labeled with the words "**X-RAY ON**" or words having a similar intent, shall be located near any switch that energizes an x-ray tube and shall be illuminated only when the tube is energized.~~

~~B. On equipment installed after January 1, 1979, warning lights shall have fail-safe characteristics.~~

~~7. **Radiation source housing**.~~

~~Each radiation source housing shall be subject to the following requirements:~~

~~A. Each x-ray tube housing shall be equipped with an interlock that shuts off the tube if it is removed from the radiation source housing or if the housing is disassembled.~~

~~RH-1612.b. (Cont'd)~~

~~8. **Generator cabinet**.~~

~~Each x-ray generator shall be supplied with a protective cabinet which limits leakage radiation measured at a distance of five (5) centimeters from its surface such that it is not capable of producing a dose in excess of 0.25 millirem in one hour.~~

~~c. **Area Requirements**.~~

~~1. **Radiation levels**.~~

~~The local components of an analytical x-ray system shall be located and arranged and shall include sufficient shielding or access control such that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits given in RH-1208. These levels shall be met at any specified tube rating.~~

~~2. **Surveys**.~~

~~**A. Radiation surveys, as required by RH-1300., of all analytical x-ray systems sufficient to show compliance with RH-1612.c.1. shall be performed:**~~

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i. Upon installation of the equipment;

ii. Following any change in the initial arrangement, number or type of local components in the system;

iii. Following any maintenance requiring the disassembly or removal of a local component in the system;

iv. During the performance of maintenance and alignment procedures, if the procedures require the presence of a primary x-ray beam when any local component in the system is disassembled or removed;

v. Any time a visual inspection of the local components in the system reveals an abnormal condition; and

vi. Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the limits specified in RH-1200.

B. Radiation survey measurements shall not be required if a registrant can demonstrate compliance to the satisfaction of the Department with RH-1612.e.1. in some other manner.

3. **Posting**.

Each area or room containing analytical x-ray equipment shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words "**CAUTION - X-RAY EQUIPMENT**" or words having a similar intent.

d. **Operating Requirements**.

1. **Procedures**.

Normal operating procedures shall be written and available to all analytical x-ray equipment workers. No person shall be permitted to operate analytical x-ray equipment in any manner other than that specified in the procedures unless such person has obtained written approval of the Radiation Safety Officer.

2. **Bypassing**.

No person shall bypass a safety device unless such person has obtained the approval of the Radiation Safety Officer. When a safety device has been bypassed, a readily discernible sign bearing the words "**SAFETY DEVICE NOT WORKING**," or words having a similar intent, shall be placed on the radiation source housing.

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~~3. **Repair or modification of x-ray tube systems**.~~

~~Except as specified in RH-1612.d.2., no operation involving removal of covers, shielding materials or tube housings or modifications to shutters, collimators or beam stops shall be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.~~
~~RH-1612. (Cont'd)~~

~~e. **Personnel Requirements**.~~

~~1. **Instruction**.~~

~~A. No person shall be permitted to operate or maintain analytical x-ray equipment unless such person has received instruction in and demonstrated competence as to:~~

~~i. Identification of radiation hazards associated with the use of the equipment;~~

~~ii. Significance of the various radiation warning and safety devices incorporated into the equipment or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;~~

~~iii. Proper operating procedures for the equipment;~~

~~iv. Symptoms of an acute localized exposure; and~~

~~v. Proper procedures for reporting an actual or suspected exposure.~~

~~2. **Personnel monitoring**.~~

~~A. Finger or wrist dosimetric devices shall be provided to and shall be used by:~~

~~i. Analytical x-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device; and~~

~~ii. Personnel maintaining analytical x-ray equipment if the maintenance procedures require the presence of a primary x-ray beam when any local component in the analytical x-ray system is disassembled or removed.~~

~~B. Reported dose values shall not be used for the purpose of determining compliance with RH-1200. and RH-1208. unless evaluated by a qualified expert.~~

~~RH-1613. **Computed Tomography**.~~

~~a. **Definitions**.~~

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Computed tomography dose index (CTDI) - The integral from 7T to +7T of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan.

NOTE: This definition assumes that the dose profile is centered around z = 0 and that, for a multiple tomogram system, the scan increment between adjacent scans is nT.

Contrast scale (CS) - The change in the linear attenuation coefficient per CTN relative to water, that is:

$\overline{CTN}_x$ = of the material of interest; and
$\overline{CTN}_w$ = of water.

CT conditions of operation - All selectable parameters governing the operation of a CT x-ray system including, but not limited to, nominal tomographic section thickness, filtration, and the technique factors as defined.

CT gantry - The tube housing assemblies, beam-limiting devices, detectors, and the supporting structures and frames that hold these components.

CT number (CTN) - The number used to represent the x-ray attenuation associated with each elemental area of the CT image.

$$\overline{CTN} = \frac{k(\mu_x - \mu_w)}{\mu_w}$$

where: k = A constant, a normal value of 1,000 when the Houndsfield scale of CTN is used;

μ_x = Linear attenuation coefficient of the material of interest; and

μ_w = Linear attenuation coefficient of water.

Dose profile - The dose as a function of position along a line.

RH-1613.a. (Cont'd)

Elemental area - The smallest area within a tomogram for which the x-ray attenuation properties of a body are depicted. (See also "Picture element.")

Multiple tomogram system - A computed tomography x-ray system that obtains x-ray transmission data simultaneously during a single scan to produce more than one tomogram.

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Noise - The standard deviation of the fluctuation in CTN expressed as a percentage of the attenuation coefficient of water. Its estimate (S_n) is calculated using the following expression:

$$S_n = \frac{100 \cdot \overline{CS} \cdot s}{\mu_w}$$

where: $\overline{CS}$ = Linear attenuation coefficient of the material of interest;

μ_w = Linear attenuation coefficient of water; and

s = Standard deviation of the CTN of picture elements in a specified area of the CT image.

Nominal tomographic section thickness - The full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which x-ray transmission data are collected.

Picture element - An elemental area of a tomogram.

Reference plane - A plane that is displaced from and parallel to the tomographic plane.

Scan - The complete process of collecting x-ray transmission data for the production of a tomogram. Data can be collected simultaneously during a single scan for the production of one or more tomograms.

Scan increment - The amount of relative displacement of the patient with respect to the CT x-ray system between successive scans measured along the direction of such displacement.

Scan sequence - A pre-selected set of two or more scans performed consecutively under pre-selected CT conditions of operation.

Scan time - The period of time between the beginning and end of x-ray transmission data accumulation for a single scan.

Single tomogram system - A CT x-ray system that obtains x-ray transmission data during a scan to produce a single tomogram.

Tomographic plane - That geometric plane which is identified as corresponding to the output tomogram.

Tomographic section - The volume of an object whose x-ray attenuation properties are imaged in a tomogram.

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b. **Requirements for equipment.**

1. **Termination of exposure.**

A. Means shall be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110 percent (110%) of its preset value through the use of either a backup timer or devices which monitor equipment function.

B. A visible signal shall indicate when the x-ray exposure has been terminated

C. The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans under CT x-ray system control, of greater than one-half second duration.

2. **Tomographic plane indication and alignment.**

A. For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

B. For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes.

RH-1613.b.2. (Cont'd)

C. If a device is using a light source, the light source shall provide illumination levels sufficient to permit visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

3. **Beam-on and shutter status indicators and control switches.**

A. The CT x-ray control and gantry shall provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed.

B. Each emergency button or switch shall be clearly labeled as to its function.

4. **Indication of CT conditions of operation.**

A. The CT x-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of

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operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

B. **Extraneous radiation**.

When data are not being collected for image production, the radiation adjacent to the tube port shall not exceed that permitted by RH-1602.b.3.

C **Maximum surface Computed Tomography Dose Index (CTDI) identification**.

The angular position where the maximum surface CTDI occurs shall be identified to allow for reproducible positioning of a CT dosimetry phantom.

RH-1613.b. (Cont'd)

5. **Additional requirements applicable to CT x-ray systems containing a gantry manufactured after September 3, 1985**.

A. The total error in the indicated location of the tomographic plane or reference plane shall not exceed five (5) millimeters.

B. If the x-ray production period is less than one-half second, the indication of x-ray production shall be actuated for at least one-half second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

C. The deviation of indicated scan increment versus actual increment shall not exceed plus or minus one (±1) millimeter with any mass from 0 to 100 kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or 30 centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

D. Premature termination of the x-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

c. **Facility design requirements**.

1. Aural communication.

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~~**A. Provision shall be made for two-way aural communication between the patient and the operator at the control panel.**~~

~~2. **Viewing systems.**~~

~~A. Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.~~

~~RH-1613.c.2. (Cont'd)~~

~~B. When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.~~

~~d. **Surveys, calibrations, spot checks, and operating procedures.**~~

~~1. **Surveys.**~~

~~A. All CT x-ray systems shall have a survey made by, or under the direction of, a qualified expert. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.~~

~~B. The registrant shall obtain a written report of the survey from the qualified expert, and a copy of the report shall be made available to the Department upon request.~~

~~2. **Radiation calibrations.**~~

~~A. The calibration of the radiation output of the CT x-ray system shall be performed by, or under the direction of, a qualified expert who is physically present at the facility during such calibration.~~

~~B. The calibration of a CT x-ray system shall be performed at intervals specified by a qualified expert and after any change or replacement of components that, in the opinion of the qualified expert, could cause a change in the radiation output.~~

~~C. The calibration of the radiation output of a CT x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding two (2) years.~~

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RH-1613.d.2. (Cont'd)

D. CT dosimetry phantom(s) shall be used in determining the radiation output of a CT x-ray system. Such phantom(s) shall meet the following specifications and conditions of use:

i. CT dosimetry phantom(s) shall be right circular cylinders of polymethyl methacrylate of density 1.19 plus or minus 0.01 grams per cubic centimeter. The phantom(s) shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing CT x-ray systems designed to image any section of the body and 16.0 centimeters for systems designed to image the head or for whole body scanners operated in the head scanning mode;

ii. CT dosimetry phantom(s) shall provide means for the placement of a dosimeter(s) along the axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of dosimeters or alignment devices at other locations may be provided;

iii. Any effects on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom; and

iv. All dose measurements shall be performed with the CT dosimetry phantom placed on the patient couch or support device without additional attenuation materials present.

E. The calibration shall be required for each type of head, body, or whole-body scan performed at the facility.

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RH-1613.d.2. (Cont'd)

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F. Calibration shall meet the following requirements:

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i. The dose profile along the center axis of the CT dosimetry phantom for the minimum, maximum, and midrange values of the nominal tomographic section thickness used by the registrant shall be measurable. Where less than three (3) nominal tomographic thicknesses can be selected, the dose profile determination shall be performed for each available nominal tomographic section thickness;

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ii. The CTDI along the two (2) axes shall be measured. (For the purpose of determining the CTDI, the manufacturer's statement as to the nominal tomographic section thickness for that

particular system may be utilized.) The CT dosimetry phantom shall be oriented so that the measurement point 1.0 centimeter from the outer surface and within the phantom is in the same angular position within the gantry as the point of maximum surface CTDI identified. The CT conditions of operation shall correspond to typical values used by the registrant; and

iii. Spot checks shall be made in accordance with RH-1613.d.3.

G. Calibration procedures shall be in writing. Records of calibrations performed shall be maintained for inspection by the Department.

3. **Spot checks**.

A. The spot-check procedures shall be in writing and shall have been developed by a qualified expert.

B. The spot-check procedures shall incorporate the use of a CT dosimetry phantom which has a capability of providing an indication of contrast scale, noise, nominal tomographic section thickness, the resolution capability of the system for low and high contrast objects, and measuring the mean CTN for water or other reference material.

RH-1613.d.3. (Cont'd)

C. All spot checks shall be included in the calibration required by RH-1613.d.2. and at time intervals and under system conditions specified by a qualified expert.

D. Spot checks shall include acquisition of images obtained with the CT dosimetry phantom(s) using the same processing mode and CT conditions of operation as are used to perform calibrations. The images shall be retained, until a new calibration is performed, in two (2) forms as follows:

i. Photographic copies of the images obtained from the image display device; and

ii. Images stored in digital form on a storage medium compatible with the CT x-ray system.

E. Written records of the spot checks performed shall be maintained for inspection by the Department.

4. **Operating procedures**.

A. The CT x-ray system shall not be operated except by an individual who has been specifically trained in its operation.

B. Information shall be available at the control panel regarding the operation and calibration of the system. Such information shall include the following:

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~~i. Dates of the latest calibration and spot checks and the location within the facility where the results of those tests may be obtained;~~

~~ii. Instructions on the use of the CT dosimetry phantom(s) including a schedule of spot checks appropriate for the system, allowable variations for the indicated parameters, and the results of at least the most recent spot checks conducted on the system;~~

~~RH-1613.d.4.B. (Cont'd)~~

~~iii. The distance in millimeters between the tomographic plane and the reference plane if a reference plane is utilized; and a current technique chart available at the control panel which specifies for each routine examination the CT conditions of operation and the number of scans per examination.~~

~~C. If the calibration or spot check of the CT x-ray system identifies that a system operating parameter has exceeded a tolerance established by the qualified expert, use of the CT x-ray system on patients shall be limited to those uses permitted by established written instructions of the qualified expert.~~

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RH-1614.- RH-1699.– _Reserved.

PART H.
[RESERVED]

RH-1700.- RH-1702._————————Deleted.

RH-1703.- RH-1799._————————Reserved.

PART I.
LICENSES AND REGISTRATIONS FOR INDUSTRIAL RADIOGRAPHY AND RADIATION SAFETY REQUIREMENTS FOR INDUSTRIAL RADIOGRAPHIC OPERATIONS

RH-1800. **General Provisions**.

a. **Purpose and scope.**

1. The rules in this Part prescribe requirements for the issuance of licenses or registrations for the ~~industrial~~ use of ~~sealed~~ sources of radiation in industrial radiography and establish radiation safety requirements for persons utilizing sources of radiation in industrial radiography. ~~-~~The rules in this Part apply to all licensees or registrants who use sources of radiation for industrial radiography. Except for the rules in this Part clearly applicable only to sealed radioactive sources - radiation machines as defined in RH-1800.c., ~~accelerators,~~ and sealed radioactive sources are both covered by this Part. ~~-~~The provisions of this Part do not apply to medical uses of sources of radiation addressed in Sections 9, 10, and 11 of these Rules or to radiation generating devices (RGDs) addressed in Section 13 of these Rules.~~-~~

2. The requirements of this Part are in addition to, and not in substitution for, other applicable requirements of these Rules.~~-~~ In particular, requirements in Sections ~~1,~~ 2, 3, 4, 5, ~~6,~~ and 12 apply to ~~applicants, licensees, and registrants~~ radioactive material licensees and radioactive material license applicants subject to this Part. Sections 1, 3, and 5 apply to registrants and registration applicants subject to this Part. Sections 3, 5, and 6 apply to accelerator licensees and accelerator license applicants subject to this Part.

b. ~~**Specific licensing provisions.**~~Licensing and registration requirements for industrial radiography.

~~1. **Application for a specific license.**~~

1. A. A person, ~~as defined in RH-1100.,~~ shall file an application for a specific license authorizing the use of sealed sources in industrial radiography in accordance with RH-403.~~ and RH-404.~~

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B. A person shall apply for a registration authorizing the use of radiation machines, as defined in RH-10., in industrial radiography in accordance with RH-21.

C. A person shall file an application for an accelerator license authorizing the use of accelerators in industrial radiography in accordance with RH-5201.

2. ~~**Specific licenses for industrial radiography**~~.

An application for a specific license for the use of licensed material, for a registration for the use of radiation machine as defined in RH-10, or for an accelerator license, in industrial radiography will be approved if:

A. The applicant satisfies the ~~general~~ requirements specified in RH-404. For sealed sources, in Part C of Section 1 for radiation machines as defined in RH-10, or Part C of Section 6 for accelerators, as applicable, and any special requirements contained in this Part;

B. The applicant submits an adequate program for training radiographers and radiographers' assistants that meets the requirements of RH-1802.b.;

~~RH-1800.b.2. (Cont'd)~~

C. The applicant submits adequate procedures for verifying and documenting the certification status of radiographers and for ensuring that the certification of individuals acting as radiographers remains valid;

D. The applicant submits written operating and emergency procedures as described in RH-1802.e.;

E. The applicant submits a description of a program for inspections of the job performance of each radiographer and radiographer's assistant at intervals not to exceed 6 months as described in RH-1802.b.5.;

F. The applicant submits a description of the applicant's overall organizational structure as it applies to the radiation safety responsibilities in industrial radiography, including specified delegations of authority and responsibility;

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G. The applicant submits the qualifications of the individual(s) designated as the Radiation Safety Officer as described in RH-1802.d.;

H. The applicant who intends to collect leak test samples of sealed sources or exposure devices containing depleted uranium (DU) shielding has described the procedures for performing the sampling and the qualifications of the individual(s) authorized to do the sampling. If the applicant intends to analyze its own wipe samples, the application shall include a description of the procedures to be followed. The description shall include the:

i. Instrumentation to be used;

ii. Methods of performing the analysis; and

iii. Pertinent experience of the individual(s) who will analyze the wipe samples.

I. The applicant who intends to perform calibrations of survey instruments ~~and/or~~ or alarming ratemeters describes methods to be used and the experience of the individual(s) who will perform the calibrations. All calibrations must be performed according to the procedures described and at the intervals prescribed in RH-1801.e.3. and RH-1802.f.7.~~D~~E.

~~RH-1800.b.2. (Cont'd)~~

J. The applicant identifies ~~and describes~~ the location(s) of and describes all field stations permanent storage and use sites, and permanent radiographic installations; Radioactive material or radiation machines shall not be stored or used at a permanent use site unless such site is specifically authorized by the license or registration, as applicable. Any licensee or registrant conducting radiographic operations or storing radioactive material or radiation machines at any location not listed on the license or registration, as applicable, for a period in excess of 180 days in a calendar year, shall notify the Department prior to exceeding the 180 days. The number of days of use or storage of radioactive material and the number of days of use or storage of radiation machines are counted separately. A storage site is permanent if radioactive material or radiation machines are stored at that location and if one (1) or more of the following applies: ~~and~~

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i. The licensee or registrant establishes telephone service that is used for contracting or providing industrial radiographic services for the licensee or registrant;

ii. Industrial radiographic services are advertised for or from the site;

iii. Radioactive material or radiation machines stored at that location are used for industrial radiographic operations conducted at other sites; or

iv. The licensee or registrant conducts radiographic operations or stores radioactive material or radiation machines at any location not listed on the license or registration, as applicable, for a period in excess of 180 days in a calendar year. The number of days of use or storage of radioactive material and the number of days of use or storage of radiation machines are counted separately.

K. The applicant identifies the locations(s) where all records required by this Part and other Sections of these Rules will be maintained.

c. **Definitions**.

~~**Access panel** - Any barrier or panel which is designed to be removed or opened for maintenance or service purposes, requires tools to open and permits access to the interior of the cabinet.~~

ALARA (acronym for "as low as is reasonably achievable") ~~–~~ Making every reasonable effort to maintain exposures to radiation as far below the dose limits specified in Part C, "Permissible Doses, Levels, and Concentrations," of Section 3 as is practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvement in relation to benefits to the public health and safety, and other societal and socio-economic considerations, and in relation to utilization of nuclear energy~~,~~ and licensed or registered sources of radiation ~~materials, and x-ray equipment~~ in the public interest.

Annual refresher safety training - A review conducted or provided by the licensee or registrant for its employees on radiation safety aspects of industrial radiography. The review may include, as appropriate, the results of internal inspections, new procedures or equipment, new or

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revised Department rules, accidents or errors that have been observed, and should also provide opportunities for employees to ask safety questions.

ANSI – The American National Standards Institute. ~~**Aperture** - Any opening in the outside surface of the cabinet, other than a port, which remains open during generation of x-radiation.~~

Associated equipment - Equipment that is used in conjunction with a radiographic exposures device to make radiographic exposures that drives, guides, or comes in contact with the source, (e.g., guide tube, control tube, control (drive) cable, removable source stop, "J" tube and collimator when it is used as an exposure head.)

Becquerel (Bq) - One (1) disintegration per second.

~~RH-1800.c. (Cont'd)~~

~~**Cabinet radiography** - Industrial radiography conducted in an enclosed cabinet which is so shielded that every location on the exterior meets conditions for an unrestricted area as specified in RH-1208.~~

~~**Cabinet x-ray system** - An x-ray system with the x-ray tube installed in an enclosure (hereinafter termed "cabinet") which, independently of existing architectural structures except the floor on which it may be placed, is intended to contain at least that portion of a material being irradiated, provide radiation attenuation and exclude personnel from its interior during generation of x-radiation. Included are all x-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad and bus terminals and in similar facilities. An x-ray tube used within a shielded part of a building or x-ray equipment which may temporarily or occasionally incorporate portable shielding is not considered a cabinet x-ray system.~~

~~**Certified cabinet system** - X-ray systems which are subject to regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968.~~

Certifying Entity - An independent certifying organization meeting the requirements in Schedule B of this Section or a State or an Agreement State, as applicable, meeting the requirements in Schedule B, Parts II and III.

Collimator - a radiation shield that is placed on the end of the guide tube or directly onto a radiographic exposure device to restrict the size of the radiation beam when the sealed source is cranked into position to make a radiographic exposure.

Control (drive) cable - The cable that is connected to the source assembly and used to drive the source to and from the exposure location.

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Control drive mechanism - A device that enables the source assembly to be moved to and from the exposure device.

Control tube - A protective sheath for guiding the control cable. The control tube connects the control drive mechanism to the radiographic exposure device.

~~**Door** - Any barrier which is designed to be movable or opened for routine operations purposes, does not generally require tools to open and permits access to the interior of the cabinet. For the purposes of RH-1803.g.1.A. of this Section, inflexible hardware rigidly affixed to the door shall be considered part of the door.~~
~~RH-1800.c. (Cont'd)~~

~~**Enclosed radiography** - Industrial radiography conducted in an enclosed cabinet or room and includes cabinet radiography, cabinet x-ray systems and shielded room radiography.~~

Exposure head - A device that locates the gamma radiography sealed source in the selected working position. (An exposure head is also known as a source stop).

~~**External surface** - The outside surface of the cabinet x-ray system, including the high-voltage generator, doors, access panels, latches, control knobs and other permanently mounted hardware and including the plane across any aperture or port.~~

Field station - A facility where licensed ~~material~~ or registered ~~x-ray equipment~~ sources of radiation may be stored or used and from which equipment is dispatched.

~~**Floor** - The underside external surface of the cabinet.~~

Gray - The SI unit of absorbed dose. ~~A~~ One (1) gray is equal to an absorbed dose of one (1) Joule/kilogram. It is also equal to 100 rads.

~~**Ground fault** - An accidental electrical grounding of an electrical conductor.~~

Guide tube (Projection sheath) - A flexible or rigid tube (i.e., "J" tube) for guiding the source assembly and the attached control cable from the exposure device to the exposure head. The guide tube may also include the connections necessary for attachment to the exposure device and to the exposure head.

Hands-on experience - Experience in all of those areas considered to be directly involved in the radiography process, and includes taking radiographs, calibration of survey instruments, operational and

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performance testing of survey instruments and devices, film development, posting of radiation areas, transportation of radiography equipment, posting of records, radiation area surveillance, etc., as applicable. Excessive time spent in only one or two of these areas, such as film development or radiation area surveillance, should not be counted toward the 2000 hours of hands-on experience required for a Radiation Safety Officer in RH-1802.d.1. or the hands-on experience for a radiographer as required by RH-1802.b.1.

Independent Certifying Organization - An independent organization that meets all the criteria of Schedule B to Section 3.

Industrial radiography (radiography) - An examination of the structure of materials by non-destructive methods, utilizing ionizing radiation to make radiographic images.

Lay-barge radiography - Industrial radiography performed on any water vessel used for laying pipe.

Licensee - Any person who is licensed by the Department in accordance with these Rules and the Act.

Licensed material - Source material, special nuclear material, or byproduct material received, possessed, used, transferred or disposed of under a general license provided by rule or a specific license issued by the Department.

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Offshore platform radiography – Industrial radiography performed from a platform over a body of water.

Permanent radiographic installation - An enclosed shielded room, cell, or vault, not located at a temporary jobsite, in which radiography is performed.

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~~**Port** - Any opening in the outside surface of the cabinet which is designed to remain open, during generation of x-rays, for the purpose of conveying material to be irradiated into and out of the cabinet or for partial insertion for irradiation of an object whose dimensions do not permit complete insertion into the cabinet.~~

Practical examination - A demonstration through practical application of the safety rules and principles in industrial radiography including use of all appropriate equipment and procedures.

~~**Primary beam** - The x-radiation emitted directly from the target and passing through the window of the x-ray tube.~~

Radiation machine - Any device emitting or capable of producing radiation, but excluding devices with radioactive material as the only source of radiation and devices exempted by these Rules. Some requirements in Part I may reference accelerators specifically.

Radiation Safety Officer for industrial radiography - An individual with the responsibility for the overall radiation safety program on behalf of the licensee or registrant and who meets the requirements of RH-1802.d.

Radiographer - Any individual who performs or who, in attendance at the site where sources of radiation are being used, personally supervises industrial radiographic operations and who is responsible to the licensee or registrant for assuring compliance with the requirements of these Rules and the conditions of ~~registration or of a~~ the license or registration.

Radiographer's assistant - Any individual who, under the direct supervision of a radiographer, uses radiographic exposure devices, radiation machines~~sources of radiation~~, sealed sources or related handling tools, or radiation survey instrumentation in industrial radiography.

Radiographer certification - Written approval received from a ~~e~~Certifying ~~e~~Entity stating that an individual has satisfactorily met certain established radiation safety, testing, and experience criteria.

Radiographic exposure device - Any instrument containing a sealed source fastened or contained therein, in which the sealed source or shielding thereof may be moved or otherwise changed, from a shielded to unshielded position for purposes of making a radiographic exposure.

~~RH-1800.c. (Cont'd)~~

Radiographic operations - All activities associated with the presence of ~~x-ray machines, accelerators, or~~ radioactive sources in radiographic exposure devices, or with radiation machines, during use of the ~~machine, accelerator, or~~ device, or transport (except when being transported by a common or contract carrier), to include surveys to confirm the adequacy of boundaries, setting up equipment, and any activity inside restricted area boundaries. Transporting a radiation machine ~~or accelerator~~ is not considered a radiographic operation.

Radiography - See "industrial radiography."

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~~**Safety interlock** - A device which is intended to prevent the generation of x-radiation when access by any part of the human body to the interior of the cabinet x-ray system through a door or access panel is possible.~~

Sealed source - Any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

~~**Shielded room radiography** - Industrial radiography conducted in an enclosed room, the interior of which is not occupied during radiographic operations, which is so shielded that every location on the exterior meets the conditions for an unrestricted area as specified in RH-1208.~~

Shielded position - The location within the radiographic exposure device or source changer where the sealed source is secured and restricted from movement.

Sievert - The SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1 Sv = 100 rem).

Source Assembly - An assembly that consists of the sealed source and a connector that attaches the source to the control cable.~~-~~ The source assembly may also include a stop ball used to secure the source in the shielded position.

Source changer - A device designed and used for replacement of sealed sources in radiographic exposure devices, including those also used for transporting and storage of sealed sources.

S-tube - A tube through which the radioactive source travels~~–~~ when inside a radiographic exposure device.

~~RH-1800.c. (Cont'd)~~

Storage area - Any location, facility, or vehicle ~~which~~ that is used to store, ~~to transport, or to~~ and secure a radiographic exposure device, a radiation machine, ~~a storage container, or~~ a sealed source or a storage container when it is not ~~in use and which is~~ used for radiographic operations. Storage areas are locked or ~~has~~ have a physical barrier to prevent accidental exposure, tampering with, or unauthorized removal of the device, machine, ~~container, or~~ source or container.

Storage container - A container in which sealed sources are secured and stored.

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Temporary job site - Any location where radiographic operations are conducted and where licensed ~~material~~ or registered sources of radiation may be stored other than the location(s) of use authorized on the license or registration.

Transport container - A package that is designed to provide radiation safety and security when sealed sources are transported and meets all applicable requirements of the U.S. Department of Transportation.

Underwater radiography - Industrial radiography performed when the radiographic exposure device, radiation machine,~~and/or~~ or related equipment are~~–~~ beneath the surface of the water.

~~**X-ray system** - An assemblage of components for the controlled generation of x-rays.~~

~~**X-ray tube** - Any electron tube which is designed for the conversion of electrical energy into x-ray energy.~~

d. **Recordkeeping Requirements**.

1. **Records of the ~~specific~~ license ~~for industrial radiography~~or registration**.

   Each licensee or registrant shall maintain a copy of its license or registration, ~~license conditions,~~ documents incorporated by reference, and amendments to each of these items until superseded by new documents approved by the Department or until the Department terminates the license or registration.

2. **Records of receipt and transfer of ~~sealed~~ sources of radiation**.

   A Each licensee or registrant shall maintain records showing the receipts and transfers of sealed sources, ~~and~~ devices using depleted uranium (DU) for shielding, and radiation machines, and retain each record for three (3) years after it is made.

~~RH-1800.d.2. (Cont'd)~~

   B These records must include the date, the name of the individual making the record, radionuclide, number of curies (becquerels) or mass (for ~~depleted uranium (~~DU~~)~~) and manufacturer, model, and serial number of each ~~sealed~~ source of radiation ~~and/or device~~, as appropriate.

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3. **Records of radiation survey instruments**.

Each licensee or registrant shall maintain records of the calibrations of its radiation survey instruments that are required in RH-1801.e. and retain each record for three (3) years after it is made.

4. **Records of leak testing of sealed sources and devices containing depleted uranium (DU).**

Each licensee shall maintain records of leak test results for sealed sources and for devices containing depleted uranium (DU). The results must be stated in units of microcuries (~~bequerels~~becquerels). The licensee shall retain each record for three (3) years after it is made or until the source in storage is removed.

5. **Records of quarterly inventory**.

A. Each licensee or registrant shall maintain records of the quarterly inventory of ~~sealed~~ sources of radiation and of devices containing depleted uranium (DU) as required by RH-1801.g. and retain each record for three (3) years after it is made.

B. The record must include the date of the inventory, name of the individual conducting the inventory, radionuclide, number of curies (becquerels) or mass (for DU) in each device, location of ~~sealed~~ sources of radiation ~~and/or~~or devices, and manufacturer, model, and serial number of each ~~sealed~~ source of radiation~~and/or~~ or device, as appropriate.

6. ~~**Records of u**~~**Utilization logs**.

A Each licensee or registrant shall maintain utilization logs showing for each ~~sealed~~ source or ~~x-ray unit~~ of radiation the following information:

~~RH-1800.d.6. (Cont'd)~~

i A description, including the make, model, and serial number of the radiation machine or of the radiographic exposure device or transport or storage container in which the sealed source ~~or x-ray tube~~ is located;

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ii The identity and signature of the radiographer to whom assigned;~~ and~~

iii The plant or site where used and dates of use, including the dates removed and returned to storage~~.~~ :

iv. For permanent radiographic installations, the dates each radiation machine is energized.

B. The licensee or registrant shall retain the logs required by RH-1800. Paragraph d.6.A. of this section for three (3) years after the log is made.

7. **Records of inspection and maintenance of radiographic exposure devices, radiation machines, transport and storage containers, associated equipment, source changers, and survey instruments**.

A. Each licensee or registrant shall maintain records specified in RH-1801.i. of equipment problems found in daily visual and operability checks and quarterly inspections of radiographic exposure devices, radiation machines, transport and storage containers, associated equipment, source changers, and survey instruments and retain each record for three (3) years after it is made.

B. The record must include the date of the check or inspection, name of the inspector, equipment involved, any problems found, and what repair ~~and/or~~or maintenance, if any, was done.

8. **Records of alarm system and entrance control checks at permanent radiographic installations**.

Each licensee or registrant shall maintain records of alarm system and entrance control device tests required under RH-1801.j. and retain each record for three (3) years after it is made.

9. **Records of training and certification**.

Each licensee or registrant shall maintain the following records (of training and certification) for three (3) years after the record is made:

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~~RH-1800.d.9. (Cont'd)~~

A. Records of training of each radiographer and each radiographer's assistant. The record must include radiographer certification documents and verification of certification status, copies of written ~~tests~~examinations, and, for practical examinations, dates of ~~oral and practical~~ the examinations, ~~and~~ names of individuals conducting and receiving the ~~oral and practical~~ examinations, a list of items tested, and the results; and

B. Records of annual refresher safety training and semi-annual inspections of job performance for each radiographer and each radiographer's assistant. The records must list the topics discussed during the refresher safety training, the dates the annual refresher safety training was conducted, and the names of the instructors and attendees. For inspections of job performance, the records must also include a list showing the items checked by the Radiation Safety Officer or designee and any non-compliances observed by the Radiation Safety Officer (RSO).

10. **Copies of Operating and Emergency Procedures**.

Each licensee or registrant shall maintain a copy of current operating and emergency procedures until the Department terminates the license or registration. Superseded material must be retained for three (3) years after the change is made.

11. **Records of Personnel Monitoring Procedures**.

Each licensee or registrant shall maintain the following exposure records specified in RH-1802.f.:

A. Direct reading dosimeter readings and yearly operability checks required by RH-1802.f.2. and f.3., respectively, for three (3) years after the record is made.

B. Records of alarming ratemeter calibrations for three (3) years after the record is made.

C. Personnel dosimeter results until the Department terminates the license or registration.

D. Records of estimates of exposures as a result of off-scale personal direct reading dosimeters, or lost or damaged

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personnel dosimeters, until the Department terminates the license or registration.

~~RH-1800.d. (Cont'd)~~

12. **Records of Radiation Surveys**.

Each licensee ~~or registrant~~ shall maintain a record of each exposure device survey conducted before the device is placed in storage as specified in RH-1803.c.3. if that survey is the last one performed in the workday. ~~-~~Each record must be maintained for three (3) years after it is made.

13. **Form of Records**.

Each record required by ~~RH-1800.d.~~ this Part must be legible throughout the specified retention period. ~~-~~The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of reproducing a clear copy throughout the required retention period. ~~-~~The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. ~~-~~Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials, and signatures. ~~-~~The licensee or registrant shall maintain adequate safeguards against tampering with and loss of records.

14. **Location of documents and records**.

A. Each licensee or registrant shall maintain copies of records required by ~~RH-1800.d.~~ this part and other applicable Sections of these ~~r~~Rules at the location specified in ~~the licensee's license application~~RH-1800.b.2.K.

B. Each licensee or registrant shall also maintain copies of the following documents and records sufficient to demonstrate compliance at each applicable field station and each temporary jobsite:

i. The license or ~~certificate of~~ registration authorizing the use of licensed ~~material or x-ray equipment~~or registered sources of radiation.

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ii. A current copy of the Arkansas State Board of Health Rules for Control of Sources of Ionizing Radiation.

iii. Utilization records for each ~~radiographic exposure device~~ source of radiation dispatched from that location as required by RH-1800.d.6.;

iv. Records of equipment problems identified in daily checks of equipment as required by RH-1800.d.7.A;

v. Records of alarm system and entrance control checks as required by RH-1801.j., if applicable.;

vi. Records of direct reading dosimeters such as pocket dosimeter ~~and/or~~ or electronic personal dosimeters readings as required by RH-1800.d.11.~~,~~;

vii. Operating and emergency procedures as required by ~~RH-1802.e.~~ RH-1800.d.10;

viii. Evidence of the latest calibration of the radiation survey instruments in use at the site as required by ~~RH-1801.e.~~1800.d.3.;

ix. Evidence of the latest calibration of alarm rate-meters and operability checks of pocket dosimeters ~~and/or~~ or electronic personal dosimeters as required by RH-1800.d.11.;

x. Latest survey records as required by RH-~~1803.c.~~1800.d.12., and RH-1500.c., as applicable, for the period of operation at the site;

xi. Latest leak test record for devices in use at the site as required by RH-1800.d.4;

xii. The shipping papers for the transportation of radioactive materials as required by RH-3005; and

xiii. When operating under reciprocity pursuant to RH-750., a copy of the Agreement State or U.S. Nuclear Regulatory Commission license, authorizing the use of licensed or registered sources of radiation.

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~~xii. When operating under reciprocity pursuant to RH-750, a copy of the Agreement State or U.S. Nuclear Regulatory Commission license authorizing the use of licensed materials.~~

RH-1801. **Equipment Control**.

a. **Performance requirements for industrial radiography equipment**.

Equipment used in industrial radiographic operations must meet the following minimum criteria:

~~RH-1801.a.. (Cont'd)~~

1. Each radiographic exposure device, source assembly or sealed source, and all associated equipment must meet the requirements specified in American National Standards Institute N432-1980, "Radiological Safety for the Design and Construction of Apparatus for Gamma Radiography," (published as NBS Handbook 136, issued January 1981).

   This publication may be purchased from the American National Standards Institute, Inc., 25 West 43rd Street, New York, New York 10036; Telephone:- (212) 642-4900.

   A copy of the document is available for inspection in the office of the Arkansas Department of Health, Radiation Control, 5800 West 10th Street, Suite 100, Little Rock, Arkansas 72204.

   Engineering analysis may be submitted by an applicant or licensee to demonstrate the applicability of previously performed testing on similar individual radiography equipment components. -Upon review, the Department may find this an acceptable alternative to actual testing of the component pursuant to the above referenced standard.

2. In addition to the requirements specified in ~~RH-1801.~~ paragraph a.1. of this section, the following requirements apply to radiographic exposure devices, source changers, source assemblies and sealed sources.

   A. The licensee shall ensure that each radiographic exposure device has attached to it by the user a durable, legible, clearly visible label bearing the:

      i. Chemical symbol and mass number of the radionuclide in the device;

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ii. Activity and the date on which this activity was last measured;

iii. Model number (or product code) and serial number of the sealed source;

iv. ~~Manufacturer's identity~~Name of the manufacturer of the sealed source; and

v. Licensee's name, address, and telephone number.

~~RH-1801.a. (Cont'd)~~

B. Radiographic exposure devices intended for use as Type B transport containers must meet the applicable requirements of Section 4, "Transportation of Radioactive Materials."

C. Modification of radiographic exposure devices, source changers, source assemblies, and associated equipment is prohibited, unless the design of any replacement component, including the source holder, source assembly, controls or guide tubes would not compromise the design safety features of the system.

3. In addition to the requirements specified in ~~RH-1801.~~a.1. and a.2., the following requirements apply to radiographic exposure devices, source assemblies, and associated equipment that allow the source to be moved out of the device for radiographic operation or to source changers.

A. The coupling between the source assembly and the control cable must be designed in such a manner that the source assembly will not become disconnected if cranked outside the guide tube. -The coupling must be such that it cannot be unintentionally disconnected under normal and reasonably foreseeable abnormal conditions.

B. The device must automatically secure the source assembly when it is cranked back into the fully shielded position within the device. -This securing system may only be released by means of a deliberate operation on the exposure device.

C. The outlet fittings, lock box, and drive cable fittings on each radiographic exposure device must be equipped with

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safety plugs or covers which must be installed during storage and transportation to protect the source assembly from water, mud, sand, or other foreign matter.

D. Each sealed source or source assembly must have attached to it or engraved on it, a durable, legible, visible label with the words "**DANGER – RADIOACTIVE**." The label must not interfere with the safe operation of the exposure device or associated equipment.

~~RH-1801.a.3. (Cont'd)~~

E. The guide tube must be able to withstand a crushing test that closely approximates the crushing forces that are likely to be encountered during use and be able to withstand a kinking resistance test that closely approximates the kinking forces likely to be encountered during use.

F. Guide tubes must be used when moving the source out of the device.

G. An exposure head or similar device designed to prevent the source assembly from passing out of the end of the guide tube must be attached to the outermost end of the guide tube during industrial radiographic operations.

H. The guide tube exposure head connection must be able to withstand the tensile test for control units specified in ANSI N432- 1980.

I. Source changers must provide a system for ensuring that the source will not be accidentally withdrawn from the changer when connecting or disconnecting the drive cable to or from a source assembly.

4. All radiographic exposure devices and associated equipment in use after January 10, 1996 must comply with the requirements of this ~~section~~paragraph.

5. Notwithstanding ~~RH-1801.~~paragraph a.1.of this section, equipment used in industrial radiographic operations need not comply with Section 8.9.2(c) of the Endurance Test in American National Standards Institute N432-1980, if the prototype equipment has been tested using a torque value representative of the torque that an individual using the radiography equipment can realistically exert on the lever or crankshaft of the drive mechanism.

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b. **Limits on external radiation levels from storage containers and source changers**.

The maximum exposure rate limit for storage containers and source changers are 200 millirem (2 millisieverts) per hour at any exterior surface and ten (10) millirem (0.1 millisieverts) per hour at one (1) meter from any exterior surface with the sealed source in the shielded position.

~~RH-1801.b. (Cont'd)~~

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c. **Locking ~~of radiographic exposure devices~~sources of radiation, storage containers, and source changers**.

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1. Each radiographic exposure device must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. ~~-~~The exposure device ~~and/or~~ and its container must be kept locked (and if a keyed-lock, with the key removed at all times) when not under the direct surveillance of a radiographer or a radiographer's assistant except at permanent radiographic installations as in RH-1803.a. ~~-~~In addition, during radiographic operations, the sealed source assembly must be secured in the shielded position each time the source is returned to that position.

2. Each sealed source storage container and source changer must have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position.~~-~~ Storage containers and source changers must be kept locked (and if a keyed-lock, with the key removed at all times) when containing sealed sources except when under the direct surveillance of a radiographer or a radiographer's assistant.

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3. The control panel of each radiation machine shall be equipped with a lock that will prevent ~~the~~ unauthorized use of ~~an x-ray system~~ the machine ~~or~~ and ~~the~~ accidental production of radiation. ~~-~~The radiation machine shall be kept locked (and if a keyed-lock, with the key removed at all times except when under the direct visual surveillance of a radiographer or a radiographer's assistant.

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d. **Additional Sstorage precautions.**

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~~1. Locked radiographic exposure devices, storage containers and radiation machines shall be physically secured to prevent~~

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~~tampering or removal by unauthorized personnel. The licensee shall store radioactive material in a manner which will minimize danger from explosion or fire.~~

~~2~~1. Radiographic exposure devices, source changers, or transport containers that contain radioactive material ~~may~~ shall not be stored in residential locations. ~~-~~ This rule does not apply to storage of radioactive material in a vehicle in transit for use at temporary job sites, if the licensee complies with ~~RH-1801.~~ Paragraph d.~~3~~2 of this section. and if the vehicle does not constitute a permanent storage location as described in ~~RH-1801.~~paragraph d.~~4~~3 of this section.

~~RH-1801.d. (Cont'd)~~

~~3~~2. If a vehicle is to be used for storage of radioactive material, a vehicle survey shall be performed after securing radioactive material in the vehicle and before transport to ensure that radiation levels do not exceed the limits specified in RH-1208. at the exterior surface of the vehicle.

~~4. A storage or use location is permanent if radioactive material is stored or used at the location for more than ninety (90) days and any one (1) or more of the following applies to the location:~~

~~A. Telephone service is established by the licensee;~~

~~B. Industrial radiographic services are advertised for or from the location;~~

~~C. Industrial radiographic operations are conducted at other sites due to arrangements made from the location.~~

e. **Radiation survey instruments**.

1. The licensee or registrant shall keep sufficient calibrated and operable radiation survey instruments at each location where ~~radioactive material or industrial radiographic x-ray equipment~~ sources of radiation ~~is~~ are present to make the radiation surveys as required by this Part and ~~RH-1300~~Section 3 of these Rules.

2. Instrumentation required by this ~~Part~~ paragraph must be capable of measuring a range from two (2) ~~milliroentgens~~ millirems (0.02 millisieverts) per hour through one (1) ~~roentgen~~rem (0.01 sievert) per hour.

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3. The licensee or registrant shall have each radiation survey instrument required in ~~RH-1801.e.1.~~ under paragraph 3.1. of this section calibrated:

A. At energies appropriate for use and ~~A~~at intervals not to exceed six (6) months and after each instrument servicing, except for battery changes;

B. For linear scale instruments, at two (2) points located approximately one-third and two-thirds of full-scale; for logarithmic scale instruments, at midrange of each decade and at two (2) points on at least one decade; and for digital instruments, at three (3) points between 2 and 1000 millirems (0.02 and 10 millisieverts) per hour; and

~~RH-1801.e. (Cont'd)~~

C. So that an accuracy within plus or minus twenty percent (± 20%) of the ~~calibration source~~ true radiation dose rate can be demonstrated at each point checked.

4. The licensee or registrant shall maintain records of the results of these calibrations in accordance with RH-1800.d.3.

5. Each radiation survey instrument shall be checked with a radiation source at the beginning of each day of use and at the beginning of each work shift to ensure it is operating properly.

f. **Leak testing and replacement of sealed sources**.

1. The replacement of any sealed source fastened to or contained in a radiographic exposure device and leak testing of any sealed source must be performed only by persons specifically authorized to do so by the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State.

2. The opening, repair, or modification of any sealed source must be performed only by persons specifically authorized to do so by the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State.

~~RH-1801.f. (Cont'd)~~

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3. **Testing and recordkeeping requirements**.

A. Each licensee who uses a sealed source shall have the source tested for leakage in accordance with RH-1212. and as prescribed in this Part. Tests for leakage must be performed at intervals not to exceed six (6) months. The leak testing of the source must be performed using a method approved by the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State. The wipe sample should be taken from the nearest accessible point to the sealed source where contamination might accumulate. The wipe sample must be analyzed for radioactive contamination. The analysis must be capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample and must be performed by a person specifically authorized by the Department~~, or designee~~, the U.S. Nuclear Regulatory Commission, or an Agreement State to perform the analysis.

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B. The licensee shall maintain records of the leak tests in accordance with RH-1800.d.4.

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C. Unless a sealed source is accompanied by a certificate from the transferor that shows that it has been leak tested within six (6) months before the transfer, it may not be used by the licensee until tested for leakage. Sealed sources that are in storage and not in use do not require leak testing but must be tested before use or transfer to another person if the interval of storage exceeds six (6) months.

4. Any test conducted pursuant to the requirements of ~~RH-1801.~~f.3. of this section which reveals the presence of 0.005 microcurie (185 Bq) or more of removable radioactive material must be considered evidence that the sealed source is leaking. The licensee shall immediately withdraw the equipment involved from use and shall cause it to be decontaminated and repaired or disposed of in accordance with Department rules ~~of the Department~~. A report must be filed with the Department within five (5) days of any test with results that exceed the threshold in this paragraph RH-1801.f.4., describing the equipment involved, the test results, and the corrective action taken.

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5. Each exposure device using depleted uranium (DU) shielding and an "S" tube configuration must be tested for DU contamination at intervals not to exceed twelve (12) months. The analysis must be

capable of detecting the presence of 0.005 microcurie (185 Bq) of radioactive material on the test sample and must be performed by a person specifically authorized by the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State to perform the analysis.

Should such testing reveal the presence of 0.005 microcurie (185 Bq) or more of removable DU contamination, the exposure device must be removed from use until an evaluation of the wear on the S-tube has been made. –Should the evaluation reveal that the S-tube is worn through, the device may not be used again. -DU shielded devices do not have to be tested for DU contamination while in storage and not in use. –Before using or transferring such a device however, the device must be tested for DU contamination if the interval of storage exceeds twelve (12) months. –A record of the DU leak test must be made in accordance with RH-1800.d.4.

~~RH-1801. (Cont'd)~~

g. **Quarterly inventory**.

1. Each licensee or registrant shall conduct a quarterly physical inventory to account for all ~~sealed~~ sources of radiation, and for devices containing depleted uranium (DU) received and possessed under ~~this~~ the license.

2 The licensee or registrant shall maintain records of the quarterly inventory in accordance with RH-1800.d.5.

~~h. **Utilization logs.**~~

~~Each licensee or registrant shall maintain current logs, which shall be kept available for inspection by the Department, showing for each source of radiation the following information:~~

~~1. A description, including the make, model and serial number of each radiation machine, each radiographic exposure device or transport or storage container in which a sealed source is located, and each sealed source;~~

~~2. The identity and signature of the radiographer to whom assigned;~~

~~3. Locations where used and dates of use; and~~

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~~4. The date(s) each source of radiation is removed from storage and returned to storage.~~

~~i~~h. **Inspection and maintenance of radiographic exposure devices, radiation machines, transport and storage containers, associated equipment, source changers, and survey instruments**.

1. The licensee or registrant shall perform visual and operability checks on survey ~~meters~~instruments, radiographic exposure devices, radiation machines, transport and storage containers, associated equipment, and source changers, ~~and shutters on x-ray units~~ before ~~use on~~ each day of use, or work shift, ~~the equipment is used~~ to ensure that the equipment is in good working condition, that the sources are adequately shielded, and that required labeling is present. ~~-~~Survey instrument operability must be performed using check sources or other appropriate means.~~-~~ If equipment problems are found, the equipment must be removed from service until repaired.

~~RH-1801.i. (Cont'd)~~

2. Each licensee or registrant shall have written procedures for:

   A. Inspection and routine maintenance of radiographic exposure devices, radiation machines,~~source changers, associated equipment,~~ transport and storage containers, associated equipment source changers and survey instruments at intervals not to exceed three (3) months or before the first use thereafter to ensure the proper functioning of components important to safety.

      Replacement components shall meet design specifications. If equipment problems are found, the equipment must be removed from service until repaired.

   B. Inspection and maintenance necessary to maintain the Type B packaging used to transport radioactive materials. ~~-~~The inspection and maintenance program must include procedures to assure that Type B packages are shipped and maintained in accordance with the Certificate of Compliance or other approval.

3. ~~C.~~ Records of equipment problems and of any maintenance performed under ~~RH-1801.i.1.and i.2.~~ paragraphs h.1. and h.2. of this section must be made in accordance with RH-1800.d.7.

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~~j~~i. **Permanent radiographic installations**.

1. Each entrance that is used for personnel access to the high radiation area in a permanent radiographic installation must have either:

   A. An entrance control of the type described in RH-1303.c.2.A. that causes ~~reduces~~ the radiation level upon entry into the area to be reduced, or

   B. Both conspicuous visible and audible warning signals to warn of the presence of radiation. ~~-~~The visible signal must be activated by radiation whenever the source is exposed or the machine is energized.~~-~~ The audible signal must be actuated when an attempt is made to enter the installation while the source is exposed or the machine is energized.

~~RH-1801. (Cont'd)~~

2. The alarm system must be tested for proper operation with a radiation source each day before the installation is used for radiographic operations. ~~-~~The test must include a check of both the visible and audible signals.~~-~~ Entrance control devices that reduce the radiation level upon entry (designated in ~~RH-1801.~~paragraph ji.1.A.of this section) must be tested monthly.~~-~~ If an entrance control device or an alarm is operating improperly, it must be immediately labeled as defective and repaired within seven (7) calendar days.

   The facility may continue to be used during this seven (7) day period, provided the licensee or registrant implements the continuous surveillance requirements of RH-1803.a. and uses an alarming ratemeter. ~~-~~Alarming ratemeter use must be in accordance with Part I of Section 3 requirements. Test records for entrance controls and audible and visual alarm must be maintained in accordance with RH-1800.d.8.
   ~~RH-1800.d.8.~~

~~k~~j. **Notifications**.

1. In addition to the reporting requirements specified in RH-601. and under other Sections, each licensee or registrant shall provide a written report to the Arkansas Department of Health, Radiation

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Control Section, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867 within thirty (30) days of the occurrence of any of the following incidents involving radiographic equipment:

A. Unintentional disconnection of the source assembly from the control cable~~.~~;

B. Inability to retract the source assembly to its fully shielded position and secure it in this position~~.~~;

C. Failure of any component (critical to safe operation of the device) to properly perform its intended function~~.~~; or

D. An indicator on a radiation machine fails to show that radiation is being produced, an exposure switch fails to terminate production of radiation when turned to the "**OFF**" position, or a safety interlock fails to terminate x-ray production.

2. The licensee or registrant shall include the following information in each report submitted under ~~RH-1801.~~ Paragraph ~~k~~j.1. of this section and in each report of overexposure submitted under RH-1504. which involves failure of safety components of radiography equipment:

~~RH-1801.k.2. (Cont'd)~~

A. A description of the equipment problem~~.~~;

B. Cause of each incident, if known~~.~~;

C. Name of the manufacturer and model number of equipment involved in the incident~~.~~;

D. Place, time, and date of the incident~~.~~;

E. Actions taken to establish normal operations~~.~~;

F. Corrective actions taken or planned to prevent recurrence~~.~~; and

G. Qualifications of personnel involved in the incident.

3. Any licensee or registrant conducting radiographic operations or storing radioactive material at any location not listed on the license or registration for a period in excess of 180 days in a calendar year, shall notify the Department prior to exceeding the 180 days.

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~~l~~k. **Labeling, storage, and transportation**.

1. The licensee may not use a source changer or a container to store radioactive material unless the source changer or the storage container has securely attached to it a durable, legible, and clearly visible label bearing the standard trefoil radiation caution symbol in conventional colors, i.e., magenta, purple or black on a yellow background having a minimum diameter of 25 mm, and the wording

"**CAUTION**,*
RADIOACTIVE MATERIAL,
NOTIFY CIVIL AUTHORITIES [or name of company]."

*or **DANGER**

2. The licensee may not transport ~~licensed~~ radioactive material unless the material is packaged, and the package is labeled, marked, and accompanied with appropriate shipping papers in accordance with rules set forth in Section 4, "Transportation of Radioactive Materials."

~~RH-1801. (Cont'd)~~

3. ~~Locked r~~Radiographic exposure devices, storage containers, source changers and radiation machines must be physically secured to prevent tampering or removal by unauthorized personnel.~~-~~ The licensee shall store radioactive material in a manner ~~which~~ that will minimize danger from explosion or fire.

4. The licensee shall lock and physically secure the transport package containing radioactive material in the transport vehicle to prevent accidental loss, tampering, or unauthorized removal of the radioactive material from the vehicle.

RH-1802. **Personnel Radiation Safety Requirements for Radiographers and Radiographer's Assistants**.

a. **Conducting industrial radiographic operations**.

1. Whenever radiography is performed at a location other than a permanent radiographic installation, the radiographer must be accompanied by at least one other qualified radiographer or an individual who has at a minimum met the requirements of

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RH-1802.b.3. The additional qualified individual shall observe the operations and be capable of providing immediate assistance to prevent unauthorized entry. Radiography may not be performed if only one (1) qualified individual is present.

2. All radiographic operations conducted at locations of use authorized on the license or ~~on the x-ray~~ registration must be conducted in a permanent radiographic installation, unless specifically authorized by the Department.

3. A licensee or registrant may conduct lay-barge or underwater radiography only if the procedures have been approved by the Department, by a State or an Agreement State, as applicable or by the U.S. Nuclear Regulatory Commission.

b. **Training**.

1. The licensee or registrant may not permit any individual to act as a radiographer until the individual has received training in the subjects outlined in RH-1804., in addition to ~~a minimum of two (2) months of~~ on-the-job training consisting of hands-on experience under the supervision of a radiographer, and is certified through a radiographer certification program by a ~~e~~Certifying ~~e~~Entity in accordance with the criteria specified in Schedule B to Section 3. The on-the-job training shall include a minimum of two (2) months (320 hours) of active participation in the performance of industrial radiography utilizing radioactive material or one (1) month (160 hours) of active participation in the performance of industrial radiography utilizing radiation machines, as applicable. Individuals performing industrial radiography utilizing radioactive materials and radiation machines must complete both segments of the on-the-job training (3 months or 480 hours).

~~RH-1802.b. (Cont'd)~~

2. In addition, the licensee or registrant may not permit any individual to act as a radiographer until the individual:

A. Has received copies of and instructions in the requirements described in rules contained in this Part; in RH-106. And RH-107., or RH-7 and RH-8., as applicable; in the applicable sections of Section 3, "Standards for Protection Against Radiation," (including its Part N, "Notices, Instructions, and Reports to Workers; Inspections"); in applicable U.S. Department of Transportation ~~(DOT)~~ regulations as referenced in Section 4 of these Rules ~~and the U.S. Nuclear Regulatory Commission's (NRC) 10 CFR~~

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~~Part 71~~; in the ~~Department~~ license~~(s)~~ or registration under which the radiographer will perform industrial radiography; and the licensee's or registrant's operating and emergency procedures;

B. Has demonstrated an understanding of ~~the licensee's license and the licensee's or registrant's operating and emergency procedures~~ items in paragraph b.2.A of this section by successful completion of a written or oral examination covering this material.~~.~~;

C. Has received training in the use of the licensee's or registrant's radiographic exposure devices, sealed sources, radiation machines, in the daily inspection of devices and associated equipment, and in the use of radiation survey instruments~~.~~; and

D. Has demonstrated understanding of the use of ~~radiographic exposure devices, sources, survey instruments and associated~~ the equipment described ~~above in RH-1802.b.2.A. and RH-1802.~~Paragraphs b.2.A and b.2.C. of this section by the successful completion of a practical examination covering this material.

3. The licensee or registrant may not permit any individual to act as a radiographer's assistant until the individual:

A. ~~A.~~ Has received copies of and instructions in the requirements described in rules contained in this Part; in RH-106. And RH-107.; or RH-7. And RH-8., as applicable; in the applicable sections of Section 3, "Standards for Protection Against Radiation," (including its Part N, "Notices, Instructions, and Reports to Workers; Inspections"); in applicable U.S. Department of Transportation ~~(DOT)~~ regulations as referenced in Section 4 of these Rules ~~and the U.S. Nuclear Regulatory Commission's (NRC) 10 CFR Part 71;~~ in the ~~Department~~ license~~(s)~~ or registration under which the radiographer's assistant will perform industrial radiography; and the licensee's or registrant's operating and emergency procedures;

B. Has demonstrated an understanding of items in paragraph b.3.A. of this section by successful completion of a written examination covering this material;

~~RH-1802.b.3. (Cont'd)~~

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~~B~~C. Has developed competence ~~in the~~ to use, under the personal supervision of the radiographer, the radiation machines or radiographic exposure devices, sealed sources, associated equipment, and radiation survey instruments that the assistant will use; and

D. ~~C. Has demonstrated understanding of the instructions provided above in RH-1802.b.3.A. by the successful completion of a written test on the subjects covered and~~ hHas demonstrated ~~competence in~~ understanding of the use of ~~hardware~~ the equipment described in ~~RH-1802.~~paragraph b.3.~~B~~C. of this section by the successful completion of a practical examination ~~on the use of such hardware~~covering this material.

4. The licensee or registrant shall provide annual refresher safety training for each radiographer and radiographer's assistant at intervals not to exceed twelve (12) months.

5. A. Except as provided in ~~RH-1802.~~paragraph b.5.~~D~~C. of this section, the Radiation Safety Officer (RSO) or designee shall conduct an inspection program of the job performance of each radiographer and radiographer's assistant to ensure that the Department's rules, license or registration requirements, and ~~the applicant's~~ operating and emergency procedures are followed. ~~-~~ The inspection program must:

~~A~~i. Include observation of the performance of each radiographer and radiographer's assistant during an actual industrial radiographic operation, at intervals not to exceed six (6) months; and

~~B~~ii. Provide that, if a radiographer or radiographer's assistant has not participated in an industrial radiographic operation for more than six (6) months since the last inspection, the radiographer must demonstrate knowledge of the training requirements of ~~RH-1802.~~paragraph b.2.C. if this section, and the radiographer's assistant must ~~re-~~demonstrate knowledge of the training requirements of ~~RH-1802.~~paragraph b.3.~~B~~C. of this section~~,~~ by a practical examination before these individuals can next participate in a radiographic operation.

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~~C~~B. The Department may consider alternatives in those situations where the individual serves as both radiographer and RSO.

~~D~~C. In those operations where a single individual serves as both radiographer and RSO, and performs all radiography operations, an inspection program is not required.

~~RH-1802.b. (Cont'd)~~

6. The licensee or registrant shall maintain records of the above training to include certification documents, written and practical examinations, refresher safety training and inspections of job performance in accordance with RH-1800.d.9.

~~7. The licensee or registrant shall include the subjects detailed in RH-1804.~~

~~8. Records of radiographer certification maintained in accordance with RH-1800.d.9.A. provide appropriate affirmation of certification requirements specified in RH-1802.b.1.~~

~~c. **Radiographer certificate card confiscation.**~~

~~The Department may confiscate any radiographer's certification card should there be serious health and safety violations relating to the rules, license conditions, and/or licensee operating and emergency procedures. The radiographer will be restricted from conducting radiographic operations within the State of Arkansas.~~

~~1. Following the confiscation of the radiographer's certification card, the conduct of any radiographic operations by this radiographer within the State of Arkansas shall be deemed deliberate misconduct as detailed in RH-107.~~

~~2. The Department shall notify the licensee's management and the Certifying Entity of the certification card confiscation and the restrictions placed on the radiographer.~~

~~3. The Department shall return the Certification Card when the radiographer has been satisfactorily retrained and/or recertified by a Certifying Entity.~~

~~d~~c. **Radiation Safety Officer for industrial radiography**.

The Radiation Safety Officer (RSO) shall ensure that radiation safety activities are being performed in accordance with approved procedures

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and regulatory requirements in the daily operation of the licensee's or registrant's program.

~~RH-1802. (Cont'd)~~

1. The minimum qualifications, training, and experience of ~~Radiation Safety Officers (~~RSOs~~)~~ for industrial radiography are as follows:

   A. Completion of the training and testing requirements of ~~RH-1802.b.1.~~paragraphs b.1 and b.2. of RH-1802.;

   B. 2000 hours of hands-on experience as a qualified radiographer in industrial radiographic operations; and

   C. Formal training in the establishment and maintenance of a radiation protection program.

2. The Department will consider alternatives when the RSO has appropriate training ~~and/or~~ and experience in the field of ionizing radiation, and in addition, has adequate formal training with respect to the establishment and maintenance of a radiation safety protection program.

3. The specific duties and authorities of the RSO include, but are not limited to:

   A. Establishing and overseeing all operating, emergency, and ALARA procedures as required by ~~this~~ Section 3, "Standards for Protection Against Radiation," and reviewing them regularly to ensure that the procedures in use conform to current Section 3 procedures, conform to other Department rules, and to the license or registration conditions~~.~~;

   B. Overseeing and approving all phases of the training program for radiographic personnel, ensuring that appropriate and effective radiation protection practices are taught;

   C. Ensuring that required radiation surveys and leak tests are performed and documented in accordance with the rules, including any corrective measures when levels of radiation exceed established limits;

   D. Ensuring that personnel monitoring devices are calibrated, if applicable, and used properly by occupationally exposed

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personnel, that records are kept of the monitoring results, and that timely notifications are made as required by RH-1504.; and

~~RH-1802.d.3. (Cont'd)~~

E. Ensuring that operations are conducted safely and to assume control for instituting corrective actions including stopping of operations when necessary.

~~e~~d. **Operating and emergency procedures**.

1. The licensee's or registrant's operating and emergency procedures must include as a minimum, instructions in the following:

A. Appropriate handling and use of licensed ~~sealed sources, radiographic exposure devices, and x-ray equipment (if used)~~ or registered sources of radiation so that no person is likely to be exposed to radiation doses in excess of the limits established in Part C of ~~this~~ Section 3, "Standards for Protection Against Radiation";

B. Methods and occasions for conducting radiation surveys;

C. Methods for posting and controlling access to radiographic areas;

D. Methods and occasions for locking and securing radiation machines, radiographic exposure devices, transport and storage containers and sealed sources;

E. Personnel monitoring and the use of personnel monitoring equipment;

F. Transporting sealed sources to field locations, including packing of radiographic exposure devices and storage containers in the vehicles, placarding of vehicles when needed, and control of the sealed sources during transportation~~.~~ as described in Section 4 of these Rules:

G. The inspection, maintenance, and operability checks of radiographic exposure devices, radiation machines, ~~survey instruments,~~ transport containers, ~~and~~ storage containers, associated equipment, source changers, and survey instruments;

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H. Steps that must be taken immediately by radiography personnel in the event a pocket dosimeter is found to be off-scale or an alarming ratemeter alarms unexpectedly~~.~~;

I. The procedure for reporting component failures as required by RH-1801.j.1.;

~~I~~J. The procedure for notifying proper persons in the event of an accident;

~~RH-1802.e.1. (Cont'd)~~

~~J~~K. Minimizing exposure of persons in the event of an accident, including a source disconnect, a transportation accident, or loss of a source of radiation;

~~K~~L. Source recovery procedure if licensee will perform source recovery; and

~~L~~M. Maintenance of records.

2. The licensee or registrant shall maintain copies of current operating and emergency procedures in accordance with RH-1800.d.10.and RH-1800.d.14.

~~f~~e. **Personnel monitoring**.

1. A licensee or registrant may not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, each individual wears, on the trunk of the body, a combination of a direct reading pocket dosimeter, an operable alarming ratemeter, and a personnel dosimeter.~~-~~ At permanent radiographic installations where other appropriate alarming or warning devices are in routine use, the wearing of an alarming ratemeter is not required.

   A. Pocket dosimeters shall have a range from zero to 200 millirems (2 millisieverts) and must be recharged at the start of each shift. ~~-~~Electronic personal dosimeters may only be used in place of ion-chamber pocket dosimeters.

   B. Each personnel dosimeter must be assigned to and worn by only one (1) individual.

   C. Personnel dosimeters that require replacement must be replaced at periods not to exceed one (1) month. ~~-~~All

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personnel dosimeters must be evaluated at periods not to exceed one (1) month.

D. After replacement, each personnel dosimeter must be processed as soon as possible.

2. Direct reading dosimeters such as pocket dosimeters or electronic personal dosimeters, must be read and the exposures recorded at the beginning and end of each shift, and records must be maintained in accordance with RH-1800.d.11.

~~RH-1802.f. (Cont'd)~~

3. Pocket dosimeters, or electronic personal dosimeters, must be checked at periods not to exceed twelve (12) months for correct response to radiation, and records must be maintained in accordance with RH-1800.d.11. ~~-~~Acceptable dosimeters shall be read within plus or minus twenty percent (± 20%) of the true radiation exposure.

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4. If an individual's pocket dosimeter is found to be off-scale, or if his or her electronic personal dosimeter reads greater than 200 millirems (2 millisieverts), and the possibility of radiation exposure cannot be ruled out as the cause, the individual's personnel dosimeter that requires processing must be sent for processing and evaluation within twenty-four (24) hours. ~~-~~For personnel dosimeters that do not require processing, evaluation of the dosimeter must be started within twenty-four (24) hours.~~-~~ In addition, the individual may not resume work associated with licensed or registered sources of radiation until a determination of the individual's radiation dose has been made. ~~-~~This determination must be made by the Radiation Safety Officer (RSO) or the RSO's designee. ~~-~~The results of this determination must be included in the records maintained in accordance with RH-1800.d.11.

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5. Dosimetry results must be retained in accordance with RH-1800.d.11.

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6. If a personnel dosimeter that is required by RH-1802.~~f~~e.1. is lost or damaged, the worker shall cease work immediately until a replacement personnel dosimeter meeting the requirements in RH-1802.~~f.~~e.1. is provided and the exposure is calculated for the time period from issuance to loss or damage of the personnel dosimeter.

-The results of the calculated exposure and the time period for which the personnel dosimeter was lost or damaged must be included in the records maintained in accordance with RH-1800.d.11.

7. Each alarming ratemeter shall:

A. Be checked without being exposed to radiation prior to use at the start of each work shift, to ensure that the audible alarm is functioning properly;

~~RH-1802.f. (Cont'd)~~

B. Have an audible alarm sufficient to be heard by the individual wearing the alarming ratemeter or have other visual or physical notification of alarming conditions;

C. Be set to give an alarm signal at a preset dose rate of 500 mrem/hr (5 mSv/hr) or lower with an accuracy of plus or minus twenty percent (± 20%) of the true radiation dose rate;

D. Require special means to change the preset alarm function; and

E. Be calibrated for correct response to radiation at intervals not to exceed twelve (12) months. -The licensee or registrant shall maintain records of alarming ratemeter calibrations in accordance with RH-1800.d.11.

~~f~~g. **Reciprocity of a radiographer certification**.

1. Reciprocal recognition by the Department of an individual radiographer certification will be granted provided that:

A. The individual holds a valid certification in the appropriate category issued by a ~~e~~Certifying ~~e~~Entity, as defined in RH-1800.c.;

B. The requirements and procedures of the ~~e~~Certifying ~~e~~Entity issuing the certification affords the same or comparable certification standards as those afforded by RH-1802.b.1.; and

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C. The individual presents the certification to the Department prior to entry into the State.

2. The Department may withdraw, limit, or qualify its acceptance of any individual radiographer certification based on enforcement actions with the Department, another State or Agreement State, as applicable, or the U.S. Nuclear Regulatory Commission or on sanctions by an independent ~~e~~Certifying ~~e~~Entity in order to prevent undue hazard to public health and safety or property.

~~RH-1802.g. (Cont'd)~~

3. Certified individuals who are granted reciprocity by the Department shall maintain the certification upon which the reciprocal recognition was granted, or prior to the expiration of such certification, shall meet the requirements of RH-1802.b.1.

RH-1803. **Precautionary Procedures in Radiographic Operations**.

a. **Surveillance**.

During each radiographic operation, the radiographer or the other individual present as required in RH-1802.a. shall maintain continuous, direct visual surveillance of the operation to protect against unauthorized entry into a high radiation area, as defined in Section 3~~, Part D, RH-1303.c.~~ of these Rules, except at permanent radiographic installations where all entryways are locked and the requirements of RH-1801.ji. are met.

b. **Posting.**

All areas in which industrial radiography is being performed must be conspicuously posted as required by RH-1303.b.1. and b.2. ~~-~~Exceptions listed in RH-1304. do not apply to industrial radiographic operations.

c. **Radiation surveys**.

The licensee or registrant shall:

1. Conduct all surveys with a calibrated and operable radiation survey instrument that meets the requirements of RH-1801.e.;

2. ~~Using a survey instrument meeting the requirement of RH-1803.c.1. above, c~~Conduct a survey of the radiographic exposure device and the guide tube after each exposure when approaching

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the device or the guide tube. -The survey must determine that the sealed source has been returned to its shielded position before exchanging films, repositioning the exposure head, or dismantling equipment. -Radiation machines shall be surveyed after each exposure to determine that the machine is off.;

3. Conduct a survey of the radiographic exposure device ~~with a calibrated radiation survey instrument any time~~ whenever the source is exchanged and whenever a radiographic exposure device is placed in a storage area (as defined in RH-1800.c.), to ensure that the sealed source is in its shielded position.; and

~~RH-1803.c. (Cont'd)~~

4. Maintain records in accordance with RH-1800.d.12.

d. **Supervision of radiographer's assistants**.

Whenever a radiographer's assistant uses radiographic exposure devices, radiation machines, associated equipment, or sealed sources or conducts radiation surveys required by RH-1803.c.2. to determine that the sealed source has returned to the shielded position, or that the radiation machine is off, after an exposure, the assistant shall be under the personal supervision of a radiographer. –The personal supervision shall include:

1. The radiographer's physical presence at the site where the ~~sealed sources~~ sources of radiation are being used.;

2. The availability of the radiographer to give immediate assistance if required.; and

3. The radiographer's direct observation of the assistant's performance of the operations referred to in this ~~section~~ paragraph.

e. Deleted. See RH-1800.d.14 ~~**Records required at temporary job sites**.~~

~~Each licensee or registrant conducting industrial radiography at temporary job sites shall have the following records available at that site for inspection by the Department:~~

~~1. Current copy of appropriate license, certificate of registration or an equivalent document.~~

~~2. Operating and emergency procedures.~~

~~3. Applicable rules.~~

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~~4. Survey records required pursuant to RH-1803.e. for the period of operation at the site.~~

~~5. Daily pocket dosimeter records for the period of operation at the site.~~

~~6. The latest instrument calibration and leak test record for specific devices in use at the site.~~

~~RH-1803. (Cont'd)~~

f. **Specific requirements for radiographic personnel performing industrial radiography**.

1. At a job site, the following shall be supplied by the licensee or registrant:

A. At least one operable, calibrated survey instrument for each exposure device or radiation machine in use;

B. A current whole-body personnel dosimeter for each individual performing radiographic operations;

C. An operable, calibrated direct reading dosimeter for each individual performing radiographic operations;

D. An operable, calibrated alarming ratemeter for each individual performing radiographic operations; and

E. The appropriate barrier ropes and signs.

2. Each radiographer shall have available at the job site a valid certification ID card issued by a Certifying Entity.

3. Industrial radiographic operations shall not be performed if any of the items in paragraphs f.1. and f.2. of this section are not available at the job site or are inoperable.

4. During an inspection by the Department, the inspector may terminate an operation if any of the items in paragraphs f.1. and f.2. of this section are not available and operable, or if the required number of radiographic personnel are not present. ~~-~~Operations shall not be resumed until all required conditions are met.

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~~g. **Special requirements and exemptions for enclosed radiography.**~~

~~1. **Cabinet x-ray systems.**~~

~~A. **Emission limit.**~~

~~i. Radiation emitted from the cabinet x-ray system shall not exceed an exposure of 0.5 milliroentgen in one hour at any point five (5) centimeters outside the external surface.~~

~~RH-1803.g. (Cont'd)~~

~~ii. Compliance with the exposure limit in RH-1803.g.1.A.i. of this section shall be determined by measurements averaged over a cross-sectional area of 10 (ten) square centimeters with no linear dimension greater than five (5) centimeters, with the cabinet x-ray system operated at those combinations of x-ray tube potential, current, beam orientation and conditions of scatter radiation which produce the maximum x-ray exposure at the external surface and with the door(s) and access panel(s) fully closed as well as fixed at any other position(s) which will allow the generation of x-radiation.~~

~~B. **Floors.**~~

~~A cabinet x-ray system shall have a permanent floor. Any support surface to which a cabinet x-ray system is permanently affixed may be deemed the floor of the system.~~

~~C. **Ports and apertures.**~~

~~i. The insertion of any part of the human body through any port into the primary beam shall not be possible.~~

~~ii. The insertion of any part of the human body through any aperture shall not be possible.~~

~~D. **Safety interlocks.**~~

~~i. Each door of a cabinet x-ray system shall have a minimum of two (2) safety interlocks. One (1), but not both, of the required interlocks shall be such that door opening results in physical disconnection of the energy supply circuit to the high-voltage generator, and such disconnection shall not be dependent upon any moving part other than the door.~~

~~ii. Each access panel shall have at least one safety interlock.~~

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~~iii. Following interruption of x-ray generation by the functioning of any safety interlock, use of a control provided in accordance with RH-1803.g.1.F. shall be necessary for resumption of x-ray generation.~~

~~iv. Failure of any single component of the cabinet x-ray system shall not cause failure of more than one (1) required safety interlock.~~

~~E. **Ground fault.**~~

~~A ground fault shall not result in the generation of x-rays.~~

~~F. **Controls and indicators for all cabinet x-ray systems.**~~

~~For all systems to which this section is applicable, there shall be provided:~~

~~i. A key-actuated control to insure that x-ray generation is not possible with the key removed.~~

~~ii. A control or controls to initiate and terminate the generation of x-rays other than by functioning of a safety interlock or the main power control.~~

~~iii. Two independent means which indicate when and only when x-rays are being generated, unless the x-ray generation period is less than one-half second, in which case the indicators shall be activated for one-half second, and which are discernible from any point at which initiation of x-ray generation is possible. Failure of a single component of the cabinet x-ray system shall not cause failure of both indicators to perform their intended function. One, but not both, of the indicators required by this subdivision may be a milliammeter labeled to indicate x-ray tube current. All other indicators shall be legibly labeled "**X-RAY ON**."~~

~~RH-1803.g.1.F. (Cont'd)~~

~~iv. Additional means other than milliammeters which indicate when and only when x-rays are being generated,~~

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unless the x-ray generation period is less than one-half second, in which case the indicators shall be activated for one-half second, as needed to ensure that at least one indicator is visible from each door, access panel and port and is legibly labeled "**X-RAY ON**."

G. **Additional controls and indicators for cabinet x-ray systems designed to admit humans**.

For cabinet x-ray systems designed to admit humans, there shall also be provided:

i. Compliance with all applicable requirements of this Part and RH-1208. If such a system is a certified cabinet x-ray system, it shall comply with all applicable requirements of this Part and 21 CFR 1020.40.

ii. Evaluation at intervals not to exceed one (1) year to assure compliance with the applicable requirements as specified in RH-1803.g.1.A. Records of these evaluations shall be maintained for inspection by the Department for a period of (5) years after the evaluation.

iii. A control within the cabinet for preventing and terminating x-ray generation, which cannot be reset, over-ridden or bypassed from the outside of the cabinet.

iv. No means by which x-ray generation can be initiated from within the cabinet.

v. Audible and visible warning signals within the cabinet which are actuated for at least ten (10) seconds immediately prior to the first initiation of x-ray generation after closing any door designed to admit humans. Failure of any single component of the cabinet x-ray system shall not cause failure of both the audible and visible warning signals.

RH-1803.g.1.G. (Cont'd)

vi. A visible warning signal within the cabinet which remains actuated when and only when x-rays are being generated, unless the x-ray generation period

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is less than one-half second, in which case the indicators shall be activated for one-half second.

vii. Signs indicating the meaning of the warning signals provided pursuant to RH-1803.g.1.G.v. and vi. and containing instructions for the use of the control provided pursuant to RH-1803.g.1.G.iii. These signs shall be legible, accessible to view and illuminated when the main power control is in the "**on**" position.

H. **Warning labels**.

i. There shall be permanently affixed or inscribed on the cabinet x-ray system at the location of any controls which can be used to initiate x-ray generation, a clearly legible and visible label bearing the statement:

CAUTION:
X-RAYS PRODUCED WHEN ENERGIZED

ii. There shall be permanently affixed or inscribed on the cabinet x-ray system at the location of any controls which can be used to initiate x-ray generation, a clearly legible and visible label bearing the statement:

CAUTION:
DO NOT INSERT ANY PART OF THE BODY
WHEN SYSTEM IS ENERGIZED--
X-RAY HAZARD

RH-1803.g.1.H. (Cont'd)

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I. **Instructions**.

i. Manufacturers of cabinet x-ray systems shall provide for purchasers and to others upon request at a cost not to exceed the cost of preparation and distribution, manuals and instructions which shall include at least the following technical and safety information: Potential, current and duty cycle ratings of the x-ray generation equipment; adequate instructions concerning any radiological safety

procedures and precautions which may be necessary because of unique features of the system; and a schedule of maintenance necessary to keep the system in compliance with this section.

ii. Manufacturers of cabinet x-ray systems which are intended to be assembled or installed by the purchaser, shall provide instructions for assembly, installation, adjustment and testing of the cabinet x-ray system adequate to assure the system is in compliance with applicable provisions of this section when assembled, installed, adjusted and tested as directed.

J. **Additional requirements for x-ray baggage inspection systems.**

X-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad and bus terminals and at similar facilities, shall be provided with means, pursuant to RH-1803.g.1.J.i. and ii., to insure operator presence at the control area in a position which permits surveillance of the ports and doors during generation of x-radiation.

i. During an exposure or preset succession of exposures of one-half second or greater duration, the means provided shall enable the operator to terminate the exposure or preset succession of exposures at any time.

RH-1803.g.1. (Cont'd)

ii. During an exposure or preset succession of exposures of less than one-half second or greater duration, the means provided may allow completion of the exposure in progress but shall enable the operator to prevent additional exposures.

2. **Cabinet Radiography.**

Cabinet radiography units are exempt from other requirements of this Part; however,

A. No licensee or registrant shall permit any individual to operate a cabinet radiography unit until such individual has received a copy of, and instruction in, and has

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demonstrated an understanding of operating procedures for the unit, and has demonstrated competence in its use.

B. A cabinet radiography unit shall not be operated until a physical radiation survey of the unit and areas adjacent to the unit has been performed. The licensee or registrant shall perform the survey with a properly calibrated instrument as described in RH-1803.c. to determine conformance with RH-1200.

C. The registrant shall perform an evaluation, at intervals not to exceed one (1) year, to determine conformance with Part C of Section 3. If such a system is a certified cabinet x-ray system, it shall be evaluated at intervals not to exceed (1) year to determine conformance with 21 CFR 1020.40. Records of these evaluations shall be maintained for inspection by the Department for a period of five (5) years after the evaluation.

D. The operating personnel must be provided with either a film badge or a thermoluminescent dosimeter, and reports of the results must be maintained for inspection by the Department.

E. Tests for proper operation of high radiation control devices or alarm systems must be conducted and recorded in accordance with RH-1801.i.

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3. **Shielded room radiography.**

Shielded room radiography shall comply with all applicable requirements of this Part.

4. Certified cabinet x-ray systems shall be maintained in compliance with 21 CFR 1020.40 unless prior approval has been granted by the Department pursuant to RH-55.

g. **Prohibitions.**

Industrial radiography performed with a sealed source which is not fastened to or contained in a radiographic exposure device (fish pole technique) is prohibited unless specifically authorized in a license issued by the Department.

RH-1804. **Subjects to be Covered During the Instruction of Radiographers**.

a. **Fundamentals of radiation safety including~~.~~:**

1. Characteristics of gamma ~~and/or~~ or x-ray radiation~~.~~;

2. Units of radiation dose and quantity of radioactivity~~.~~;

3. Hazards of exposure to radiation~~.~~;

4. Levels of radiation from licensed or registered sources of radiation~~.~~; and

5. Methods of controlling radiation dose (time, distance, and shielding)~~.~~;

~~A. Time.~~

~~B. Distance.~~

~~C. Shielding.~~

b. **Radiation detection instruments including~~.~~:**

1. Use, operation, calibration, and limitations of radiation survey instruments~~.~~;

~~A. Operation.~~

~~B. Calibration.~~

~~RH-1804. (Cont'd)~~

~~C. Limitations.~~

2. Survey techniques~~.~~; and

3. Use of personnel monitoring equipment~~.~~;

~~A. Film badges.~~

~~B. Thermoluminescent dosimeters (TLDs).~~

~~C. Optically Stimulated Luminescent dosimeters.~~

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~~D. Pocket dosimeters.~~

~~E. Alarm ratemeters.~~

c. **Equipment to be used including~~.~~;**

1. Operation and control of radiographic exposure equipment, remote handling equipment, and storage containers, including pictures or models of source assemblies (pigtails), as applicable;

2. Operation and control of radiation machines, as applicable;

~~2~~3. Storage, control, and disposal of licensed ~~material~~ or registered sources of radiation~~.~~; and

~~3~~4. Inspection and maintenance of equipment~~.~~;

~~4. Operation and control of x-ray equipment if applicable.~~

~~5. Collimators.~~

d. The requirements of pertinent Federal and State regulations~~.~~;

~~e. The licensee's or registrant's written operating and emergency procedures.~~

~~f~~e. Case histories of accidents in radiography.

RH-1805.- RH-1899.~~–~~ _Reserved.

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SCHEDULE B TO SECTION 3

RADIOGRAPH~~IC~~ER CERTIFICATION

I. **Requirements for an Independent Certifying Organization**.

An independent certifying organization shall:

1. Be an organization such as a society or association, whose members participate in, or have an interest in, the fields of industrial radiography;

2. Make its membership available to the general public nationwide. Membership shall ~~that is~~ not be restricted because of race, color, religion, sex, age, national origin or disability;

3. Have a certification program open to nonmembers, as well as members;

4. Be an incorporated, nationally recognized organization, that is involved in setting national standards of practice within its fields of expertise;

5. Have an adequate staff, a viable system for financing its operations, and a policy-and-decision-making review board;

6. Have a set of written organizational by-laws and policies that provide adequate assurance of lack of conflict of interest and a system for monitoring and enforcing those by-laws and policies;

7. Have a committee, whose members can carry out their responsibilities impartially, to review and approve the certification guidelines and procedures, and to advise the organization's staff in implementing the certification program;

8. Have a committee, whose members can carry out their responsibilities impartially, to review complaints against certified individuals and to determine appropriate sanctions;

9. Have written procedures describing all aspects of its certification program, maintain records of the current status of each individual's certification and the administration of its certification program;

10. Have procedures to ensure that certified individuals are provided due process with respect to the administration of its certification program, including the process of becoming certified and any sanctions imposed against certified individuals;

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~~Schedule B to Section 3 (Cont'd)~~

11. Have procedures for proctoring examinations, including qualifications for proctors.~~-~~ These procedures must ensure that the individuals proctoring each examination are not employed by the same company or corporation (or a wholly-owned subsidiary of such company or corporation) as any of the examinees;

12. Exchange information about certified individuals with the Department, U.S. Nuclear Regulatory Commission (NRC), ~~and~~ other independent certifying organizations ~~and/or the U.S. Nuclear Regulatory Commission~~States ~~and/or~~or Agreement States and allow periodic review of its certification program and related records; and

13. Provide a description to the ~~Department~~ NRC of its procedures for choosing examination sites and for providing an appropriate examination environment.

II. **Requirements for Certification Programs**.

All certification programs must:

1. Require applicants for certification to:

   A. Receive training in the topics set forth in RH-1804. or equivalent NRC ~~and/or~~ or State or Agreement State regulations; and

   B. Satisfactorily complete a written examination covering these topics.

2. Require applicants for certification to provide documentation that demonstrates that the applicant has:

   A. Received training in the topics set forth in RH-1804. or equivalent NRC ~~and/or~~ or State or Agreement State regulations;

   B. Satisfactorily completed a minimum period of on-the-job training; and

   C. Received verification by a State registrant, or equivalent, an Agreement State licensee, or an NRC licensee that the applicant has demonstrated the capability of independently working as a radiographer~~;~~.

3. Include procedures to ensure that all examination questions are protected from disclosure;

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~~Schedule B to Section 3 (Cont'd)~~

4. Include procedures for denying an application, revoking, suspending, and reinstating a certificate;

5. Provide a certificate period of not less ~~that~~ than three (3) years nor more than five (5) years;

6. Include procedures for renewing certifications and, if the procedures allow renewals without examination, require evidence of recent full-time employment and annual refresher training; and

7. Provide a timely response to inquiries, by telephone or letter, from members of the public, about an individual's certification status.

III. **Requirements for Written Examinations**.

All examinations must be:

1. Designed to test an individual's knowledge and understanding of the topics listed in RH-1804. or equivalent NRC ~~and/or~~or State or Agreement State~~-~~ regulations;

2. Written in a multiple-choice format; and

3. Have test items drawn from a question bank containing psychometrically valid questions based on the material in RH-1804.

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PART J.
LICENSES AND RADIATION SAFETY REQUIREMENTS FOR WIRELINE SERVICE OPERATIONS AND SUBSURFACE TRACER STUDIES

RH-1900. **General Provisions**.

a. **Scope**.

The rules in this Part apply to all licensees who use sources of radiation for wireline service operations including mineral logging, radioactive markers or subsurface tracer studies.

b. **Purpose**.

The rules in this Part establish radiation safety requirements for persons utilizing sources of radiation for wireline service operations including mineral logging, radioactive markers and subsurface tracer studies. The requirements of this Part are in addition to and not in substitution for other applicable requirements of these Rules.

c. **Definitions**.

Energy compensation source (ECS) - A small sealed source, with an activity not exceeding 100 microcuries (3.7 MBq), used within a logging tool, or other tool components, to provide a reference standard to maintain the tool's calibration when in use.

Field station - A facility where radioactive sources may be stored or used and from which equipment is dispatched to temporary job sites.

Fresh water aquifer - A geologic formation that is capable of yielding fresh water to a well or spring.

Injection tool - A device used for controlled subsurface injection of radioactive tracer material.

Irretrievable well logging source - Any sealed source containing radioactive material that is pulled off or not connected to the wireline that suspends the source in the well and for which all reasonable effort at recovery has been expended.

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Logging assistant - Any individual who, under the personal supervision of a logging supervisor, handles sealed sources, tracers, or radiation producing machines that are not in logging tools or shipping containers or who performs surveys required by RH-1967.

Logging supervisor - Any individual who uses radioactive material or radiation producing machines, or provides personal supervision in the use of radioactive material or radiation producing machines at a temporary jobsite and who is responsible to the licensee for assuring compliance with the requirements of the Department's rules and the conditions of the license.

Logging tool - Any device used subsurface to perform well-logging.

Mineral logging - Any logging performed for the purpose of mineral exploration other than oil or gas.

Particle accelerator - Any machine capable of accelerating elections, protons, deuterons or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of one (1) MeV.

Personal supervision - Guidance and instruction by the logging supervisor who is physically present at the job site and watching the performance of the operation in such proximity that contact can be maintained and immediate assistance given as required.

Radioactive marker - Radioactive material placed subsurface or on a structure intended for subsurface use for the purpose of depth determination or direction orientation.

Radioactive material - Byproduct, source or special nuclear material received, processed, used or transferred under a license issued by the Arkansas State Board of Health, Arkansas Department of Health under the rules of this Part.

Sealed source - Any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

Source holder - A housing or assembly into which a radioactive source is placed for the purpose of facilitating the handling and use of the source in well-logging operations.

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Subsurface tracer study - the release of a substance tagged with radioactive material for the purpose of tracing the movement or position of the tagged substance in the well-bore or adjacent formation.

Surface casing for protecting fresh water aquifers - a pipe or tube used as a lining in a well to isolate fresh water aquifers from the well.

Temporary jobsite - A location to which radioactive materials have been dispatched to perform wireline service operations or subsurface tracer studies.

Tritium neutron generator target source - A tritium source used within a neutron generator tube to produce neutrons for use in well-logging applications.

Uranium sinker bar - A weight containing depleted uranium used to pull a logging tool toward the bottom of a well.

Well-bore - A drilled hole in which wireline service operations and subsurface tracer studies are performed.

Well-logging - the lowering and raising of measuring devices or tools which may contain sources of radiation into well-bores or cavities for the purpose of obtaining information about the well ~~and/or~~ or adjacent formations.

Wireline - A cable containing one or more electrical conductors which is used to lower and raise logging tools in the well-bore.

Wireline service operation - Any evaluation or mechanical service which is performed in the well-bore using devices on a wireline.

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RH-1901- RH-1910.– _Reserved.

RH-1911. **Application for a Specific License**.

A person, as defined in RH-1100., shall file an application for a specific license authorizing the use of radioactive material in well logging in accordance with RH-403. and RH-404.

RH-1912. Reserved.

RH-1913. **Specific Licenses for Well Logging**.

The Department will approve an application for a specific license for the use of radioactive material in well logging if the applicant meets the following requirements:

a. The application shall satisfy the general requirements specified in RH-404., and any special requirements contained in this Part.

b. The applicant shall develop a program for training logging supervisors and logging assistants and submit to the Department a description of this program which specifies the:

1. Initial training;

2. On-the-job training;

3. Annual safety reviews provided by the licensee;

4. Means the applicant will use to demonstrate the logging supervisor's knowledge and understanding of and ability to comply with the Department's rules and licensing requirements and the applicant's operating and emergency procedures; and

5. Means the applicant will use to demonstrate the logging assistant's knowledge and understanding of and ability to comply with the applicant's operating and emergency procedures.

c. The applicant shall submit to the Department written operating and emergency procedures as described in RH-1963. or an outline or summary of the procedures that includes the important radiation safety aspects of the procedures.

d. The applicant shall establish and submit to the Department its program for annual inspections of the job performance of each logging supervisor to ensure that the Department's rules, license requirements, and the applicant's operating and emergency procedures are followed.– Inspection records must be retained for three (3) years after each annual internal inspection.

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~~RH-1913. (Cont'd)~~

e. The applicant shall submit a description of its overall organizational structure as it applies to the radiation safety responsibilities in well logging, including specified delegations of authority and responsibility.

f. If an applicant wants to perform leak testing of sealed sources, the applicant shall identify the manufacturers and model numbers of the leak test kits to be used. If an applicant wants to analyze its own wipe samples, the applicant shall establish procedures to be followed and submit a description of these procedures to the Department. The description must include the:

1. Instruments to be used;

2. Methods of performing the analysis; and

3. Pertinent experience of the person who will analyze the wipe samples.

RH-1914. Reserved.

RH-1915. **Agreement with Well Owner or Operator**.

a. A licensee may perform well logging with a sealed source only after the licensee has a written agreement with the employing well owner or operator. This written agreement must identify who will meet the following requirements:

1 If a sealed source becomes lodged in the well, a reasonable effort will be made to recover it.

2. A person may not attempt to recover a sealed source in a manner which, in the licensee's opinion, could result in its rupture.

3. The radiation monitoring required in RH-1969. will be performed.

4. If the environment, any equipment, or personnel are contaminated with radioactive material, they must be decontaminated before release from the site or release for unrestricted use; and

5. If the sealed source is classified as irretrievable after reasonable efforts at recovery have been expended, the following requirements must be implemented within thirty (30) days:

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~~RH-1915.a.5. (Cont'd)~~

A. Each irretrievable well logging source must be immobilized and sealed in place with a cement plug;

B. A means to prevent inadvertent intrusion on the source unless the source is not accessible to any subsequent drilling operations; and

C. A permanent identification plaque, constructed of long-lasting material such as stainless steel, brass, bronze, or monel, must be mounted at the surface of the well, unless the mounting of the plaque is not practical. -The size of the plaque must be at least seven (7) inches (17cm) square and 1/8-inch (3 mm) thick. -The plaque[14/] must contain:

i. The word "**CAUTION**";

ii. The radiation symbol (the color requirement in RH-1303.a.1. need not be met);

iii. The date the source was abandoned;

iv. The name of the well owner or operator, as appropriate;

v. The well name and well identification numbers(s) or other designation;

vi. An identification of the sealed source(s) by radionuclide and quantity;

vii. The depth of the source and depth to the top of the plug; and

viii. An appropriate warning, such as "**DO NOT RE-ENTER THIS WELL**."[15/]

b. The licensee shall retain a copy of the written agreement for three (3) years after the completion of the well logging operation.

c. A licensee may apply, pursuant to RH-1991., for Department approval, on a case-by-case basis, of proposed procedures to abandon an irretrievable well logging source in a manner not otherwise authorized in RH-1915.a.5. of this section.

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~~RH-1915. (Cont'd)~~

d. A written agreement between the licensee and the well owner or operator is not required if the licensee and the well owner or operator are part of the same corporate structure or otherwise similarly affiliated. However, the licensee shall still otherwise meet the requirements of RH-1915.a.1. through RH-1915.a.5.

RH-1916. Reserved.

RH-1917. **Request for Written Statements**.

Each license is issued with the condition that the licensee will, at any time before expiration of the license, upon the Department's request, submit written statements, signed under oath or affirmation, to enable the Department to determine whether or not the license should be modified, suspended, or revoked.

RH-1918.- RH-1930. Reserved.

RH-1931. **Labels, Security, and Transportation Precautions**.

a. **Labels**.

1. The licensee may not use a source, source holder, or logging tool that contains radioactive material unless the smallest component that is transported as a separate piece of equipment with the radioactive material inside bears a durable, legible, and clearly visible marking or label. The marking or label must contain the radiation symbol specified in RH-1303.a.1. and 2., without the conventional color requirements, and the wording

"**DANGER (or CAUTION) RADIOACTIVE MATERIAL**."

~~RH-1931.a. (Cont'd)~~

2. The licensee may not use a container to store radioactive material unless the container has securely attached to it a durable, legible,

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and clearly visible label. The label must contain the radiation symbol specified in RH-1303.a. and the wording

"**CAUTION**,*
RADIOACTIVE MATERIAL,
NOTIFY CIVIL AUTHORITIES [or name of company]."

*or **DANGER**

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3. The licensee may not transport radioactive material unless the material is packaged, labeled, marked, and accompanied with appropriate shipping papers in accordance with Section 4 of these Rules.

b. **Security precautions during storage and transportation**.

1. The licensee shall store each source containing radioactive material in a storage container or transportation package. The container or package must be locked and physically secured to prevent tampering or removal of radioactive material from storage by unauthorized personnel. The licensee shall store the radioactive material in a manner which will minimize the danger from explosion or fire.

2. The licensee shall lock and physically secure the transport package containing radioactive material in the transporting vehicle to prevent accidental loss, tampering, or unauthorized removal of the radioactive material from the vehicle.

RH-1932. Reserved.

RH-1933. **Radiation Detection Instruments**.

a. The licensee shall keep a calibrated and operable radiation survey instrument capable of detecting beta and gamma radiation at each field station and temporary jobsite to make the radiation surveys required by this Part and by other Parts of Section 3. To satisfy this requirement, the radiation survey instrument must be capable of measuring 0.1 mrem (0.001 mSv) per hour through at least 50 mrem (0.5 mSv) per hour.

b. The licensee shall have available additional calibrated and operable radiation detection instruments sensitive enough to detect the low radiation and contamination levels that could be encountered if a sealed source ruptured. The licensee may own the instruments or may have a procedure to obtain them quickly from a second party.

~~RH-1933. (Cont'd)~~

c. The licensee shall have each radiation survey instrument required under RH-1933.a.of this section calibrated:

1. At intervals not to exceed six (6) months and after instrument servicing;

2. For linear scale instruments, at two (2) points located approximately 1/3 and 2/3 of full-scale on each scale; for logarithmic scale instruments, at midrange of each decade, and at two (2) points of at least one decade; and for digital instruments, at appropriate points; and

3. So that an accuracy within plus or minus twenty percent (± 20%) of the calibration standard can be demonstrated on each scale.

d. The license shall retain calibration records for a period of three (3) years after the date of calibration for inspection by the Department.

RH-1934. Reserved.

RH-1935. **Leak Testing of Sealed Sources**.

a. **Testing and recordkeeping requirements**.

Each licensee who uses a sealed source shall have the source leak tested for leakage in accordance with RH-1212. and as prescribed in this section. The licensee shall keep a record of leak test results in units of microcuries and retain the record for inspection by the Department for three (3) years after the leak test is performed.

b. **Method of testing**.

The wipe of a sealed source must be performed using a leak test kit or method approved by the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State. The wipe sample must be taken from the nearest accessible point to the sealed source where contamination might accumulate. The wipe sample must be analyzed for radioactive contamination. The analysis must be capable of detecting the presence of 0.005 microcuries (185 Bq) of radioactive material on the test sample and

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must be performed by a person approved by the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State to perform the analysis.

~~RH-1935. (Cont'd)~~

c. **Test frequency**.

1. Each sealed source (except an energy compensation source (ECS)) must be tested at intervals not to exceed six (6) months. In the absence of a certificate from a transferor that a test has been made within the six (6) months before the transfer, the sealed source may not be used until tested.

2. Each ECS that is not exempt from testing in accordance with RH-1935.e. must be tested at intervals not to exceed three (3) years. In the absence of a certificate from a transferor that a test has been made within the three (3) years before the transfer, the ECS may not be used until tested.

d. **Removal of leaking source from service**.

1. If the test conducted pursuant to RH-1935.a. and RH-1935.b. reveals the presence of 0.005 microcuries (185 Bq) or more of removable radioactive material, the licensee shall remove the sealed source from service immediately and have it decontaminated, repaired, or disposed of by a Department, U.S. Nuclear Regulatory Commission, or an Agreement State licensee that is authorized to perform these functions. The licensee shall check the equipment associated with the leaking source for radioactive contamination and, if contaminated, have it decontaminated or disposed of by a Department, U.S. Nuclear Regulatory Commission, or an Agreement State licensee that is authorized to perform these functions.

2. The licensee shall submit a report to the Department within five (5) days of receiving the test results. The report must describe the equipment involved in the leak, the test results, any contamination which resulted from the leaking source, and the corrective actions taken up to the time the report is made.

e. **Exemptions from testing requirements**.

The following sealed sources are exempt from the periodic leak requirements set out in RH-1935.a. through RH-1935.d.:

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1. Hydrogen-3 (tritium) sources;

2. Sources containing licensed material with a half-life of thirty (30) days or less;

~~RH-1935.e. (Cont'd)~~

3. Sealed sources containing licensed material in gaseous form;

4. Sources of beta- or gamma-emitting radioactive material with an activity of 100 microcuries (3.7 MBq) or less; and

5. Sources of alpha- or neutron-emitting radioactive material with an activity of ten (10) microcuries (0.37 MBq) or less.

RH-1936. Reserved.

RH-1937. **Physical Inventory**.

Each licensee shall conduct a quarterly physical inventory to account for all radioactive material received and possessed under the license. The licensee shall retain records of the inventory for three (3) years from the date of the inventory for inspection by the Department. The inventory must indicate the quantity and type of radioactive material, the location of the radioactive material, the date of the inventory, and the name of the individual conducting the inventory.

RH-1938. Reserved.

RH-1939. **Records of Material Use**.

a. Each licensee shall maintain records for each use of radioactive material showing:

1. The make, model number, and a serial number or a description of each sealed source used;

2. In the case of unsealed radioactive material used for subsurface tracer studies, the radionuclide and quantity of activity used in a particular well and the disposition of any unused tracer material;

3. The identity of the logging supervisor who is responsible for the licensed material and the identity of logging assistants present; and

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4. The location and date of use of the radioactive material.

b. The licensee shall make the records required by RH-1939.a. of this section available for inspection by the Department. -The licensee shall retain the records for three (3) years from the date of the recorded event.

RH-1940. Reserved.

RH-1941. **Design and Performance Criteria for Sealed Sources**.

a. A licensee may use a sealed source in well-logging applications if:

1. The sealed source is doubly encapsulated;

2. The sealed source licensed material whose chemical and physical forms are as insoluble and nondispersible as practical; and

3. Meets the requirements in RH-1941.b., c. or d.

b. For a sealed source manufactured on or before July 14, 1989, a licensee may use the sealed source, for use in well-logging applications if it meets the requirements of USASI N5.10-1968, "Classification of Sealed Radioactive Sources," or the requirements in RH-1941.c. or d.

c. For a sealed source manufactured after July 14, 1989, a licensee may use the sealed source, for use in well-logging applications if it meets the oil-well logging requirements of ANSI/HPS N43.6-1997, "Sealed Radioactive Sources-Classification."

d. For a sealed source manufactured after July 14, 1989, a licensee may use the sealed source, for use in well-logging applications, if:

1. The sealed source's prototype has been tested and found to maintain its integrity after each of the following tests:

A. **Temperature**.

The test source must be held at - 40º C for 20 minutes, 600º C for one (1) hour, and then be subject to a thermal shock test with a temperature drop from 600º C to 20º C within 15 seconds.

B. **Impact test**.

A 5 kg steel hammer, 2.5 cm in diameter, must be dropped from a height of one (1) meter onto the test source.

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C. **Vibration test**.

The test source must be subject to a vibration from 25 Hz to 500 Hz at 5 gram amplitude for 30 minutes.

D. **Puncture test**.

A one (1) gram hammer and pin, 0.3 cm pin diameter, must be dropped from a height of one (1) meter onto the test source.

E. **Pressure test**.

The test source must be subject to an external pressure of 24,600 pounds per square inch absolute (1.695×10^7 pascals).

e. The requirements of RH-1941.a., b., c., and d. do not apply to sealed sources that contain radioactive material in gaseous form.

f. The requirements in RH-1941.a., b., c., and d. do not apply to energy compensation sources (ECS). ECSs must be registered with the U.S. Nuclear Regulatory Commission or with an Agreement State.

RH-1942. Reserved.

RH-1943. **Inspection, Maintenance, and Opening of a Source or Source Holder**.

a. Each licensee shall visually check source holders, logging tools, and source handling tools for defects before each use to ensure that the equipment is in good working condition and that required labeling is present. If defects are found, the equipment must be removed from service until repaired, and a record must be made listing: the date of the check, name of inspector, equipment involved, defects found, and repairs made. These records must be retained for three (3) years after the defect is found.

b. Each licensee shall have a program for semiannual visual inspection and routine maintenance of source holders, logging tools, injection tools, source handling tools, storage containers, transport containers, and uranium sinker bars to ensure that the required labeling is legible and that no physical damage is visible. If defects are found, the equipment must be removed from service until repaired, and a record must be made listing: date, equipment involved, inspection and maintenance operations

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performed, any defects found, and any actions taken to correct the defects. These records must be retained for three (3) years after the defect is found.

c. Removal of a sealed source from a source holder or logging tool, and maintenance on sealed sources or holders in which sealed sources are contained may not be performed by the licensee unless a written procedure developed pursuant to RH-1963. has been approved either by the Department, the U.S. Nuclear Regulatory Commission, or by an Agreement State pursuant to RH-1913.c.

d. If a sealed source is stuck in the source holder, the licensee may not perform any operation, such as drilling, cutting, or chiseling, on the source holder unless the licensee is specifically approved by the Department, the U.S. Nuclear Regulatory Commission, or by an Agreement State to perform this operation.

e. The opening, repair, or modification of any sealed source must be performed by persons specifically approved to do so by the Department, the U.S. Nuclear Regulatory Commission, or by an Agreement State.

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RH-1944. Reserved.

RH-1945. **Subsurface Tracer Studies**.

a. The licensee shall require all personnel handling radioactive tracer material to use protective gloves and, if required by the license, other protective clothing and equipment. -The licensee shall take precautions to avoid ingestion or inhalation of radioactive tracer material and to avoid contamination of field stations and temporary jobsites.

b. A licensee may not knowingly inject radioactive material into fresh water aquifers unless specifically authorized to do so by the Department.

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RH-1946. **Particle Accelerators**.

No licensee shall permit above-ground testing of particle accelerators that results in the production of radiation, except in areas or facilities controlled or shielded so as to meet the requirements of RH-1200. and RH-1208., as applicable.

RH-1947. **Radioactive Markers**.

The licensee may use radioactive markers in wells only if the individual markers contain quantities of radioactive material not exceeding the quantities specified in RH-901., Schedule B. The use of markers is subject to the requirements of RH-1937.

RH-1948. Reserved.

RH-1949. **Uranium Sinker Bars**.

The licensee may use a uranium sinker bar in well logging applications after July 14, 1988, only if it is legibly impressed with the words

"**CAUTION - RADIOACTIVE - DEPLETED URANIUM**"
and
"**NOTIFY CIVIL AUTHORITIES** [or name of company] **IF FOUND**."

RH-1950. Reserved.

RH-1951. **Use of a Sealed Source in a Well Without a Surface Casing**.

The licensee may use a sealed source in a well without a surface casing for protecting fresh water aquifers only if the licensee follows a procedure for reducing the probability of the source becoming lodged in the well. The procedure must be approved by the Department pursuant to RH-1913.

RH-1952. Reserved.

RH-1953. **Energy Compensation Source**.

The licensee may use an energy compensation source (ECS) which is contained within a logging tool, or other tool components, only if the ECS contains quantities of licensed material not exceeding 100 microcuries (3.7 MBq).

a. For well logging applications with a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of RH-1935., RH-1937., and RH-1939.

b. For well logging applications without a surface casing for protecting fresh water aquifers, use of the ECS is only subject to the requirements of RH-1915., RH-1935., RH-1937., RH-1939., RH-1951., and RH-1977.

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RH-1954. Reserved.

RH-1955. **Tritium Neutron Generator Target Source**.

a. Use of a tritium neutron generator target source, containing quantities not exceeding thirty (30) curies (1,110 MBq) and in a well with a surface casing to protect fresh water aquifers, is subject to the requirements of this part except for RH-1915., RH-1941., and RH-1977.

b. Use of a tritium neutron generator target source, containing quantities exceeding thirty (30) curies (1,110 MBq) or in a well without a surface casing to protect fresh water aquifers, is subject to the requirements of this Part except for RH-1941.

RH-1956- RH-1960.– _Reserved.

RH-1961. **Training**.

a. The licensee may not permit an individual to act as a logging supervisor until that person:

1. Has completed training in the subjects outlined in RH-1961.e. of this section;

2. Has received copies of, and instruction in:

A. The applicable Parts of Section 3;

B. The license under which the logging supervisor will perform well logging; and

C. The licensee's operating and emergency procedures required by RH-1963.

3. Has completed on-the-job training and demonstrated competence in the use of radioactive materials, remote handling tools, and radiation survey instruments by a field evaluation; and

4. Has demonstrated understanding of the requirements in

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RH-1961.a.1. and RH-1961.a.2. by successfully completing a written test.

b. The licensee may not permit an individual to act as a logging assistant until that person:

1. Has received instruction in applicable Parts of Section 3;

2. Has received copies of, and instruction in, the licensee's operating and emergency procedures required by RH-1963.;

3. Has demonstrated understanding of the material in RH-1961.b.1. and RH-1961.b.2. of this section by successfully completing a written or oral test; and

4. Has received instruction in the use of radioactive materials, remote handling tools, and radiation survey instruments, as appropriate for the logging assistant's intended job responsibilities.

c. The licensee shall provide safety reviews for logging supervisors and logging assistants at least once during each calendar year.

d. The licensee shall maintain a record on each logging supervisor's and logging assistant's training and annual safety review. –The training records must include copies of written tests and dates of oral tests given after July 14, 1987. -The training records must be retained until three (3) year following the termination of employment. –Records of annual safety reviews must list the topics discussed and be retained for three (3) years.

e. The licensee shall include the following subjects in the training required in RH-1961.a.1. of this section.

1. Fundamentals of radiation safety, including:

A. Characteristics of radiation;

B. Units of radiation dose and quantity of radioactivity;

C. Hazards of exposure to radiation;

D. Levels of radiation from licensed material;

E. Methods of controlling radiation dose (time, distance, and shielding); and

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F. Radiation safety practices, including prevention of contamination, and methods of decontamination.

2. Radiation detection instruments, including:

A. Use, operation, calibration, and limitations of radiation survey instruments;

B. Survey techniques; and

~~RH-1961. (Cont'd)~~

C. Use of personnel monitoring equipment.

3. Equipment to be used, including:

A. Operation of equipment, including source handling equipment and remote handling tools;

B. Storage, control, and disposal of licensed material; and

C. Maintenance of equipment.

4. The requirements of pertinent Department rules; and

5. Case histories of accidents in well-logging.

RH-1962. Reserved.

RH-1963. **Operating and Emergency Procedures**.

Each licensee shall develop and follow written operating and emergency procedures that cover:

a. The handling and use of radioactive materials including the use of sealed sources in wells without surface casing for protecting fresh water aquifers, if appropriate;

b. The use of remote handling tools for handling sealed sources and radioactive tracer material except low-activity calibration sources;

c. Methods and occasions for conducting radiation surveys, including surveys for detecting contamination, as required by RH-1967.c. through RH-1967.e.;

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d. Minimizing personnel exposure including exposures from inhalation and ingestion of radioactive tracer materials;

e. Methods and occasions for locking and securing stored radioactive materials;

f. Personnel monitoring and the use of personnel monitoring equipment;

~~RH-1961.e. (Cont'd)~~

g. Transportation of radioactive material to field stations or temporary jobsites, packaging of radioactive materials for transport in vehicles; placarding of vehicles when needed, and physically securing radioactive materials in transport vehicles during transportation to prevent accidental loss, tampering, or unauthorized removal;

h. Picking up, receiving, and opening packages containing radioactive materials, in accordance with RH-1307.;

i. For the use of tracers, decontamination of the environment, equipment, and personnel;

j. Maintenance of records generated by logging personnel at temporary jobsites;

k. The inspection and maintenance of sealed sources, source holders, logging tools, injection tools, source handling tools, storage containers, transport containers, and uranium sinker bars as required by RH-1943.;

l. Actions to be taken if a sealed source is lodged in a well;

m. Notifying proper persons in the event of an accident;

n. Actions to be taken if a sealed source is ruptured including actions to prevent the spread of contamination and minimize inhalation and ingestion of radioactive materials and actions to obtain suitable radiation survey instruments as required by RH-1933.b.; and

o. Identifying and reporting to the Department defects and noncompliance as required by RH-1935.d.2. and RH-1977.a., b., and d.

p. For particle accelerators, testing and use of the accelerator.

RH-1964. Reserved.

RH-1965. **Personnel Monitoring**.

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a. The licensee may not permit an individual to act as a logging supervisor or logging assistant unless that person wears a personnel dosimeter at all times during the handling of licensed radioactive materials. -Each personnel dosimeter must be assigned to and worn by only one (1) individual.- Film badges must be replaced at least monthly and all other personnel dosimeters that require replacement must be replaced at least quarterly.- All personnel dosimeters must be evaluated at least quarterly or promptly after replacement, whichever is more frequent.

~~RH-1963. (Cont'd)~~

b. The licensee shall provide bioassay services to individuals using radioactive materials in subsurface tracer studies if required by the license.

c. The licensee shall retain records of personnel dosimeters and bioassay results for inspection until the Department authorizes disposition of the records.

RH-1966. Reserved.

RH-1967. **Radiation Surveys**.

a. The licensee shall make radiation surveys, including but not limited to the surveys required under RH-1967.b. through RH-1967.e. of this section, of each area where radioactive materials are used and stored.

b. Before transporting radioactive materials, the licensee shall make a radiation survey of the position occupied by each individual in the vehicle and of the exterior of each vehicle used to transport the radioactive materials.

c. If the sealed source assembly is removed from the logging tool before departure from the temporary jobsite, the licensee shall confirm that the logging tool is free of contamination by energizing the logging tool detector or by using a survey meter.

d. If the licensee has reason to believe that, as a result of any operation involving a sealed source, the encapsulation of the sealed source could be damaged by the operation, the licensee shall conduct a radiation survey, including a contamination survey, during and after the operation.

e. The licensee shall make a radiation survey at the temporary jobsite before and after each subsurface tracer study to confirm the absence of contamination, except those using hydrogen-3, carbon-14 and sulfur-35.

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These surveys shall include measurement of radiation levels before and after the operation.

f. The results of surveys required under RH-1967.a. through RH-1967.e. of this Section must be recorded and must include the date of the survey, the name of the individual making the survey, the identification of the survey, instrument used, and the location of the survey. The licensee shall retain records of surveys for inspection by the Department for three (3) years after they are made.

RH-1968. Reserved.

RH-1969. **Radioactive Contamination Control**.

a. If the licensee detects evidence that a sealed source has ruptured or radioactive materials have caused contamination, the licensee shall initiate immediately the emergency procedures required by RH-1963.

~~RH-1969. (Cont'd)~~

b. If contamination results from the use of radioactive material in well logging, the licensee shall decontaminate all work areas, equipment, and unrestricted areas.

c. During efforts to recover a sealed source lodged in the well, the licensee shall continuously monitor, with an appropriate radiation detection instrument or a logging tool with a radiation detector, the circulating fluids from the well, if any, to check for contamination resulting from damage to the sealed source.

RH-1970. Reserved.

RH-1971. **Security**.

a. A logging supervisor must be physically present at a temporary jobsite whenever radioactive materials are being handled or are not stored and locked in a vehicle or storage place. The logging supervisor may leave the jobsite in order to obtain assistance if a source becomes lodged in a well.

b. During well logging, except when radiation sources are below ground or in shipping or storage containers, the logging supervisor or other individual designated by the logging supervisor shall maintain direct surveillance of the operation to prevent unauthorized entry into a restricted area, as defined in RH-1100.

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RH-1972. Reserved.

RH-1973. **Documents and Records Required at Field Stations**.

Each licensee shall maintain the following documents and records at the field station:

a. A copy of these Rules;
~~RH-1973. (Cont'd)~~

b. The license authorizing the use of radioactive material;

c. Operating and emergency procedures required by RH-1963.;

d. The record of radiation survey instrument calibrations required by RH-1933.;

e. The record of leak test results required by RH-1935.;

f. Physical inventory records required by RH-1937.;

g. Utilization records required by RH-1939.;

h. Records of inspection and maintenance required by RH-1943.;

i. Training records required by RH-1961.d.; and

j. Survey records required by RH-1967.

RH-1974. Reserved.

RH-1975. **Documents and Records Required at Temporary Jobsites**.

Each licensee conducting operations at a temporary jobsite shall maintain the following documents and records at the temporary jobsite until the well-logging operation is completed:

a. Operating and emergency procedures required by RH-1963.;

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b. Evidence of latest calibration of the radiation survey instruments in use at the site required by RH-1933.;

c. Latest survey records required by RH-1967.b., RH-1967.c., and RH-1967.e.

d. The shipping papers for the transportation of radioactive materials required by Section 4;

e. When operating under reciprocity pursuant to Section 2, Part H of these Rules, a copy of the U.S. Nuclear Regulatory Commission license or Agreement State license authorizing use of radioactive materials.

RH-1976. Reserved.

RH-1977. **Notification of Incidents and Lost Sources; Abandonment Procedures for Irretrievable Sources**.

a. The licensee shall immediately notify the Department by telephone and subsequently, within thirty (30) days, by confirmatory letter if the licensee knows or has reason to believe that a sealed source has been ruptured. The letter must designate the well or other location, describe the magnitude and extent of the escape of radioactive materials, assess the consequences of the rupture, and explain efforts planned or being taken to mitigate these consequences.

b. The licensee shall notify the Department of the theft or loss of radioactive materials, radiation overexposures, excessive levels and concentrations of radiation, and certain other accidents as required by RH-601., RH-1501., RH-1502., and RH-1504.

c. If a sealed source becomes lodged in a well, and when it becomes apparent that efforts to recover the sealed source will not be successful, the licensee shall:

1. Notify the Department by telephone of the circumstances that resulted in the inability to retrieve the source and

A. Obtain the Department's approval to implement abandonment procedures; or

B. That the licensee implemented abandonment before receiving the Department's approval because the licensee

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believed there was an immediate threat to public health and safety; and

2. Advise the well owner or operator, as appropriate, of the abandonment procedures under RH-1915.a. or RH-1915.c.; and

3. Either ensure that abandonment procedures are implemented within thirty (30) days after the sealed source has been classified as irretrievable or request an extension of time if unable to complete the abandonment procedures.

~~RH-1977. (Cont'd)~~

d. The licensee shall, within thirty (30) days after a sealed source has been classified as irretrievable, make a report in writing to the Department. -The licensee shall send a copy of the report to each appropriate State or Federal agency that issued permits or otherwise approved the drilling operation. -The report shall contain the following information:

1. Date of occurrence;

2. A description of the irretrievable well-logging source involved including the radionuclide and its quantity, chemical, and physical form;

3. Surface location and identification of the well;

4. Results of effort to immobilize and seal the source in place;

5. A brief description of the attempted recovery effort;

6. Depth of the source;

7. Depth of the top of the cement plug;

8. Depth of the well;

9. The immediate threat to public health and safety justification for implementing abandonment if prior Department approval was not obtained in accordance with RH-1977.c.1.B.;

10. Any other information, such as a warning statement, contained on the permanent identification plaque; and

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11. State and Federal agencies receiving a copy of this report.

RH-1978.- RH-1990. Reserved.

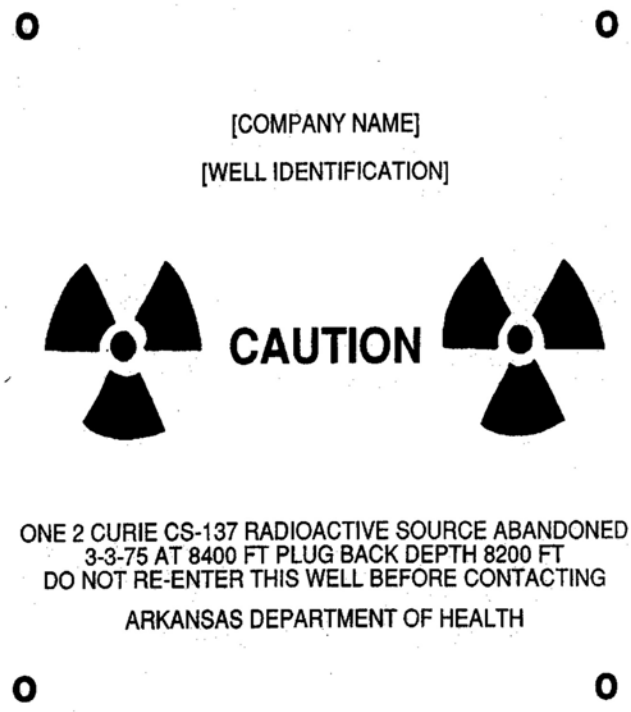
RH-1991. **Specific Exemptions**.

The Department may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the rules in this Part as it determines are authorized by law and will not result in undue hazard to public health and safety or property, and are otherwise in the public interest.

RH-1992.- RH-1999. Reserved.

SCHEDULE C TO SECTION 3

EXAMPLE OF PLAQUE FOR IDENTIFYING WELLS CONTAINING SEALED SOURCES OF RADIOACTIVE MATERIAL ABANDONED DOWNHOLE



The size of the plaque should be convenient for use on active or inactive wells, e.g., a 7 inch square. Letter size of the word "CAUTION" should be approximately twice the letter size of the rest of the information, e.g., ½-inch and ¼-inch letter size, respectively.

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PART K.
EXEMPTIONS AND ADDITIONAL REQUIREMENTS

RH-2000. **Specific Exemptions**.

The Department may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the rules in this Section as it determines are authorized by law and will not result in undue hazard to public health and safety or property, and are otherwise in the public interest.

RH-2001. **Additional Requirements**.

The Department may, by rule or order, impose upon any licensee or registrant such requirements in addition to those established in the rules in this Section as it deems appropriate or necessary to minimize danger to public health and safety or property.

RH-2002.- RH-2109.– _Reserved.

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PART L.
ENFORCEMENT

RH-2110. **Violations**.

a. An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any rule or order issued thereunder. Any person who willfully violates any provision of the Act or any rule or order issued thereunder may be guilty of a felony, misdemeanor, or crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law. Arkansas Code Annotated §20-21-204 describes criminal and civil penalties which may be assessed.

b. **Impounding**.

Sources of radiation shall be subject to impounding pursuant to Section 5 of these Rules.

RH-2111. - RH-2199. Reserved.

PART M.
[RESERVED]

RH-2200. - RH-2799. Reserved.

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PART N.
NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS; INSPECTIONS

RH-2800. Reserved.

RH-2801. **Purpose and Scope**.

This Part establishes requirements for notices, instructions, and reports by licensees or registrants to individuals engaged in work under a license or registration; and options available to such individuals in connection with Department inspection of licensees or registrants to ascertain compliance with the provisions of the Act and the rules, orders, and licenses issued thereunder regarding radiological working conditions. The rules in this Part apply to all persons who receive, possess, use, own, or transfer sources of radiation licensed by or registered with the Department pursuant to these Rules in Sections 1 and 2, Part I of Section 3, Part J of Section 3, and Sections 6, 7, 8, and 9, 10, and 13.

RH-2802. **Posting of Notices to Workers**.

a. Each licensee or registrant shall post current copies of the following documents:

1. A copy of tThese Rules;

2. The license or certificate of registration, conditions or documents incorporated into the license or registration by reference and amendments thereto;

3. The operating procedures applicable to work under the license or registration; and

4. Any notice of violation involving radiological working conditions, proposed imposition of civil penalty, or order issued pursuant to Part B of Section 5 and any response from the licensee or registrant.

b. If posting of a document specified in RH-2802.a.1., 2., or 3. is not practicable, the licensee or registrant may post a notice which describes the document and states where it may be examined.

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c. RC FORM 100, **"**Notice to Employees,**"** shall be posted by each licensee or registrant wherever individuals work in or frequent any portion of a restricted area.

~~RH-2802. (Cont'd)~~

d. Documents, notices or forms posted pursuant to this section shall appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from any particular work location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

e. Department documents posted pursuant to RH-2802.a.4. shall be posted within two (2) working days after receipt of the documents from the Department; the licensee's or registrant's response, if any, shall be posted within two (2) working days after dispatch from the licensee or registrant. Such documents shall remain posted for a minimum of five (5) working days or until action correcting the violation has been completed, whichever is later.

RH-2803. **Instructions to Workers**.

a. All individuals working in or frequenting any portion of a restricted area:

1. Shall be kept informed of the storage, transfer or use of radiation or radioactive material ~~s or of radiation in such portions of the restricted area~~the licensee's or registrant's workplace;

2. Shall be instructed in the health protection problems associated with exposure to radiation ~~and/or~~ or radioactive material, in precautions or procedures to minimize exposure, and the purposes and functions of protective devices employed;

3. Shall be instructed in, and required to observe, to the extent within the worker's control, the applicable provisions of Department rules and licenses or registrations for the protection of personnel from exposures to radiation or radioactive material;

4. Shall be instructed of their responsibility to report promptly to the licensee or registrant any condition which may lead to or cause a violation of Department rules ~~and~~ or the licenses or registration, or unnecessary exposure to radiation ~~and/or~~ or radioactive material;

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5. Shall be instructed in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation ~~and/or~~ or radioactive material; and

6. Shall be advised as to the radiation exposure reports which workers may request pursuant to RH-2804.

~~RH-2803. (Cont'd)~~

b. In determining those individuals subject to the requirements of RH-2803.a., licensees and registrants must take into consideration assigned activities during normal and abnormal situations involving exposure to radiation ~~and/or~~ or radioactive material which can reasonably be expected to occur during the life of a licensed or registered facility. The extent of these instructions shall be commensurate with potential radiological health protection problems present in the work place.

RH-2804. **Notifications and Reports to Individuals**.

a. ~~a.~~ 1. Radiation exposure data for an individual and the results of any measurements, analyses and calculations of radioactive material deposited or retained in the body of an individual shall be reported to the individual as specified in this section. The information reported shall include data and results obtained pursuant to Department rules, orders or license conditions, as shown in records maintained by the licensee or registrant pursuant to Department rules. Each notification and report shall:

~~1~~A. Be in writing;

~~2~~B. Include appropriate identifying data such as the name of the licensee or registrant, the name of the individual, the individual's date of birth and the individual's social security number or other unique identifier;

~~3~~C. Include the individual's exposure information; and

~~4~~D. Contain the following statement:

"This report is furnished to you under the provisions of the Arkansas Department of Health rules entitled ~~'Standards for Protection Against Radiation.'~~ Part N of Section 3. You should preserve this report for further reference."

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2. Documentation demonstrating compliance with the provision of reports required in this section shall be maintained by the licensee or registrant for Department inspection.

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b. Each licensee or registrant shall make dose information available to workers as shown in records maintained by the licensee or registrant under the provisions of RH-1500.f. The licensee or registrant shall provide an annual report to each individual monitored under RH-1302. of the dose received in that monitoring year if:

1. The individual's occupational dose exceeds 100 mrem (1 mSv) TEDE or 100 mrem (1 mSv) to any individual organ or tissue; or

~~RH-2804.b. (Cont'd)~~

2. The individual requests his or her annual dose report.

c. At the request of a worker formerly engaged in work controlled by the licensee or the registrant, each licensee or registrant shall furnish to the worker a report of the worker's exposure to radiation or radioactive material. Such report shall:

1. Be furnished within thirty (30) days from the time the request is made or within thirty (30) days after the exposure of the individual has been determined by the licensee or registrant, whichever is later;

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2. Cover, within the period of time specified in the request, each calendar year in which the worker's activities involved exposure to radiation from radioactive material licensed by, or radiation machines registered with, the Department; and

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3. Include the dates and locations of work under the license or registration in which the worker participated during this period.

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d. Each licensee or registrant shall furnish to each worker a report of the worker's exposure to radiation or radioactive material upon termination of employment. Such report shall be furnished within thirty (30) days from the time of termination of employment or within thirty (30) days after the exposure of the individual has been determined by the licensee or registrant, whichever is later. The report shall cover each calendar year in which the worker's activities involved exposure to sources of radiation and shall include the dates and locations of work under the license or registration in which the worker participated.

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e. At the request of a worker who is terminating employment with the licensee or registrant in work involving radiation dose, or of a worker who, while employed by another person, is terminating assignment to work involving radiation dose in the licensee's or registrant's facility, to each such worker, or to the worker's designee, at termination, a written report regarding the radiation dose received by that worker from operations of the licensee or registrant during that specifically identified calendar year or fraction thereof shall be provided, or a written estimate of that dose must be provided if the finally determined personnel monitoring results are not available at that time. Estimated doses shall be clearly indicated as such.

~~RH-2804. (Cont'd)~~

f. When a licensee or registrant is required pursuant to RH-1502., RH-1503., or RH-1504. to report to the Department any exposure of an individual to radiation or radioactive material, the licensee or the registrant shall also provide the individual a report on his or her exposure data included in the report to the Department. The report must be transmitted no later than the transmittal to the Department.

RH-2805. **Presence of Representatives of Licensees or Registrants and Workers During Inspections**.

a. Each licensee or registrant shall afford to the Department at all reasonable times opportunity to inspect materials, machines, activities, facilities, premises, and records pursuant to these Rules.

b. During an inspection, Department inspectors may consult privately with workers as specified in RH-2806. The licensee or registrant may accompany Department inspectors during other phases of an inspection.

c. If, at the time of inspection, an individual has been authorized by the workers to represent them during Department inspections, the licensee or registrant shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

d. Each workers' representative shall be routinely engaged in work under control of the licensee or registrant and shall have received instructions as specified in RH-2803.

e. Different representatives of licensees or registrants and workers may accompany the inspectors during different phases of an inspection if there

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is no resulting interference with the conduct of the inspections; however, only one workers' representative at a time may accompany the inspectors.

f. With the approval of the licensee or registrant and the workers' representative, an individual who is not routinely engaged in work under control of the licensee or registrant, for example, a consultant to the licensee or registrant or to the workers' representative, shall be afforded the opportunity to accompany Department inspectors during the inspection of physical working conditions.

~~RH-2805. (Cont'd)~~

g. Notwithstanding the other provisions of this section, Department inspectors are authorized to refuse to permit accompaniment by any individual who deliberately interferes with a fair and orderly inspection. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the licensee or registrant to enter that area.

RH-2806. **Consultation With Workers During Inspections**.

a. Department inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of Department rules and licenses or registrations to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

b. During the course of an inspection, any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which he or ~~/~~she has reason to believe may have contributed to or caused any violation of the Act, these Rules, or the license or registration ~~condition,~~ or any unnecessary exposure of an individual to sources of radiation ~~from licensed radioactive material or a registered radiation machine~~ under the licensee's or registrant's control. ~~-~~ Any such notice in writing shall comply with the requirements of RH-2807.a.

RH-2807. **Requests by Workers for Inspections**.

a. Any worker or representative of workers who believes that a violation of the Act, these Rules or license conditions exists or has occurred in work under a license or registration with regard to radiological working

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conditions in which the worker is engaged, may request an inspection by giving notice of the alleged violation to the Department. -Any such notice shall be in writing, shall set forth the specific grounds for the notice and shall be signed by the worker or representative of the workers. -A copy shall be provided to the licensee or registrant by the Department no later than at the time of the inspection except that, upon the request of the worker giving such notice, his or ~~/~~her name and the name of individuals referred to therein shall not appear in such copy or on any record published, released or made available by the Department, except for good cause shown.

~~RH-2807. (Cont'd)~~

b. If, upon receipt of such notice, the Department determines that the complaint meets the requirements set forth in RH-2807.a., and that there are reasonable grounds to believe that the alleged violation exists or has occurred, an inspection shall be made as soon as practicable, to determine if such alleged violation exists or has occurred.- Inspections pursuant to this section need not be limited to matters referred to in the complaint.

c. No licensee or registrant shall discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under these Rules or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of himself~~/~~ or herself or others of any option afforded by this Part.

RH-2808. **Inspections Not Warranted; Informal Review**.

a. If the Department determines, with respect to a complaint under RH-2807., that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the Department shall notify the complainant in writing of such determination.

1. The complainant may obtain review of such determination by submitting a written statement of position to the Director who will provide the licensee or registrant with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant.

2. The licensee or registrant may submit an opposing written statement of position to the Director who will provide the complainant with a copy of such statement by certified mail.

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3. Upon the request of the complainant, the Director may hold an informal conference in which the complainant and the licensee or registrant may orally present their views. An informal conference may also be held at the request of the licensee or registrant, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant.

4. After considering all written or oral views presented, the Director shall affirm, modify, or reverse the determination of the Department and furnish the complainant and the licensee or registrant a written notification of ~~his/her~~ his or her decision and the reason therefore.

~~RH-2808. (Cont'd)~~

b. If the Director determines that an inspection is not warranted because the requirements of RH-2807.a. have not been met, ~~he/she~~ he or she shall notify the complainant in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of RH-2807.a.

~~RH-2809. RH-2899. Reserved.~~

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PART O.
RADIATION SAFETY REQUIREMENTS FOR ANALYTICAL X-RAY EQUIPMENT

RH-2900. **Scope and Purpose**.

This Part provides special requirements for analytical x-ray equipment. The requirements of this Part are in addition to, and not in substitution for, applicable requirements in other parts of these Rules.

RH-2901. **Definitions**.

Analytical x-ray equipment - X-Ray equipment used for x-ray diffraction fluorescence analysis or spectroscopy.

Analytical x-ray system - A group of local and remote components utilizing x-rays to determine the elemental composition or to examine the microstructure of materials. Local components include those that are struck by x-rays such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors and shielding. Remote components include power supplies, transformers, amplifiers, readout devices, and control panels.

Fail-safe characteristics - A design feature which causes beam port shutters to close or otherwise prevents emergence of the primary beam, upon the failure of a safety or warning device.

Local components - Part of an analytical x-ray system and include areas exposed to x-rays, such as radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors and shielding, but does not include power supplies, transformers, amplifiers, readout devices and control panels.

Normal operating procedures - Operating procedures for conditions suitable for analytical purposes with shielding and barriers in place. These do not include maintenance but do include routine alignment procedures. Routine and emergency radiation safety considerations are part of these procedures.

Open-beam configuration - An analytical x-ray system in which an individual could accidentally place some part of his/her body in the primary beam path during normal operation.

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RH-2901. (Cont'd)

Primary beam - Ionizing radiation which passes through an aperture of the source housing by a direct path from the x-ray tube located in the radiation source housing.

RH-2902. **Equipment Requirements**.

a. **Safety device**.

A device which prevents the entry of any portion of an individual's body into the primary x-ray beam path or which causes the beam to be shut off upon entry into its path shall be provided on all open-beam configurations. A registrant may apply to the Department for an exemption from the requirement of a safety device. Such application shall include:

1. A description of the various safety devices that have been evaluated;

2. The reason each of these devices cannot be used; and

3. A description of the alternative methods that will be employed to minimize the possibility of an accidental exposure, including procedures to assure that operators and others in the area will be informed of the absence of safety devices.

b. **Warning devices**.

1. Open-beam configurations shall be provided with a readily discernible indication of:

A. X-ray tube status **(ON-OFF)** located near the radiation source housing, if the primary beam is controlled in this manner; and/or

B. Shutter status **(OPEN-CLOSED)** located near each port on the radiation source housings, if the primary beam is controlled in this manner.

2. Warning devices shall be labeled so that their purpose is easily identified. On equipment installed after January 1, 1979, warning devices shall have fail-safe characteristics.

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RH 2902. (Cont'd)

e. **Ports.**

Unused ports on radiation machine source housings shall be secured in the closed position in a manner which will prevent casual opening.

d. **Labeling**.

All analytical x-ray equipment shall be labeled with a readily discernible sign or signs bearing the radiation symbol and the words:

1. "**CAUTION - HIGH INTENSITY X-RAY BEAM**," or words having a similar intent, on the x-ray source housing; and

2. "**CAUTION RADIATION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED**," or words having a similar intent, near any switch that energizes an x-ray tube.

e. **Shutters**.

On open-beam configurations installed after January 1, 1979, each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or a coupling has been connected to the port.

f. **Warning lights**.

1. An easily visible warning light labeled with the words "**X-RAY ON**" or words having a similar intent, shall be located near any switch that energizes an x-ray tube and shall be illuminated only when the tube is energized.

2. On equipment installed after January 1, 1979, warning lights shall have fail-safe characteristics.

g. **Radiation source housing**.

Each radiation source housing shall be subject to the following requirements:

1. Each x-ray tube housing shall be equipped with an interlock that shuts off the tube if it is removed from the radiation source housing or if the housing is disassembled.

RH-2902. (Cont'd)

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h. **Generator cabinet.**

Each x-ray generator shall be supplied with a protective cabinet which limits leakage radiation measured at a distance of 5 centimeters from its surface such that it is not capable of producing a dose in excess of 0.25 millirem in one hour.

RH-2903. **Area Requirements.**

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a. **Radiation levels.**

The local components of an analytical x-ray system shall be located and arranged and shall include sufficient shielding or access control such that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits given in RH-1208. These levels shall be met at any specified tube rating.

b. **Surveys.**

1. Radiation surveys, as required by RH-1300., of all analytical x-ray systems sufficient to show compliance with RH-2903.a. shall be performed:

A. Upon installation of the equipment;

B. Following any change in the initial arrangement, number or type of local components in the system;

C. Following any maintenance requiring the disassembly or removal of a local component in the system;

D. During the performance of maintenance and alignment procedures, if the procedures require the presence of a primary x-ray beam when any local component in the system is disassembled or removed;

E. Any time a visual inspection of the local components in the system reveals an abnormal condition; and

F. Whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the limits specified in RH-1200.

RH-2903.b. (Cont'd)

2. Radiation survey measurements shall not be required if a registrant can demonstrate compliance to the satisfaction of the Department with RH-2903.a. in some other manner.

c. **Posting**.

Each area or room containing analytical x-ray equipment shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words "**CAUTION - X-RAY EQUIPMENT**" or words having a similar intent.

RH-2904. **Operating Requirements**.

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a. **Procedures**.

Normal operating procedures shall be written and available to all analytical x-ray equipment workers. No person shall be permitted to operate analytical x-ray equipment in any manner other than that specified in the procedures unless such person has obtained written approval of the Radiation Safety Officer.

b. **Bypassing**.

No person shall bypass a safety device unless such person has obtained the approval of the Radiation Safety Officer. When a safety device has been bypassed, a readily discernible sign bearing the words "**SAFETY DEVICE NOT WORKING**," or words having a similar intent, shall be placed on the radiation source housing.

c. **Repair or modification of x-ray tube systems**.

Except as specified in RH-2904.b., no operation involving removal of covers, shielding materials or tube housings or modifications to shutters, collimators or beam stops shall be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.

~~RH-2905. **Personnel Requirements.**~~

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~~a. **Instruction.**~~

~~1. No person shall be permitted to operate or maintain analytical x-ray equipment unless such person has received instruction in and demonstrated competence as to:~~

~~A. Identification of radiation hazards associated with the use of the equipment;~~

~~B. Significance of the various radiation warning and safety devices incorporated into the equipment or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;~~

~~C. Proper operating procedures for the equipment;~~

~~D. Symptoms of an acute localized exposure; and~~

~~E. Proper procedures for reporting an actual or suspected exposure.~~

~~b. **Personnel monitoring.**~~

~~1. Finger or wrist dosimetric devices shall be provided to and shall be used by:~~

~~A. Analytical x-ray equipment workers using systems having an open-beam configuration and not equipped with a safety device; and~~

~~B. Personnel maintaining analytical x-ray equipment if the maintenance procedures require the presence of a primary x-ray beam when any local component in the analytical x-ray system is disassembled or removed.~~

~~2. Reported dose values shall not be used for the purpose of determining compliance with RH-1200. and RH-1208. unless evaluated by a qualified expert.~~

RH-~~2906~~2900.- RH-2999.– _Reserved.

APPENDIX A TO SECTION 3

Deleted. (See Appendix G to Section 3.)

APPENDIX B TO SECTION 3

Deleted. (For RH-409.h. purposes, see Appendix E to Section 2. For RH-1303.b.5. purposes, see Appendix H to Section 3.)

APPENDIX C TO SECTION 3

Deleted. (For "Determination of A_1 and A_2 Quantities," see Appendix A to Section 4.)

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APPENDIX D TO SECTION 3

NATIONALLY TRACKED SOURCE THRESHOLDS

(for use with RH-1513.)

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The Terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only and are rounded after conversion.

Radioactive material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Actinium-227	20	540	0.2	5.4
Americium-241	60	1,600	0.6	16
Americium-241/Be	60	1,600	0.6	16
Californium-252	20	540	0.2	5.4
Cobalt-60	30	810	0.3	8.1
Curium-244	50	1,400	0.5	14
Cesium-137	100	2,700	1	27
Gadolinium-153	1,000	27,000	10	270
Iridium-192	80	2,200	0.8	22
Plutonium-238	60	1,600	0.6	16
Plutonium-239/Be	60	1,600	0.6	16
Polonium-210	60	1,600	0.6	16
Promethium-147	40,000	1,100,000	400	11,000
Radium-226	40	1,100	0.4	11
Selenium-75	200	5,400	2	54
Strontium-90	1,000	27,000	10	270
Thorium-228	20	540	0.2	5.4
Thorium-229	20	540	0.2	5.4
Thulium-170	20,000	540,000	200	5,400
Ytterbium-169	300	8,100	3	81

APPENDIX E TO SECTION 3

ASSIGNED PROTECTION FACTORS FOR RESPIRATORS [a/]

RESPIRATOR TYPE	OPERATING MODE	ASSIGNED PROTECTION FACTOR
I. Air Purifying Respirators [Particulate [b/] only][c/]		
Filtering facepiece disposable [d/]	Negative Pressure	([d/])
Facepiece, half [e/]	Negative Pressure	10
Facepiece, full	Negative Pressure	100
Facepiece, half	Powered air-purifying respirators	50
Facepiece, full	Powered air-purifying respirator	1000
Helmet/hood	Powered air-purifying respirator	1000
Facepiece, loose-fitting	Powered air-purifying respirator	25
II. Atmosphere supplying respirators [particulate, gases and vapors [f/]]		
1. Air-line respirators		
Facepiece, half	Demand	10
Facepiece, half	Continuous flow	50
Facepiece, half	Pressure demand	50
Facepiece, full	Demand	100
Facepiece, full	Continuous flow	1000
Facepiece, full	Pressure demand	1000
Helmet/hood	Continuous flow	1000
Facepiece, loose-fitting	Continuous flow	25
Suit	Continuous flow	([g/])
2. Self-contained breathing apparatus (SCBA)		
Facepiece, full	Demand	100 [h/]
Facepiece, full	Pressure demand	10,000 [i/]
Facepiece, full	Demand, re-circulating	100 [h/]
Facepiece, full	Positive pressure re-circulating	10,000 [i/]
III. Combination Respirators		
Any combination of air-purifying and atmosphere-supplying respirators	Assigned protection factor for type and mode of operation as listed above	

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Footnotes for Appendix E to Section 3:

a/ These assigned protection factors apply only in a respiratory protection program that meets the requirements of this Section. They are applicable only to airborne radiological hazards and may not be appropriate to circumstances when chemical or other respiratory hazards exist instead of, or in addition to, radioactive hazards. Selection and use of respirators for such circumstances must also comply with Department of Labor regulations. Radioactive contaminants for which the concentration values in Table I, Column 3 of Appendix G to Section 3 are based on internal dose due to inhalation may, in addition, present external exposure hazards at higher concentrations. Under these circumstances, limitation on occupancy may have to be governed by external dose limits.

b/ Air purifying respirators with APF <100 must be equipped with particulate filters that are at least ninety-five percent (95%) efficient. Air purifying respirators with APF = 100 must be equipped with particulate filters that are at least ninety-nine percent (99%) efficient. Air purifying respirators with APFs > 100 must be equipped with particulate filters that are at least 99.97 percent (99.97%) efficient.

c/ The licensee may apply to the Department for the use of an APF greater than one (1) for sorbent cartridges as protection against airborne radioactive gases and vapors (e.g., radioiodine).

d/ Licensees may permit individuals to use this type of respirator who have not been medically screened or fit tested on the device provided that no credit be taken for their use in estimating intake or dose. It is also recognized that it is difficult to perform an effective positive or negative pressure pre-use seal check on this type of device. All other respiratory protection program requirements listed in RH-1303.f. apply. An assigned protection factor has not been assigned for these devices. However, an APF equal to ten (10) may be used if the licensee can demonstrate a fit factor of at least 100 by use of a validated or evaluated, qualitative or quantitative fit test.

e/ Under-chin type only. No distinction is made in this Appendix between elastomeric half-masks with replaceable cartridges and those designed with the filter medium as an integral part of the facepiece (e.g., disposable or reusable disposable). Both types are acceptable so long as the seal area of the latter contains some substantial type of seal-enhancing material such as rubber or plastic, the two or more suspension straps are adjustable, the filter medium is at least ninety-five percent (95%) efficient and all other requirement of this Part are met.

f/ The assigned protection factors for gases and vapors are not applicable to radioactive contaminants that present an absorption or submersion hazard. For tritium oxide vapor, approximately one-third of the intake occurs by absorption through the skin so that an overall protection factor of three (3) is appropriate when atmosphere-supplying respirators are used to protect against tritium oxide. Exposure to radioactive noble gases is not considered a significant respiratory hazard, and protective actions for these contaminants should be based on external (submersion) dose considerations.

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g/ No NIOSH approval schedule is currently available for atmosphere supplying suits. This equipment may be used in an acceptable respiratory protection program as long as all the other minimum program requirements, with the exception of fit testing, are met (i.e., RH-1303.f.).

h/ The licensee should implement institutional controls to assure that these devices are not used in areas immediately dangerous to life or health (IDLH).

~~**Footnotes for Appendix E to Section 3 (Cont'd):**~~

i/ This type of respirator may be used as an emergency device in unknown concentrations for protection against inhalation hazards. External radiation hazards and other limitation to permitted exposure such as skin absorption shall be taken into account in these circumstances. This device may not be used by any individual who experiences perceptible outward leakage of breathing gas while wearing the device.

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APPENDIX F TO SECTION 3

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LIST OF ELEMENTS FOR USE WITH APPENDIX G TO SECTION 3

Name	Symbol	Atomic number	Name	Symbol	Atomic number
Actinium	Ac	89	Iodine	I	53
Aluminum	Al	13	Iridium	Ir	77
Americium	Am	95	Iron	Fe	26
Antimony	Sb	51	Krypton	Kr	36
Argon	Ar	18	Lanthanum	La	57
Arsenic	As	33	Lead	Pb	82
Astatine	At	85	Lutetium	Lu	71
Barium	Ba	56	Magnesium	Mg	12
Berkelium	Bk	97	Manganese	Mn	25
Beryllium	Be	4	Mendelevium	Md	101
Bismuth	Bi	83	Mercury	Hg	80
Bromine	Br	35	Molybdenum	Mo	42
Cadmium	Cd	48	Neodymium	Nd	60
Calcium	Ca	20	Neptunium	Np	93
Californium	Cf	98	Nickel	Ni	28
Carbon	C	6	Niobium	Nb	41
Cerium	Ce	58	Nitrogen	N	7
Cesium	Cs	55	Osmium	Os	76
Chlorine	Cl	17	Oxygen	O	8
Chromium	Cr	24	Palladium	Pd	46
Cobalt	Co	27	Phosphorus	P	15
Copper	Cu	29	Platinum	Pt	78
Curium	Cm	96	Plutonium	Pu	94
Dysprosium	Dy	66	Polonium	Po	84
Einsteinium	Es	99	Potassium	K	19
Erbium	Er	68	Praseodymium	Pr	59
Europium	Eu	63	Promethium	Pm	61
Fermium	Fm	100	Protactinium	Pa	91
Fluorine	F	9	Radium	Ra	88
Francium	Fr	87	Radon	Rn	86
Gadolinium	Gd	64	Rhenium	Re	75
Gallium	Ga	31	Rhodium	Rh	45
Germanium	Ge	32	Rubidium	Rb	37
Gold	Au	79	Ruthenium	Ru	44
Hafnium	Hf	72	Samarium	Sm	62
Holmium	Ho	67	Scandium	Sc	21
Hydrogen	H	1	Selenium	Se	34
Indium	In	49	Silicon	Si	14

Appendix F to Section 3 (Cont'd)

Name	Symbol	Atomic number
Silver	Ag	47
Sodium	Na	11
Strontium	Sr	38
Sulfur	S	16
Tantalum	Ta	73
Technetium	Tc	43
Tellurium	Te	52
Terbium	Tb	65
Thallium	Tl	81
Thorium	Th	90
Thulium	Tm	69
Tin	Sn	50
Titanium	Ti	22
Tungsten	W	74
Uranium	U	92
Vanadium	V	23
Xenon	Xe	54
Ytterbium	Yb	70
Yttrium	Y	39
Zinc	Zn	30
Zirconium	Zr	40

APPENDIX G TO SECTION 3

ANNUAL LIMITS ON INTAKE (ALIs) AND DERIVED AIR CONCENTRATIONS (DACs) OF RADIONUCLIDES FOR OCCUPATIONAL EXPOSURE; EFFLUENT CONCENTRATIONS; CONCENTRATIONS FOR RELEASE TO SEWERAGE

Introduction

For each radionuclide, Table I indicates the chemical form which is to be used for selecting the appropriate ALI or DAC value. The ALIs and DACs for inhalation are given for an aerosol with an activity median aerodynamic diameter (AMAD) of 1 µm (micron), and for three classes (D,W,Y) of radioactive material, which refer to their retention (approximately days, weeks or years) in the pulmonary region of the lung. This classification applies to a range of clearance half-times for D if less than 10 days, for W from 10 to 100 days, and for Y greater than 100 days. The class (D, W, or Y) given in the column headed "Class" applies only to the inhalation ALIs and DACs given in Table I, column 2 and 3. Table II provides concentration limits for airborne and liquid effluents released to the general environment. Table III provides concentration limits for discharges to sanitary sewerage.

Note: The values in Tables I, II, and III are presented in the computer "E" notation. In this notation a value of 6E-02 represents a value of 6×10^{-2} or 0.06, 6E+2 represents 6×10^{2} or 600, and 6E+0 represents 6×10^{0} or 6.

Table I: Occupational Values

Note that the columns in Table I of this appendix captioned "Oral Ingestion ALI," "Inhalation ALI," and "DAC," are applicable to occupational exposure to radioactive material.

The ALIs in this appendix are the annual intakes of given radionuclide by "Reference man" which would result in either (1) a committed effective dose equivalent of 0.05 sievert (5 rem), stochastic ALI, or (2) a committed dose equivalent of 0.5 sievert (50 rem) to an organ or tissue, non-stochastic ALI. The stochastic ALIs were derived to result in a risk, due to irradiation of organs and tissues, comparable to the risk associated with deep dose equivalent to the whole body of 0.05 sievert (5 rem). The derivation includes multiplying the committed dose equivalent to an organ or tissue by a weighting factor, w_T. This weighting factor is the proportion of the risk of stochastic effects resulting from irradiation of the organ or tissue, T, to the total risk of stochastic effects when the whole body is irradiated uniformly. The values of w_T are listed under the definition of weighting factor in RH-1100. The non-stochastic ALIs were derived to avoid non-stochastic effects, such as prompt damage to tissue or reduction in organ function.

A value of $w_T = 0.06$ is applicable to each of the 5 organs or tissues in the "remainder" category receiving the highest dose equivalents, and the dose equivalents of all other remaining tissues may be disregarded. The following portions of the GI tract – stomach, small intestine, upper large intestine, and lower large intestine – are to be treated as 4 separate organs.

Note that the dose equivalents for an extremity, skin and lens of the eye are not considered in computing the committed effective dose equivalent, but are subject to limits that must be met separately.

When an ALI is defined by the stochastic dose limit, this value alone is given. When an ALI is determined by the non-stochastic dose limit to an organ, the organ or tissue to which the limit applies is shown, and the ALI for the stochastic limit is shown in parentheses. Abbreviated organ or tissue designations are used:

LLI wall = lower large intestine wall;
St. wall = stomach wall;
Blad wall = bladder wall; and
Bone surf = bone surface.

The use of the ALIs listed first, the more limiting of the stochastic and non-stochastic ALIs, will ensure that non-stochastic effects are avoided and that the risk of stochastic effects is limited to an acceptably low value. If, in a particular situation involving a radionuclide for which the non-stochastic ALI is limiting, use of that non-stochastic ALI is considered unduly conservative, the licensee may use the stochastic ALI to determine the committed effective dose equivalent. However, the licensee shall also ensure that the 0.5 sievert (50 rem) dose equivalent limit for any organ or tissue is not exceeded by the sum of the external deep dose equivalent plus the internal committed dose equivalent to that organ, not the effective dose. For the case where there is no external dose contribution, this would be demonstrated if the sum of the fractions of the nonstochastic ALIs (ALI_{ns}) that contribute to the committed dose equivalent to the organ receiving the highest dose does not exceed unity, that is, $\sum$ (intake (in µCi) of each radionuclide/ALI_{ns}) <1.0. If there is an external deep dose equivalent contribution of H_d, then this sum must be less than 1 - (H_d/50), instead of < 1.0.

Note that the dose equivalents for an extremity, skin, and lens of the eye are not considered in computing the committed effective dose equivalent, but are subject to limits that must be met separately.

The derived air concentration (DAC) values are derived limits intended to control chronic occupational exposures. The relationship between the DAC and the ALI is given by:

DAC = ALI(in µCi)/(2000 hours per working year x 60 minutes/hour x 2 x 10^4 ml per minute) = [ALI/2.4 x 10^9] µCi/ml,

where 2 x 10^4 ml is the volume of air breathed per minute at work by "Reference man" under working conditions of "light work."

The DAC values relate to 1 of 2 modes of exposure: either external submersion or the internal committed dose equivalents resulting from inhalation of radioactive materials. DACs based upon submersion are for immersion in a semi-infinite cloud of uniform concentration and apply to each radionuclide separately.

The ALI and DAC values include contributions to exposure by the single radionuclide named and any in-growth of daughter radionuclides produced in the body by decay of the parent. However, intakes that include both the parent and daughter radionuclides should be treated by the general method appropriate for mixtures.

The values of ALI and DAC do not apply directly when the individual both ingests and inhales a radionuclide, when the individual is exposed to a mixture of radionuclides by either inhalation or ingestion or both, or when the individual is exposed to both internal and external irradiation. See RH-1201. When an individual is exposed to radioactive materials which fall under several of the translocation classifications of the same radionuclide, such as Class D, Class W, or Class Y, the exposure may be evaluated as if it were a mixture of different radionuclides.

It should be noted that the classification of a compound as Class D, W, or Y is based on the chemical form of the compound and does not take into account the radiological half-life of different radionuclides. For this reason, values are given for Class D, W, and Y compounds, even for very short-lived radionuclides.

Table II : Effluent Concentrations

The columns in Table II of this appendix captioned "Effluents," "Air" and "Water" are applicable to the assessment and control of dose to the public, particularly in the implementation of the provisions of RH-1209. The concentration values given in Columns 1 and 2 of Table II are equivalent to the radionuclide concentrations which, if inhaled or ingested continuously over the course of a year, would produce a total effective dose equivalent of 0.5 millisievert (0.05 rem).

Consideration of non-stochastic limits has not been included in deriving the air and water effluent concentration limits because non-stochastic effects are presumed not to occur at or below the dose levels established for individual members of the public. For radionuclides, where the non-stochastic limit was governing in deriving the occupational DAC, the stochastic ALI was used in deriving the corresponding airborne effluent limit in Table II. For this reason, the DAC and airborne effluent limits are not always proportional as was the case in Appendix B to 10 CFR Part 20.1-20.601.

The air concentration values listed in Table II, Column 1 were derived by one of two methods. For those radionuclides for which the stochastic limit is governing, the occupational stochastic inhalation ALI was divided by 2.4×10^9 (ml), relating the inhalation ALI to the DAC, as explained above, and then divided by a factor of 300. The factor of 300 includes the following components: a factor of 50 to relate the 0.05 sievert (5 rem) annual occupational dose limit to the 1 millisievert (0.1 rem) limit for members of the public, a factor of 3 to adjust for the difference in exposure time and the inhalation rate for a worker and that for members of the public; and a factor of 2 to adjust the occupational values, derived for adults, so that they are applicable to other age groups.

For those radionuclides for which submersion, that is external dose, is limiting, the occupational DAC in Table I, Column 3 was divided by 219. The factor of 219 is composed of a factor of 50, as described above, and a factor of 4.38 relating occupational exposure for 2,000 hours per year to full-time exposure (8,760 hours per year). Note that an additional factor of 2 for age considerations is not warranted in the submersion case.

The water concentrations were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by 7.3×10^7. The factor of 7.3×10^7 (ml) includes the following components: the factors of 50 and 2 described above and a factor of 7.3×10^5 (ml) which is the annual water intake of "Reference man."

Note 2 of this appendix provides groupings of radionuclides which are applicable to unknown mixtures of radionuclides. These groupings, including occupational inhalation ALIs and DACs, air and water effluent concentrations and releases to sewer, require demonstrating that the most limiting radionuclides in successive classes are absent. The limit for the unknown mixture is defined when the presence of one of the listed radionuclides cannot be definitely excluded as being present either from knowledge of the radionuclide composition of the source or from actual measurements.

Table III: Releases to Sewers

The monthly average concentrations for release to sanitary sewers are applicable to the provisions in RH-1402. The concentration values were derived by taking the most restrictive occupational stochastic oral ingestion ALI and dividing by 7.3×10^6 (ml). The factor of 7.3×10^6 (ml) is composed of a factor of 7.3×10^5 (ml), the annual water intake by "Reference Man," and a factor of 10, such that the concentrations, if the sewage released by the licensee were the only source of water ingested by a reference man during a year, would result in a committed effective dose equivalent of 0.5 rem.

~~Appendix G to Section 3 (Cont'd)~~

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Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage

			Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	Inhalation				
Atomic No.	Radionuclide	Class	ALI (µCi)	ALI (µCi)	DAC (µCi/ml)	Air (µCi/ml)	Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
1	Hydrogen-3	Water, DAC includes skin absorption	8E+4	8E+4	2E-5	1E-7	1E-3	1E-2
		Gas (HT or T_2) Submersion[a/]: Use above values as HT and T_2 oxidize in air and in the body to HTO.						
4	Beryllium-7	W, all compounds except those given for Y	4E+4	2E+4	9E-6	3E-8	6E-4	6E-3
		Y, oxides, halides, and nitrates	–	2E+4	8E-6	3E-8	–	–
4	Beryllium-10	W, see ^{7}Be	1E+3	2E+2	6E-8	2E-10	–	–
			LLI wall (1E+3)	–	–	–	2E-5	2E-4
		Y, see ^{7}Be	–	1E+1	6E-9	2E-11	–	–
6	Carbon-11[b/]	Monoxide	–	1E+6	5E-4	2E-6	–	–
		Dioxide	–	6E+5	3E-4	9E-7	–	–
		Compounds	4E+5	4E+5	2E-4	6E-7	6E-3	6E-2
6	Carbon-14	Monoxide	–	2E+6	7E-4	2E-6	–	–
		Dioxide	–	2E+5	9E-5	3E-7	–	–
		Compounds	2E+3	2E+3	1E-6	3E-9	3E-5	3E-4
7	Nitrogen-13[b/]	Submersion[a/]	–	–	4E-6	2E-8	–	–
8	Oxygen-15[b/]	Submersion[a/]	–	–	4E-6	2E-8	–	–
9	Fluorine-18[b/]	D, fluorides of H, Li, Na, K, Rb, Cs, and Fr	5E+4	7E+4	3E-5	1E-7	–	–
			St wall (5E+4)	–	–	–	7E-4	7E-3
		W, fluorides of Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Tl, As, Sb, Bi, Fe, Ru, Os, Co, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, V, Nb, Ta, Mn, Tc, and Re	–	9E+4	4E-5	1E-7	–	–
		Y, lanthanum fluoride	–	8E+4	3E-5	1E-7	–	–
11	Sodium-22	D, all compounds	4E+2	6E+2	3E-7	9E-10	6E-6	6E-5
11	Sodium-24	D, all compounds	4E+3	5E+3	2E-6	7E-9	5E-5	5E-4
12	Magnesium-28	D, all compounds except those given for W	7E+2	2E+3	7E-7	2E-9	9E-6	9E-5
		W, oxides, hydroxides, carbides, halides, and nitrates	–	1E+3	5E-7	2E-9	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation	Col. 3 Inhalation	Col. 1	Col. 2	
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
13	Aluminum-26	D, all compounds except those given for W	4E+2	6E+1	3E-8	9E-11	6E-6	6E-5
		W, oxides, hydroxides, carbides, halides, and nitrates	–	9E+1	4E-8	1E-10	–	–
14	Silicon-31	D, all compounds except those given for W and Y	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
		W, oxides, hydroxides, carbides, and nitrates	–	3E+4	1E-5	5E-8	–	–
		Y, aluminosilicate glass	–	3E+4	1E-5	4E-8	–	–
14	Silicon-32	D, see ^{31}Si	2E+3	2E+2	1E-7	3E-10	–	–
			LLI wall (3E+3)	–	–	–	4E-5	4E-4
		W, see ^{31}Si	–	1E+2	5E-8	2E-10	–	–
		Y, see ^{31}Si	–	5E+0	2E-9	7E-12	–	–
15	Phosphorus-32	D, all compounds except phosphates given for W	6E+2	9E+2	4E-7	1E-9	9E-6	9E-5
		W, phosphates of Zn^{2+}, S^{3+}, Mg^{2+}, Fe^{3+}, Bi^{3+}, and lanthanides	–	4E+2	2E-7	5E-10	–	–
15	Phosphorus-33	D, see ^{32}P	6E+3	8E+3	4E-6	1E-8	8E-5	8E-4
		W, see ^{32}P	–	3E+3	1E-6	4E-9	–	–
16	Sulfur-35	Vapor	–	1E+4	6E-6	2E-8	–	–
		D, sulfides and sulfates except those given for W	1E+4	2E+4	7E-6	2E-8	–	–
			LLI wall (8E+3)	–	–	–	1E-4	1E-3
		W, elemental sulfur, sulfides of Sr, Ba, Ge, Sn, Pb, As, Sb, Bi, Cu, Ag, Au, Zn, Cd, Hg, W, and Mo. Sulfates of Ca, Sr, Ba, Ra, As, Sb, and Bi	6E+3 –	2E+3	9E-7	3E-9	–	–
17	Chlorine-36	D, chlorides of H, Li, Na, K, Rb, Cs, and Fr	2E+3	2E+3	1E-6	3E-9	2E-5	2E-4
		W, chlorides of lanthanides, Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Tl, Ge, Sn, Pb, As, Sb, Bi, Fe, Ru, Os, Co, Rh, Ir, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, Hf, V, Nb, Ta, Cr, Mo, W, Mn, Tc, and Re	–	2E+2	1E-7	3E-10	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	Inhalation				
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
17	Chlorine-38[b/]	D, see ^{36}Cl	2E+4	4E+4	2E-5	6E-8	–	–
			St wall (3E+4)	–	–	–	3E-4	3E-3
		W, see ^{36}Cl	–	5E+4	2E-5	6E-8	–	–
17	Chlorine-39[b/]	D, see ^{36}Cl	2E+4	5E+4	2E-5	7E-8	–	–
			St wall (4E+4)	–	–	–	5E-4	5E-3
		W, see ^{36}Cl	–	6E+4	2E-5	8E-8	–	–
18	Argon-37	Submersion[a/]	–	–	1E+0	6E-3	–	–
18	Argon-39	Submersion[a/]	–	–	2E-4	8E-7	–	–
18	Argon-41	Submersion[a/]	–	–	3E-6	1E-8	–	–
19	Potassium-40	D, all compounds	3E+2	4E+2	2E-7	6E-10	4E-6	4E-5
19	Potassium-42	D, all compounds	5E+3	5E+3	2E-6	7E-9	6E-5	6E-4
19	Potassium-43	D, all compounds	6E+3	9E+3	4E-6	1E-8	9E-5	9E-4
19	Potassium-44[b/]	D, all compounds	2E+4	7E+4	3E-5	9E-8	–	–
			St wall (4E+4)	–	–	–	5E-4	5E-3
19	Potassium-45[b/]	D, all compounds	3E+4	1E+5	5E-5	2E-7	–	–
			St wall (5E+4)	–	–	–	7E-4	7E-3
20	Calcium-41	W, all compounds	3E+3	4E+3	2E-6	–	–	–
			Bone surf (4E+3)	Bone surf (4E+3)	–	5E-9	6E-5	6E-4
20	Calcium-45	W, all compounds	2E+3	8E+2	4E-7	1E-9	2E-5	2E-4
20	Calcium-47	W, all compounds	8E+2	9E+2	4E-7	1E-9	1E-5	1E-4
21	Scandium-43	Y, all compounds	7E+3	2E+4	9E-6	3E-8	1E-4	1E-3
21	Scandium-44m	Y, all compounds	5E+2	7E+2	3E-7	1E-9	7E-6	7E-5
21	Scandium-44	Y, all compounds	4E+3	1E+4	5E-6	2E-8	5E-5	5E-4
21	Scandium-46	Y, all compounds	9E+2	2E+2	1E-7	3E-10	1E-5	1E-4
21	Scandium-47	Y, all compounds	2E+3	3E+3	1E-6	4E-9	–	–
			LLI wall (3E+3)	–	–	–	4E-5	4E-4
21	Scandium-48	Y, all compounds	8E+2	1E+3	6E-7	2E-9	1E-5	1E-4

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation	Col. 3 Inhalation	Col. 1	Col. 2	
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
21	Scandium-49[b/]	Y, all compounds	2E+4	5E+4	2E-5	8E-8	3E-4	3E-3
22	Titanium-44	D, all compounds except those given for W and Y	3E+2	1E+1	5E-9	2E-11	4E-6	4E-5
		W, oxides, hydroxides, carbides, halides, and nitrates	–	3E+1	1E-8	4E-11	–	–
		Y, SrTi0	–	6E+0	2E-9	8E-12	–	–
22	Titanium-45	D, see ^{44}Ti	9E+3	3E+4	1E-5	3E-8	1E-4	1E-3
		W, see ^{44}Ti	–	4E+4	1E-5	5E-8	–	–
		Y, see ^{44}Ti	–	3E+4	1E-5	4E-8	–	–
23	Vanadium-47[b/]	D, all compounds except those given for W	3E+4	8E+4	3E-5	1E-7	–	–
			St wall (3E+4)	–	–	–	4E-4	4E-3
		W, oxides, hydroxides, carbides, and halides	–	1E+5	4E-5	1E-7	–	–
23	Vanadium-48	D, see ^{47}V	6E+2	1E+3	5E-7	2E-9	9E-6	9E-5
		W, see ^{47}V	–	6E+2	3E-7	9E-10	–	–
23	Vanadium-49	D, see ^{47}V	7E+4	3E+4	1E-5	–	–	–
			LLI wall (9E+4)	Bone surf (3E+4)	–	5E-8	1E-3	1E-2
		W, see ^{47}V	–	2E+4	8E-6	2E-8	–	–
24	Chromium-48	D, all compounds except those given for W and Y	6E+3	1E+4	5E-6	2E-8	8E-5	8E-4
		W, halides and nitrates	–	7E+3	3E-6	1E-8	–	–
		Y, oxides and hydroxides	–	7E+3	3E-6	1E-8	–	–
24	Chromium-49[b/]	D, see ^{48}Cr	3E+4	8E+4	4E-5	1E-7	4E-4	4E-3
		W, see ^{48}Cr	–	1E+5	4E-5	1E-7	–	–
		Y, see ^{48}Cr	–	9E+4	4E-5	1E-7	–	–
24	Chromium-51	D, see ^{48}Cr	4E+4	5E+4	2E-5	6E-8	5E-4	5E-3
		W, see ^{48}Cr	–	2E+4	1E-5	3E-8	–	–
		Y, see ^{48}Cr	–	2E+4	8E-6	3E-8	–	–
25	Manganese-51[b/]	D, all compounds except those given for W	2E+4	5E+4	2E-5	7E-8	3E-4	3E-3
		W, oxides, hydroxides, halides, and nitrates	–	6E+4	3E-5	8E-8	–	–
25	Manganese-52m[b/]	D, see ^{51}Mn	3E+4	9E+4	4E-5	1E-7	–	–
			St wall (4E+4)	–	–	–	5E-4	5E-3
		W, see ^{51}Mn	–	1E+5	4E-5	1E-7	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation	Col. 3	Col. 1	Col. 2	
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
25	Manganese-52	D, see ^{51}Mn	7E+2	1E+3	5E-7	2E-9	1E-5	1E-4
		W, see ^{51}Mn	–	9E+2	4E-7	1E-9	–	–
25	Manganese-53	D, see ^{51}Mn	5E+4	1E+4	5E-6	–	7E-4	7E-3
			–	Bone surf (2E+4)	-	3E-8	–	–
		W, see ^{51}Mn	–	1E+4	5E-6	2E-8	–	–
25	Manganese-54	D, see ^{51}Mn	2E+3	9E+2	4E-7	1E-9	3E-5	3E-4
		W, see ^{51}Mn	–	8E+2	3E-7	1E-9	–	–
25	Manganese-56	D, see ^{51}Mn	5E+3	2E+4	6E-6	2E-8	7E-5	7E-4
		W, see ^{51}Mn	–	2E+4	9E-6	3E-8	–	–
26	Iron-52	D, all compounds except those given for W	9E+2	3E+3	1E-6	4E-9	1E-5	1E-4
		W, oxides, hydroxides, and halides	–	2E+3	1E-6	3E-9	–	–
26	Iron-55	D, see ^{52}Fe	9E+3	2E+3	8E-7	3E-9	1E-4	1E-3
		W, see ^{52}Fe	–	4E+3	2E-6	6E-9	–	–
26	Iron-59	D, see ^{52}Fe	8E+2	3E+2	1E-7	5E-10	1E-5	1E-4
		W, see ^{52}Fe	–	5E+2	2E-7	7E-10	–	–
26	Iron-60	D, see ^{52}Fe	3E+1	6E+0	3E-9	9E-12	4E-7	4E-6
		W, see ^{52}Fe	–	2E+1	8E-9	3E-11	–	–
27	Cobalt-55	W, all compounds except those given for Y	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
		Y, oxides, hydroxides, halides, and nitrates	–	3E+3	1E-6	4E-9	–	–
27	Cobalt-56	W, see ^{55}Co	5E+2	3E+2	1E-7	4E-10	6E-6	6E-5
		Y, see ^{55}Co	4E+2	2E+2	8E-8	3E-10	–	–
27	Cobalt-57	W, see ^{55}Co	8E+3	3E+3	1E-6	4E-9	6E-5	6E-4
		Y, see ^{55}Co	4E+3	7E+2	3E-7	9E-10	–	–
27	Cobalt-58m	W, see ^{55}Co	6E+4	9E+4	4E-5	1E-7	8E-4	8E-3
		Y, see ^{55}Co	–	6E+4	3E-5	9E-8	–	–
27	Cobalt-58	W, see ^{55}Co	2E+3	1E+3	5E-7	2E-9	2E-5	2E-4
		Y, see ^{55}Co	1E+3	7E+2	3E-7	1E-9	–	–
27	Cobalt-60m[b/]	W, see ^{55}Co	1E+6	4E+6	2E-3	6E-6	–	–
			St wall (1E+6)	–	–	–	2E-2	2E-1
		Y, see ^{55}Co	–	3E+6	1E-3	4E-6	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation	Col. 3 Inhalation	Col. 1	Col. 2	
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
27	Cobalt-60	W, see ^{55}Co	5E+2	2E+2	7E-8	2E-10	3E-6	3E-5
		Y, see ^{55}Co	2E+2	3E+1	1E-8	5E-11	–	–
27	Cobalt-61[b/]	W, see ^{55}Co	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
		Y, see ^{55}Co	2E+4	6E+4	2E-5	8E-8	–	–
27	Cobalt-62m[b/]	W, see ^{55}Co	4E+4	2E+5	7E-5	2E-7	–	–
			St wall (5E+4)	–	–	–	7E-4	7E-3
		Y, see ^{55}Co	–	2E+5	6E-5	2E-7	–	–
28	Nickel-56	D, all compounds except those given for W	1E+3	2E+3	8E-7	3E-9	2E-5	2E-4
		W, oxides, hydroxides, and carbides	–	1E+3	5E-7	2E-9	–	–
		Vapor	–	1E+3	5E-7	2E-9	–	–
28	Nickel-57	D, see ^{56}Ni	2E+3	5E+3	2E-6	7E-9	2E-5	2E-4
		W, see ^{56}Ni	–	3E+3	1E-6	4E-9	–	–
		Vapor	–	6E+3	3E-6	9E-9	–	–
28	Nickel-59	D, see ^{56}Ni	2E+4	4E+3	2E-6	5E-9	3E-4	3E-3
		W, see ^{56}Ni	–	7E+3	3E-6	1E-8	–	–
		Vapor	–	2E+3	8E-7	3E-9	–	–
28	Nickel-63	D, see ^{56}Ni	9E+3	2E+3	7E-7	2E-9	1E-4	1E-3
		W, see ^{56}Ni	–	3E+3	1E-6	4E-9	–	–
		Vapor	–	8E+2	3E-7	1E-9	–	–
28	Nickel-65	D, see ^{56}Ni	8E+3	2E+4	1E-5	3E-8	1E-4	1E-3
		W, see ^{56}Ni	–	3E+4	1E-5	4E-8	–	–
		Vapor	–	2E+4	7E-6	2E-8	–	–
28	Nickel-66	D, see ^{56}Ni	4E+2	2E+3	7E-7	2E-9	–	–
			LLI wall (5E+2)	–	–	–	6E-6	6E-5
		W, see ^{56}Ni	–	6E+2	3E-7	9E-10	–	–
		Vapor	–	3E+3	1E-6	4E-9	–	–
29	Copper-60[b/]	D, all compounds except those given for W and Y	3E+4	9E+4	4E-5	1E-7	–	–
			St wall (3E+4)	–	–	–	4E-4	4E-3
		W, sulfides, halides, and nitrates	–	1E+5	5E-5	2E-7	–	–
		Y, oxides and hydroxides	–	1E+5	4E-5	1E-7	–	–
29	Copper-61	D, see ^{60}Cu	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
		W, see ^{60}Cu	–	4E+4	2E-5	6E-8	–	–
		Y, see ^{60}Cu	–	4E+4	1E-5	5E-8	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values: Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values: Col. 2 Inhalation ALI (µCi)	Table I Occupational Values: Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentrations: Col. 1 Air (µCi/ml)	Table II Effluent Concentrations: Col. 2 Water (µCi/ml)	Table III Releases to Sewers: Monthly Average Concentration (µCi/ml)
29	Copper-64	D, see ^{60}Cu	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
		W, see ^{60}Cu	–	2E+4	1E-5	3E-8	–	–
		Y, see ^{60}Cu	–	2E+4	9E-6	3E-8	–	–
29	Copper-67	D, see ^{60}Cu	5E+3	8E+3	3E-6	1E-8	6E-5	6E-4
		W, see ^{60}Cu	–	5E+3	2E-6	7E-9	–	–
		Y, see ^{60}Cu	–	5E+3	2E-6	6E-9	–	–
30	Zinc-62	Y, all compounds	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
30	Zinc-63[b/]	Y, all compounds	2E+4	7E+4	3E-5	9E-8	–	–
			St wall (3E+4)	–	–	–	3E-4	3E-3
30	Zinc-65	Y, all compounds	4E+2	3E+2	1E-7	4E-10	5E-6	5E-5
30	Zinc-69m	Y, all compounds	4E+3	7E+3	3E-6	1E-8	6E-5	6E-4
30	Zinc-69[b/]	Y, all compounds	6E+4	1E+5	6E-5	2E-7	8E-4	8E-3
30	Zinc-71m	Y, all compounds	6E+3	2E+4	7E-6	2E-8	8E-5	8E-4
30	Zinc-72	Y, all compounds	1E+3	1E+3	5E-7	2E-9	1E-5	1E-4
31	Gallium-65[b/]	D, all compounds except those given for W	5E+4	2E+5	7E-5	2E-7	–	–
			St wall (6E+4)	–	–	–	9E-4	9E-3
		W, oxides, hydroxides, carbides, halides, and nitrates	–	2E+5	8E-5	3E-7	–	–
31	Gallium-66	D, see ^{65}Ga	1E+3	4E+3	1E-6	5E-9	1E-5	1E-4
		W, see ^{65}Ga	–	3E+3	1E-6	4E-9	–	–
31	Gallium-67	D, see ^{65}Ga	7E+3	1E+4	6E-6	2E-8	1E-4	1E-3
		W, see ^{65}Ga	–	1E+4	4E-6	1E-8	–	–
31	Gallium-68[b/]	D, see ^{65}Ga	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{65}Ga	–	5E+4	2E-5	7E-8	–	–
31	Gallium-70[b/]	D, see ^{65}Ga	5E+4	2E+5	7E-5	2E-7	–	–
			St wall (7E+4)	–	–	–	1E-3	1E-2
		W, see ^{65}Ga	–	2E+5	8E-5	3E-7	–	–
31	Gallium-72	D, see ^{65}Ga	1E+3	4E+3	1E-6	5E-9	2E-5	2E-4
		W, see ^{65}Ga	–	3E+3	1E-6	4E-9	–	–
31	Gallium-73	D, see ^{65}Ga	5E+3	2E+4	6E-6	2E-8	7E-5	7E-4
		W, see ^{65}Ga	–	2E+4	6E-6	2E-8	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1 Oral Ingestion ALI (µCi)	Col. 2 Inhalation ALI (µCi)	Col. 3 Inhalation DAC (µCi/ml)	Col. 1 Air (µCi/ml)	Col. 2 Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
32	Germanium-66	D, all compounds except those given for W	2E+4	3E+4	1E-5	4E-8	3E-4	3E-3
		W, oxides, sulfides, and halides	–	2E+4	8E-6	3E-8	–	–
32	Germanium-67[b]	D, see ^{66}Ge	3E+4	9E+4	4E-5	1E-7	–	–
			St wall (4E+4)	–	–	–	6E-4	6E-3
		W, see ^{66}Ge	–	1E+5	4E-5	1E-7	–	–
32	Germanium-68	D, see ^{66}Ge	5E+3	4E+3	2E-6	5E-9	6E-5	6E-4
		W, see ^{66}Ge	–	1E+2	4E-8	1E-10	–	–
32	Germanium-69	D, see ^{66}Ge	1E+4	2E+4	6E-6	2E-8	2E-4	2E-3
		W, see ^{66}Ge	–	8E+3	3E-6	1E-8	–	–
32	Germanium-71	D, see ^{66}Ge	5E+5	4E+5	2E-4	6E-7	7E-3	7E-2
		W, see ^{66}Ge	–	4E+4	2E-5	6E-8	–	–
32	Germanium-75[b]	D, see ^{66}Ge	4E+4	8E+4	3E-5	1E-7	–	–
			St wall (7E+4)	–	–	–	9E-4	9E-3
		W, see ^{66}Ge	–	8E+4	4E-5	1E-7	–	–
32	Germanium-77	D, see ^{66}Ge	9E+3	1E+4	4E-6	1E-8	1E-4	1E-3
		W, see ^{66}Ge	–	6E+3	2E-6	8E-9	–	–
32	Germanium-78[b]	D, see ^{66}Ge	2E+4	2E+4	9E-6	3E-8	–	–
			St wall (2E+4)	–	–	–	3E-4	3E-3
		W, see ^{66}Ge	–	2E+4	9E-6	3E-8	–	–
33	Arsenic-69[b]	W, all compounds	3E+4	1E+5	5E-5	2E-7	–	–
			St wall (4E+4)	–	–	–	6E-4	6E-3
33	Arsenic-70[b]	W, all compounds	1E+4	5E+4	2E-5	7E-8	2E-4	2E-3
33	Arsenic-71	W, all compounds	4E+3	5E+3	2E-6	6E-9	5E-5	5E-4
33	Arsenic-72	W, all compounds	9E+2	1E+3	6E-7	2E-9	1E-5	1E-4
33	Arsenic-73	W, all compounds	8E+3	2E+3	7E-7	2E-9	1E-4	1E-3
33	Arsenic-74	W, all compounds	1E+3	8E+2	3E-7	1E-9	2E-5	2E-4
33	Arsenic-76	W, all compounds	1E+3	1E+3	6E-7	2E-9	1E-5	1E-4

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation	Col. 3 Inhalation	Col. 1	Col. 2	
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
33	Arsenic-77	W, all compounds	4E+3	5E+3	2E-6	7E-9	–	–
			LLI wall (5E+3)	–	–	–	6E-5	6E-4
33	Arsenic-78[b/]	W, all compounds	8E+3	2E+4	9E-6	3E-8	1E-4	1E-3
34	Selenium-70[b/]	D, all compounds except those given for W	2E+4	4E+4	2E-5	5E-8	1E-4	1E-3
		W, oxides, hydroxides, carbides, and elemental Se	1E+4	4E+4	2E-5	6E-8	–	–
34	Selenium-73m[b/]	D, see ^{70}Se	6E+4	2E+5	6E-5	2E-7	4E-4	4E-3
		W, see ^{70}Se	3E+4	1E+5	6E-5	2E-7	–	–
34	Selenium-73	D, see ^{70}Se	3E+3	1E+4	5E-6	2E-8	4E-5	4E-4
		W, see ^{70}Se	–	2E+4	7E-6	2E-8	–	–
34	Selenium-75	D, see ^{70}Se	5E+2	7E+2	3E-7	1E-9	7E-6	7E-5
		W, see ^{70}Se	–	6E+2	3E-7	8E-10	–	–
34	Selenium-79	D, see ^{70}Se	6E+2	8E+2	3E-7	1E-9	8E-6	8E-5
		W, see ^{70}Se	–	6E+2	2E-7	8E-10	–	–
34	Selenium-81m[b/]	D, see ^{70}Se	4E+4	7E+4	3E-5	9E-8	3E-4	3E-3
		W, see ^{70}Se	2E+4	7E+4	3E-5	1E-7	–	–
34	Selenium-81[b/]	D, see ^{70}Se	6E+4	2E+5	9E-5	3E-7	–	–
			St wall (8E+4)	–	–	–	1E-3	1E-2
		W, see ^{70}Se	–	2E+5	1E-4	3E-7	-	-
34	Selenium-83[b/]	D, see ^{70}Se	4E+4	1E+5	5E-5	2E-7	4E-4	4E-3
		W, see ^{70}Se	3E+4	1E+5	5E-5	2E-7	–	–
35	Bromine-74m[b/]	D, bromides of H, Li, Na, K, Rb, Cs, and Fr	1E+4	4E+4	2E-5	5E-8	–	–
			St wall (2E+4)	–	–	–	3E-4	3E-3
		W, bromides of lantha-nides, Be, Mg, Ca, Sr, Ba, Ra, Al, Ga, In, Tl, Ge, Sn, Pb, As, Sb, Bi, Fe, Ru, Os, Co, Rh, Ir, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, Hf, V, Nb, Ta, Mn, Tc, and Re	–	4E+4	2E-5	6E-8	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	Inhalation				
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
35	Bromine-74[b/]	D, see ^{74m}Br	2E+4 St wall (4E+4)	7E+4	3E-5	1E-7	–	–
				–	–	–	5E-4	5E-3
		W, see ^{74m}Br	–	8E+4	4E-5	1E-7	–	–
35	Bromine-75[b/]	D, see ^{74m}Br	3E+4 St wall (4E+4)	5E+4	2E-5	7E-8	–	–
				–	–	–	5E-4	5E-3
		W, see ^{74m}Br	–	5E+4	2E-5	7E-8	–	–
35	Bromine-76	D, see ^{74m}Br	4E+3	5E+3	2E-6	7E-9	5E-5	5E-4
		W, see ^{74m}Br	–	4E+3	2E-6	6E-9	–	–
35	Bromine-77	D, see ^{74m}Br	2E+4	2E+4	1E-5	3E-8	2E-4	2E-3
		W, see ^{74m}Br	–	2E+4	8E-6	3E-8	–	–
35	Bromine-80m	D, see ^{74m}Br	2E+4	2E+4	7E-6	2E-8	3E-4	3E-3
		W, see ^{74m}Br	–	1E+4	6E-6	2E-8	–	–
35	Bromine-80[b/]	D, see ^{74m}Br	5E+4 St wall (9E+4)	2E+5	8E-5	3E-7	–	–
				–	–	–	1E-3	1E-2
		W, see ^{74m}Br	–	2E+5	9E-5	3E-7	–	–
35	Bromine-82	D, see ^{74m}Br	3E+3	4E+3	2E-6	6E-9	4E-5	4E-4
		W, see ^{74m}Br	–	4E+3	2E-6	5E-9	–	–
35	Bromine-83	D, see ^{74m}Br	5E+4 St wall (7E+4)	6E+4	3E-5	9E-8	–	–
				–	–	–	9E-4	9E-3
		W, see ^{74m}Br	–	6E+4	3E-5	9E-8	–	–
35	Bromine-84[b/]	D, see ^{74m}Br	2E+4 St wall (3E+4)	6E+4	2E-5	8E-8	–	–
				–	–	–	4E-4	4E-3
		W, see ^{74m}Br	–	6E+4	3E-5	9E-8	–	–
36	Krypton-74[b/]	Submersion[a/]	–	–	3E-6	1E-8	–	–
36	Krypton-76	Submersion[a/]	–	–	9E-6	4E-8	–	–
36	Krypton-77[b/]	Submersion[a/]	–	–	4E-6	2E-8	–	–
36	Krypton-79	Submersion[a/]	–	–	2E-5	7E-8	–	–
36	Krypton-81	Submersion[a/]	–	–	7E-4	3E-6	–	–
36	Krypton-83m[b/]	Submersion[a/]	–	–	1E-2	5E-5	–	–
36	Krypton-85m	Submersion[a/]	–	–	2E-5	1E-7	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation	Col. 3 Inhalation	Col. 1	Col. 2	
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
36	Krypton-85	Submersion[a/]	–	–	1E-4	7E-7	–	–
36	Krypton-87[b/]	Submersion[a/]	–	–	5E-6	2E-8	–	–
36	Krypton-88	Submersion[a/]	–	–	2E-6	9E-9	–	–
37	Rubidium-79[b/]	D, all compounds	4E+4	1E+5	5E-5	2E-7	–	–
			St wall (6E+4)	–	–	–	8E-4	8E-3
37	Rubidium-81m[b/]	D, all compounds	2E+5	3E+5	1E-4	5E-7	–	–
			St wall (3E+5)	–	–	–	4E-3	4E-2
37	Rubidium-81	D, all compounds	4E+4	5E+4	2E-5	7E-8	5E-4	5E-3
37	Rubidium-82m	D, all compounds	1E+4	2E+4	7E-6	2E-8	2E-4	2E-3
37	Rubidium-83	D, all compounds	6E+2	1E+3	4E-7	1E-9	9E-6	9E-5
37	Rubidium-84	D, all compounds	5E+2	8E+2	3E-7	1E-9	7E-6	7E-5
37	Rubidium-86	D, all compounds	5E+2	8E+2	3E-7	1E-9	7E-6	7E-5
37	Rubidium-87	D, all compounds	1E+3	2E+3	6E-7	2E-9	1E-5	1E-4
37	Rubidium-88[b/]	D, all compounds	2E+4	6E+4	3E-5	9E-8	–	–
			St wall (3E+4)	–	–	–	4E-4	4E-3
37	Rubidium-89[b/]	D, all compounds	4E+4	1E+5	6E-5	2E-7	–	–
			St wall (6E+4)	–	–	–	9E-4	9E-3
38	Strontium-80[b/]	D, all soluble compounds except $SrTiO_3$	4E+3	1E+4	5E-6	2E-8	6E-5	6E-4
		Y, all insoluble compounds and $SrTi0_3$	–	1E+4	5E-6	2E-8	–	–
38	Strontium-81[b/]	D, see ^{80}Sr	3E+4	8E+4	3E-5	1E-7	3E-4	3E-3
		Y, see ^{80}Sr	2E+4	8E+4	3E-5	1E-7	–	–
38	Strontium-82	D, see ^{80}Sr	3E+2	4E+2	2E-7	6E-10	–	–
			LLI wall (2E+2)	–	–	–	3E-6	3E-5
		Y, see ^{80}Sr	2E+2	9E+1	4E-8	1E-10	–	–
38	Strontium-83	D, see ^{80}Sr	3E+3	7E+3	3E-6	1E-8	3E-5	3E-4
		Y, see ^{80}Sr	2E+3	4E+3	1E-6	5E-9	–	–
38	Strontium-85m[b/]	D, see ^{80}Sr	2E+5	6E+5	3E-4	9E-7	3E-3	3E-2
		Y, see ^{80}Sr	–	8E+5	4E-4	1E-6	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	Inhalation				
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
38	Strontium-85	D, see ^{80}Sr	3E+3	3E+3	1E-6	4E-9	4E-5	4E-4
		Y, see ^{80}Sr	–	2E+3	6E-7	2E-9	–	–
38	Strontium-87m	D, see ^{80}Sr	5E+4	1E+5	5E-5	2E-7	6E-4	6E-3
		Y, see ^{80}Sr	4E+4	2E+5	6E-5	2E-7	–	–
38	Strontium-89	D, see ^{80}Sr	6E+2	8E+2	4E-7	1E-9	–	–
			LLI wall (6E+2)	–	–	–	8E-6	8E-5
		Y, see ^{80}Sr	5E+2	1E+2	6E-8	2E-10	–	–
38	Strontium-90	D, see ^{80}Sr	3E+1	2E+1	8E-9	–	–	–
			Bone surf (4E+1)	Bone surf (2E+1)	–	3E-11	5E-7	5E-6
		Y, see ^{80}Sr	–	4E+0	2E-9	6E-12	–	–
38	Strontium-91	D, see ^{80}Sr	2E+3	6E+3	2E-6	8E-9	2E-5	2E-4
		Y, see ^{80}Sr	–	4E+3	1E-6	5E-9	–	–
38	Strontium-92	D, see ^{80}Sr	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		Y, see ^{80}Sr	–	7E+3	3E-6	9E-9	–	–
39	Yttrium-86m[b/]	W, all compounds except those given for Y	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
		Y, oxides and hydroxides	–	5E+4	2E-5	8E-8	–	–
39	Yttrium-86	W, see ^{86m}Y	1E+3	3E+3	1E-6	5E-9	2E-5	2E-4
		Y, see ^{86m}Y	–	3E+3	1E-6	5E-9	–	–
39	Yttrium-87	W, see ^{86m}Y	2E+3	3E+3	1E-6	5E-9	3E-5	3E-4
		Y, see ^{86m}Y	–	3E+3	1E-6	5E-9	–	–
39	Yttrium-88	W, see ^{86m}Y	1E+3	3E+2	1E-7	3E-10	1E-5	1E-4
		Y, see ^{86m}Y	–	2E+2	1E-7	3E-10	–	–
39	Yttrium-90m	W, see ^{86m}Y	8E+3	1E+4	5E-6	2E-8	1E-4	1E-3
		Y, see ^{86m}Y	–	1E+4	5E-6	2E-8	–	–
39	Yttrium-90	W, see ^{86m}Y	4E+2	7E+2	3E-7	9E-10	–	–
			LLI wall (5E+2)	–	–	–	7E-6	7E-5
		Y, see ^{86m}Y	–	6E+2	3E-7	9E-10	–	–
39	Yttrium-91m[b/]	W, see ^{86m}Y	1E+5	2E+5	1E-4	3E-7	2E-3	2E-2
		Y, see ^{86m}Y	–	2E+5	7E-5	2E-7	–	–
39	Yttrium-91	W, see ^{86m}Y	5E+2	2E+2	7E-8	2E-10	–	–
			LLI wall (6E+2)	–	–	–	8E-6	8E-5
		Y, see ^{86m}Y	–	1E+2	5E-8	2E-10	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	Inhalation				
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
39	Yttrium-92	W, see ^{86m}Y	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		Y, see ^{86m}Y	–	8E+3	3E-6	1E-8	–	–
39	Yttrium-93	W, see ^{86m}Y	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
		Y, see ^{86m}Y	–	2E+3	1E-6	3E-9	–	–
39	Yttrium-94[b/]	W, see ^{86m}Y	2E+4 St wall (3E+4)	8E+4 –	3E-5 –	1E-7 –	– 4E-4	– 4E-3
		Y, see ^{86m}Y	–	8E+4	3E-5	1E-7	–	–
39	Yttrium-95[b/]	W, see ^{86m}Y	4E+4 St wall (5E+4)	2E+5 –	6E-5 –	2E-7 –	– 7E-4	– 7E-3
		Y, see ^{86m}Y	–	1E+5	6E-5	2E-7	–	–
40	Zirconium-86	D, all compounds except those given for W and Y	1E+3	4E+3	2E-6	6E-9	2E-5	2E-4
		W, oxides, hydroxides, halides, and nitrates	–	3E+3	1E-6	4E-9	–	–
		Y, carbide	–	2E+3	1E-6	3E-9	–	–
40	Zirconium-88	D, see ^{86}Zr	4E+3	2E+2	9E-8	3E-10	5E-5	5E-4
		W, see ^{86}Zr	–	5E+2	2E-7	7E-10	–	–
		Y, see ^{86}Zr	–	3E+2	1E-7	4E-10	–	–
40	Zirconium-89	D, see ^{86}Zr	2E+3	4E+3	1E-6	5E-9	2E-5	2E-4
		W, see ^{86}Zr	–	2E+3	1E-6	3E-9	–	–
		Y, see ^{86}Zr	–	2E+3	1E-6	3E-9	–	–
40	Zirconium-93	D, see ^{86}Zr	1E+3 Bone surf (3E+3)	6E+0 Bone surf (2E+1)	3E-9 –	– 2E-11	– 4E-5	– 4E-4
		W, see ^{86}Zr	–	2E+1 Bone surf	1E-8	–	–	–
			–	(6E+1)	–	9E-11	–	–
		Y, see ^{86}Zr	–	6E+1 Bone surf	2E-8	–	–	–
			–	(7E+1)	–	9E-11	–	–
40	Zirconium-95	D, see ^{86}Zr	1E+3	1E+2 Bone surf	5E-8	–	2E-5	2E-4
			–	(3E+2)	–	4E-10	–	–
		W, see ^{86}Zr	–	4E+2	2E-7	5E-10	–	–
		Y, see ^{86}Zr	–	3E+2	1E-7	4E-10	–	–
40	Zirconium-97	D, see ^{86}Zr	6E+2	2E+3	8E-7	3E-9	9E-6	9E-5
		W, see ^{86}Zr	–	1E+3	6E-7	2E-9	–	–
		Y, see ^{86}Zr	–	1E+3	5E-7	2E-9	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values: Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values: Inhalation ALI (µCi)	Table I Occupational Values: Inhalation DAC (µCi/ml)	Table II Effluent Concentrations: Col. 1 Air (µCi/ml)	Table II Effluent Concentrations: Col. 2 Water (µCi/ml)	Table III Releases to Sewers: Monthly Average Concentration (µCi/ml)
41	Niobium-88[b/]	W, all compounds except those given for Y	5E+4	2E+5	9E-5	3E-7	–	–
			St wall (7E+4)	–	–	–	1E-3	1E-2
		Y, oxides and hydroxides	–	2E+5	9E-5	3E-7	–	–
41	Niobium-89[b/] (66 min)	W, see ^{88}Nb	1E+4	4E+4	2E-5	6E-8	1E-4	1E-3
		Y, see ^{88}Nb	–	4E+4	2E-5	5E-8	–	–
41	Niobium-89 (122 min)	W, see ^{88}Nb	5E+3	2E+4	8E-6	3E-8	7E-5	7E-4
		Y, see ^{88}Nb	–	2E+4	6E-6	2E-8	–	–
41	Niobium-90	W, see ^{88}Nb	1E+3	3E+3	1E-6	4E-9	1E-5	1E-4
		Y, see ^{88}Nb	–	2E+3	1E-6	3E-9	–	–
41	Niobium-93m	W, see ^{88}Nb	9E+3	2E+3	8E-7	3E-9	–	–
			LLI wall (1E+4)	–	–	–	2E-4	2E-3
		Y, see ^{88}Nb	–	2E+2	7E-8	2E-10	–	–
41	Niobium-94	W, see ^{88}Nb	9E+2	2E+2	8E-8	3E-10	1E-5	1E-4
		Y, see ^{88}Nb	–	2E+1	6E-9	2E-11	–	–
41	Niobium-95m	W, see ^{88}Nb	2E+3	3E+3	1E-6	4E-9	–	–
			LLI wall (2E+3)	–	–	–	3E-5	3E-4
		Y, see ^{88}Nb	–	2E+3	9E-7	3E-9	–	–
41	Niobium-95	W, see ^{88}Nb	2E+3	1E+3	5E-7	2E-9	3E-5	3E-4
		Y, see ^{88}Nb	–	1E+3	5E-7	2E-9	–	–
41	Niobium-96	W, see ^{88}Nb	1E+3	3E+3	1E-6	4E-9	2E-5	2E-4
		Y, see ^{88}Nb	–	2E+3	1E-6	3E-9	–	–
41	Niobium-97[b/]	W, see ^{88}Nb	2E+4	8E+4	3E-5	1E-7	3E-4	3E-3
		Y, see ^{88}Nb	–	7E+4	3E-5	1E-7	–	–
41	Niobium-98[b/]	W, see ^{88}Nb	1E+4	5E+4	2E-5	8E-8	2E-4	2E-3
		Y, see ^{88}Nb	–	5E+4	2E-5	7E-8	–	–
42	Molybdenum-90	D, all compounds except those given for Y	4E+3	7E+3	3E-6	1E-8	3E-5	3E-4
		Y, oxides, hydroxides, and MoS_2	2E+3	5E+3	2E-6	6E-9	–	–
42	Molybdenum-93m	D, see ^{90}Mo	9E+3	2E+4	7E-6	2E-8	6E-5	6E-4
		Y, see ^{90}Mo	4E+3	1E+4	6E-6	2E-8	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	Inhalation				
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
42	Molybdenum-93	D, see ^{90}Mo	4E+3	5E+3	2E-6	8E-9	5E-5	5E-4
		Y, see ^{90}Mo	2E+4	2E+2	8E-8	2E-10	–	–
42	Molybdenum-99	D, see ^{90}Mo	2E+3 LLI wall (1E+3)	3E+3 –	1E-6 –	4E-9 –	– 2E-5	– 2E-4
		Y, see ^{90}Mo	1E+3	1E+3	6E-7	2E-9	–	–
42	Molybdenum-101[b/]	D, see ^{90}Mo	4E+4 St wall (5E+4)	1E+5 –	6E-5 –	2E-7 –	– 7E-4	– 7E-3
		Y, see ^{90}Mo	–	1E+5	6E-5	2E-7	–	–
43	Technetium-93m[b/]	D, all compounds except those given for W	7E+4	2E+5	6E-5	2E-7	1E-3	1E-2
		W, oxides, hydroxides, halides, and nitrates	–	3E+5	1E-4	4E-7	–	–
43	Technetium-93	D, see ^{93m}Tc	3E+4	7E+4	3E-5	1E-7	4E-4	4E-3
		W, see ^{93m}Tc	–	1E+5	4E-5	1E-7	–	–
43	Technetium-94m[b/]	D, see ^{93m}Tc	2E+4	4E+4	2E-5	6E-8	3E-4	3E-3
		W, see ^{93m}Tc	–	6E+4	2E-5	8E-8	–	–
43	Technetium-94	D, see ^{93m}Tc	9E+3	2E+4	8E-6	3E-8	1E-4	1E-3
		W, see ^{93m}Tc	–	2E+4	1E-5	3E-8	–	–
43	Technetium-95m	D, see ^{93m}Tc	4E+3	5E+3	2E-6	8E-9	5E-5	5E-4
		W, see ^{93m}Tc	–	2E+3	8E-7	3E-9	–	–
43	Technetium-95	D, see ^{93m}Tc	1E+4	2E+4	9E-6	3E-8	1E-4	1E-3
		W, see ^{93m}Tc	–	2E+4	8E-6	3E-8	–	–
43	Technetium-96m[b/]	D, see ^{93m}Tc	2E+5	3E+5	1E-4	4E-7	2E-3	2E-2
		W, see ^{93m}Tc	–	2E+5	1E-4	3E-7	–	–
43	Technetium-96	D, see ^{93m}Tc	2E+3	3E+3	1E-6	5E-9	3E-5	3E-4
		W, see ^{93m}Tc	–	2E+3	9E-7	3E-9	–	–
43	Technetium-97m	D, see ^{93m}Tc	5E+3	7E+3	3E-6	–	6E-5	6E-4
			–	St wall (7E+3)	–	1E-8	–	–
		W, see ^{93m}Tc	–	1E+3	5E-7	2E-9	–	–
43	Technetium-97	D, see ^{93m}Tc	4E+4	5E+4	2E-5	7E-8	5E-4	5E-3
		W, see ^{93m}Tc	–	6E+3	2E-6	8E-9	–	–
43	Technetium-98	D, see ^{93m}Tc	1E+3	2E+3	7E-7	2E-9	1E-5	1E-4
		W, see ^{93m}Tc	–	3E+2	1E-7	4E-10	–	–
43	Technetium-99m	D, see ^{93m}Tc	8E+4	2E+5	6E-5	2E-7	1E-3	1E-2
		W, see ^{93m}Tc	–	2E+5	1E-4	3E-7	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation		Col. 1	Col. 2	
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
43	Technetium-99	D, see ^{93m}Tc	4E+3	5E+3 St wall	2E-6	–	6E-5	6E-4
			–	(6E+3)	–	8E-9	–	–
		W, see ^{93m}Tc	–	7E+2	3E-7	9E-10	–	–
43	Technetium-101[b/]	D, see ^{93m}Tc	9E+4	3E+5	1E-4	5E-7	–	–
			St wall (1E+5)	–	–	–	2E-3	2E-2
		W, see ^{93m}Tc	–	4E+5	2E-4	5E-7	–	–
43	Technetium-104[b/]	D, see ^{93m}Tc	2E+4	7E+4	3E-5	1E-7	–	–
			St wall (3E+4)	–	–	–	4E-4	4E-3
		W, see ^{93m}Tc	–	9E+4	4E-5	1E-7	–	–
44	Ruthenium-94[b/]	D, all compounds except those given for W and Y	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, halides	–	6E+4	3E-5	9E-8	–	–
		Y, oxides and hydroxides	–	6E+4	2E-5	8E-8	–	–
44	Ruthenium-97	D, see ^{94}Ru	8E+3	2E+4	8E-6	3E-8	1E-4	1E-3
		W, see ^{94}Ru	–	1E+4	5E-6	2E-8	–	–
		Y, see ^{94}Ru	–	1E+4	5E-6	2E-8	–	–
44	Ruthenium-103	D, see ^{94}Ru	2E+3	2E+3	7E-7	2E-9	3E-5	3E-4
		W, see ^{94}Ru	–	1E+3	4E-7	1E-9	–	–
		Y, see ^{94}Ru	–	6E+2	3E-7	9E-10	–	–
44	Ruthenium-105	D, see ^{94}Ru	5E+3	1E+4	6E-6	2E-8	7E-5	7E-4
		W, see ^{94}Ru	–	1E+4	6E-6	2E-8	–	–
		Y, see ^{94}Ru	–	1E+4	5E-6	2E-8	–	–
44	Ruthenium-106	D, see ^{94}Ru	2E+2	9E+1	4E-8	1E-10	–	–
			LLI wall (2E+2)	–	–	–	3E-6	3E-5
		W, see ^{94}Ru	–	5E+1	2E-8	8E-11	–	–
		Y, see ^{94}Ru	–	1E+1	5E-9	2E-11	–	–
45	Rhodium-99m	D, all compounds except those given for W and Y	2E+4	6E+4	2E-5	8E-8	2E-4	2E-3
		W, halides	–	8E+4	3E-5	1E-7	–	–
		Y, oxides and hydroxides	–	7E+4	3E-5	9E-8	–	–
45	Rhodium-99	D, see ^{99m}Rh	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
		W, see ^{99m}Rh	–	2E+3	9E-7	3E-9	–	–
		Y, see ^{99m}Rh	–	2E+3	8E-7	3E-9	–	–
45	Rhodium-100	D, see ^{99m}Rh	2E+3	5E+3	2E-6	7E-9	2E-5	2E-4
		W, see ^{99m}Rh	–	4E+3	2E-6	6E-9	–	–
		Y, see ^{99m}Rh	–	4E+3	2E-6	5E-9	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	Inhalation				
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
45	Rhodium-101m	D, see ^{99m}Rh	6E+3	1E+4	5E-6	2E-8	8E-5	8E-4
		W, see ^{99m}Rh	–	8E+3	4E-6	1E-8	–	–
		Y, see ^{99m}Rh	–	8E+3	3E-6	1E-8	–	–
45	Rhodium-101	D, see ^{99m}Rh	2E+3	5E+2	2E-7	7E-10	3E-5	3E-4
		W, see ^{99m}Rh	–	8E+2	3E-7	1E-9	–	–
		Y, see ^{99m}Rh	–	2E+2	6E-8	2E-10	–	–
45	Rhodium-102m	D, see ^{99m}Rh	1E+3	5E+2	2E-7	7E-10	–	–
			LLI wall					
			(1E+3)	–	–	–	2E-5	2E-4
		W, see ^{99m}Rh	–	4E+2	2E-7	5E-10	–	–
		Y, see ^{99m}Rh	–	1E+2	5E-8	2E-10	–	–
45	Rhodium-102	D, see ^{99m}Rh	6E+2	9E+1	4E-8	1E-10	8E-6	8E-5
		W, see ^{99m}Rh	–	2E+2	7E-8	2E-10	–	–
		Y, see ^{99m}Rh	–	6E+1	2E-8	8E-11	–	–
45	Rhodium-103m[b/]	D, see ^{99m}Rh	4E+5	1E+6	5E-4	2E-6	6E-3	6E-2
		W, see ^{99m}Rh	–	1E+6	5E-4	2E-6	–	–
		Y, see ^{99m}Rh	–	1E+6	5E-4	2E-6	–	–
45	Rhodium-105	D, see ^{99m}Rh	4E+3	1E+4	5E-6	2E-8	–	–
			LLI wall					
			(4E+3)	–	–	–	5E-5	5E-4
		W, see ^{99m}Rh	–	6E+3	3E-6	9E-9	–	–
		Y, see ^{99m}Rh	–	6E+3	2E-6	8E-9	–	–
45	Rhodium-106m	D, see ^{99m}Rh	8E+3	3E+4	1E-5	4E-8	1E-4	1E-3
		W, see ^{99m}Rh	–	4E+4	2E-5	5E-8	–	–
		Y, see ^{99m}Rh	–	4E+4	1E-5	5E-8	–	–
45	Rhodium-107[b/]	D, see ^{99m}Rh	7E+4	2E+5	1E-4	3E-7	–	–
			St wall					
			(9E+4)	–	–	–	1E-3	1E-2
		W, see ^{99m}Rh	–	3E+5	1E-4	4E-7	–	–
		Y, see ^{99m}Rh	–	3E+5	1E-4	3E-7	–	–
46	Palladium-100	D, all compound44s except						
		those given for W and4 Y	1E+3	1E+3	6E-7	2E-9	2E-5	2E-4
		W, nitrates	–	1E+3	5E-7	2E-9	–	–
		Y, oxides and hydroxides	–	1E+3	6E-7	2E-9	–	–
46	Palladium-101	D, see ^{100}Pd	1E+4	3E+4	1E-5	5E-8	2E-4	2E-3
		W, see ^{100}Pd	–	3E+4	1E-5	5E-8	–	–
		Y, see ^{100}Pd	–	3E+4	1E-5	4E-8	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation	Col. 3 Inhalation	Col. 1	Col. 2	
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
46	Palladium-103	D, see ^{100}Pd	6E+3	6E+3	3E-6	9E-9	–	–
			LLI wall (7E+3)	–	–	–	1E-4	1E-3
		W, see ^{100}Pd	–	4E+3	2E-6	6E-9	–	–
		Y, see ^{100}Pd	–	4E+3	1E-6	5E-9	–	–
46	Palladium-107	D, see ^{100}Pd	3E+4	2E+4	9E-6	–	–	–
			LLI wall (4E+4)	Kidneys (2E+4)	–	3E-8	5E-4	5E-3
		W, see ^{100}Pd	–	7E+3	3E-6	1E-8	–	–
		Y, see ^{100}Pd	–	4E+2	2E-7	6E-10	–	–
46	Palladium-109	D, see ^{100}Pd	2E+3	6E+3	3E-6	9E-9	3E-5	3E-4
		W, see ^{100}Pd	–	5E+3	2E-6	8E-9	–	–
		Y, see ^{100}Pd	–	5E+3	2E-6	6E-9	–	–
47	Silver-102[b/]	D, all compounds except those given for W and Y	5E+4	2E+5	8E-5	2E-7	–	–
			St wall (6E+4)	–	–	–	9E-4	9E-3
		W, nitrates and sulfides	–	2E+5	9E-5	3E-7	–	–
		Y, oxides and hydroxides	–	2E+5	8E-5	3E-7	–	–
47	Silver-103[b/]	D, see ^{102}Ag	4E+4	1E+5	4E-5	1E-7	5E-4	5E-3
		W, see ^{102}Ag	–	1E+5	5E-5	2E-7	–	–
		Y, see ^{102}Ag	–	1E+5	5E-5	2E-7	–	–
47	Silver-104m[b/]	D, see ^{102}Ag	3E+4	9E+4	4E-5	1E-7	4E-4	4E-3
		W, see ^{102}Ag	–	1E+5	5E-5	2E-7	–	–
		Y, see ^{102}Ag	–	1E+5	5E-5	2E-7	–	–
47	Silver-104[b/]	D, see ^{102}Ag	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
		W, see ^{102}Ag	–	1E+5	6E-5	2E-7	–	–
		Y, see ^{102}Ag	–	1E+5	6E-5	2E-7	–	–
47	Silver-105	D, see ^{102}Ag	3E+3	1E+3	4E-7	1E-9	4E-5	4E-4
		W, see ^{102}Ag	–	2E+3	7E-7	2E-9	–	–
		Y, see ^{102}Ag	–	2E+3	7E-7	2E-9	–	–
47	Silver-106m	D, see ^{102}Ag	8E+2	7E+2	3E-7	1E-9	1E-5	1E-4
		W, see ^{102}Ag	–	9E+2	4E-7	1E-9	–	–
		Y, see ^{102}Ag	–	9E+2	4E-7	1E-9	–	–
47	Silver-106[b/]	D, see ^{102}Ag	6E+4	2E+5	8E-5	3E-7	–	–
			St wall (6E+4)	–	–	–	9E-4	9E-3
		W, see ^{102}Ag	–	2E+5	9E-5	3E-7	–	–
		Y, see ^{102}Ag	–	2E+5	8E-5	3E-7	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	Inhalation				
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
47	Silver-108m	D, see ^{102}Ag	6E+2	2E+2	8E-8	3E-10	9E-6	9E-5
		W, see ^{102}Ag	–	3E+2	1E-7	4E-10	–	–
		Y, see ^{102}Ag	–	2E+1	1E-8	3E-11	–	–
47	Silver-110m	D, see ^{102}Ag	5E+2	1E+2	5E-8	2E-10	6E-6	6E-5
		W, see ^{102}Ag	–	2E+2	8E-8	3E-10	–	–
		Y, see ^{102}Ag	–	9E+1	4E-8	1E-10	–	–
47	Silver-111	D, see ^{102}Ag	9E+2	2E+3	6E-7	–	–	–
			LLI wall	Liver				
			(1E+3)	(2E+3)	–	2E-9	2E-5	2E-4
		W, see ^{102}Ag	–	9E+2	4E-7	1E-9	–	–
		Y, see ^{102}Ag	–	9E+2	4E-7	1E-9	–	–
47	Silver-112	D, see ^{102}Ag	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
		W, see ^{102}Ag	–	1E+4	4E-6	1E-8	–	–
		Y, see ^{102}Ag	–	9E+3	4E-6	1E-8	–	–
47	Silver-115[b/]	D, see ^{102}Ag	3E+4	9E+4	4E-5	1E-7	–	–
			St wall					
			(3E+4)	–	–	–	4E-4	4E-3
		W, see ^{102}Ag	–	9E+4	4E-5	1E-7	–	–
		Y, see ^{102}Ag	–	8E+4	3E-5	1E-7	–	–
48	Cadmium-104[b/]	D, all compounds except those given for W and Y	2E+4	7E+4	3E-5	9E-8	3E-4	3E-3
		W, sulfides, halides, and nitrates	–	1E+5	5E-5	2E-7	–	–
		Y, oxides and hydroxides	–	1E+5	5E-5	2E-7	–	–
48	Cadmium-107	D, see ^{104}Cd	2E+4	5E+4	2E-5	8E-8	3E-4	3E-3
		W, see ^{104}Cd	–	6E+4	2E-5	8E-8	–	–
		Y, see ^{104}Cd	–	5E+4	2E-5	7E-8	–	–
48	Cadmium-109	D, see ^{104}Cd	3E+2	4E+1	1E-8	–	–	–
			Kidneys	Kidneys				
			(4E+2)	(5E+1)	–	7E-11	6E-6	6E-5
		W, see ^{104}Cd	–	1E+2	5E-8	–	–	–
				Kidneys				
			–	(1E+2)	–	2E-10	–	–
		Y, see ^{104}Cd	–	1E+2	5E-8	2E-10	–	–
48	Cadmium-113m	D, see ^{104}Cd	2E+1	2E+0	1E-9	–	–	–
			Kidneys	Kidneys				
			(4E+1)	(4E+0)	–	5E-12	5E-7	5E-6
		W, see ^{104}Cd	–	8E+0	4E-9	–	–	–
				Kidneys				
			–	(1E+1)	–	2E-11	–	–
		Y, see ^{104}Cd	–	1E+1	5E-9	2E-11	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	Inhalation				
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
48	Cadmium-113	D, see ^{104}Cd	2E+1	2E+0	9E-10	–	–	–
			Kidneys	Kidneys				
			(3E+1)	(3E+0)	–	5E-12	4E-7	4E-6
		W, see ^{104}Cd	–	8E+0	3E-9	–	–	–
				Kidneys				
			–	(1E+1)	–	2E-11	–	–
		Y, see ^{104}Cd	–	1E+1	6E-9	2E-11	–	–
48	Cadmium-115m	D, see ^{104}Cd	3E+2	5E+1	2E-8	–	4E-6	4E-5
				Kidneys				
			–	(8E+1)	–	1E-10	–	–
		W, see ^{104}Cd	–	1E+2	5E-8	2E-10	–	–
		Y, see ^{104}Cd	–	1E+2	6E-8	2E-10	–	–
48	Cadmium-115	D, see ^{104}Cd	9E+2	1E+3	6E-7	2E-9	–	–
			LLI wall					
			(1E+3)	–	–	–	1E-5	1E-4
		W, see ^{104}Cd	–	1E+3	5E-7	2E-9	–	–
		Y, see ^{104}Cd	–	1E+3	6E-7	2E-9	–	–
48	Cadmium-117m	D, see ^{104}Cd	5E+3	1E+4	5E-6	2E-8	6E-5	6E-4
		W, see ^{104}Cd	–	2E+4	7E-6	2E-8	–	–
		Y, see ^{104}Cd	–	1E+4	6E-6	2E-8	–	–
48	Cadmium-117	D, see ^{104}Cd	5E+3	1E+4	5E-6	2E-8	6E-5	6E-4
		W, see ^{104}Cd	–	2E+4	7E-6	2E-8	–	–
		Y, see ^{104}Cd	–	1E+4	6E-6	2E-8	–	–
49	Indium-109	D, all compounds except those given for W	2E+4	4E+4	2E-5	6E-8	3E-4	3E-3
		W, oxides, hydroxides, halides, and nitrates	–	6E+4	3E-5	9E-8	–	–
49	Indium-110[b/] (69.1 min)	D, see ^{109}In	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{109}In	–	6E+4	2E-5	8E-8	–	–
49	Indium-110 (4.9 h)	D, see ^{109}In	5E+3	2E+4	7E-6	2E-8	7E-5	7E-4
		W, see ^{109}In	–	2E+4	8E-6	3E-8	–	–
49	Indium-111	D, see ^{109}In	4E+3	6E+3	3E-6	9E-9	6E-5	6E-4
		W, see ^{109}In	–	6E+3	3E-6	9E-9	–	–
49	Indium-112[b/]	D, see ^{109}In	2E+5	6E+5	3E-4	9E-7	2E-3	2E-2
		W, see ^{109}In	–	7E+5	3E-4	1E-6	–	–
49	Indium-113m[b/]	D, see ^{109}In	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
		W, see ^{109}In	–	2E+5	8E-5	3E-7	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values: Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values: Inhalation ALI (µCi)	Table I Occupational Values: Inhalation DAC (µCi/ml)	Table II Effluent Concentrations: Col. 1 Air (µCi/ml)	Table II Effluent Concentrations: Col. 2 Water (µCi/ml)	Table III Releases to Sewers: Monthly Average Concentration (µCi/ml)
49	Indium-114m	D, see ^{109}In	3E+2	6E+1	3E-8	9E-11	–	–
			LLI wall (4E+2)	–	–	–	5E-6	5E-5
		W, see ^{109}In	–	1E+2	4E-8	1E-10	–	–
49	Indium-115m	D, see ^{109}In	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{109}In	–	5E+4	2E-5	7E-8	–	–
49	Indium-115	D, see ^{109}In	4E+1	1E+0	6E-10	2E-12	5E-7	5E-6
		W, see ^{109}In	–	5E+0	2E-9	8E-12	–	–
49	Indium-116m[b/]	D, see ^{109}In	2E+4	8E+4	3E-5	1E-7	3E-4	3E-3
		W, see ^{109}In	–	1E+5	5E-5	2E-7	–	–
49	Indium-117m[b/]	D, see ^{109}In	1E+4	3E+4	1E-5	5E-8	2E-4	2E-3
		W, see ^{109}In	–	4E+4	2E-5	6E-8	–	–
49	Indium-117[b/]	D, see ^{109}In	6E+4	2E+5	7E-5	2E-7	8E-4	8E-3
		W, see ^{109}In	–	2E+5	9E-5	3E-7	–	–
49	Indium-119m[b/]	D, see ^{109}In	4E+4	1E+5	5E-5	2E-7	–	–
			St wall (5E+4)	–	–	–	7E-4	7E-3
		W, see ^{109}In	–	1E+5	6E-5	2E-7	–	–
50	Tin-110	D, all compounds except those given for W	4E+3	1E+4	5E-6	2E-8	5E-5	5E-4
		W, sulfides, oxides, hydroxides, halides, nitrates, and stannic phosphate	–	1E+4	5E-6	2E-8	–	–
50	Tin-111[b/]	D, see ^{110}Sn	7E+4	2E+5	9E-5	3E-7	1E-3	1E-2
		W, see ^{110}Sn	–	3E+5	1E-4	4E-7	–	–
50	Tin-113	D, see ^{110}Sn	2E+3	1E+3	5E-7	2E-9	–	–
			LLI wall (2E+3)	–	–	–	3E-5	3E-4
		W, see ^{110}Sn	–	5E+2	2E-7	8E-10	–	–
50	Tin-117m	D, see ^{110}Sn	2E+3	1E+3	5E-7	–	–	–
			LLI wall (2E+3)	Bone surf (2E+3)	–	3E-9	3E-5	3E-4
		W, see ^{110}Sn	–	1E+3	6E-7	2E-9	–	–
50	Tin-119m	D, see ^{110}Sn	3E+3	2E+3	1E-6	3E-9	–	–
			LLI wall (4E+3)	–	–	–	6E-5	6E-4
		W, see ^{110}Sn	–	1E+3	4E-7	1E-9	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation	Col. 3 Inhalation	Col. 1	Col. 2	
			ALI (µCi)	ALI (µCi)	DAC (µCi/ml)	Air (µCi/ml)	Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
50	Tin-121m	D, see ^{110}Sn	3E+3	9E+2	4E-7	1E-9	–	–
			LLI wall (4E+3)	–	–	–	5E-5	5E-4
		W, see ^{110}Sn	–	5E+2	2E-7	8E-10	–	–
50	Tin-121	D, see ^{110}Sn	6E+3	2E+4	6E-6	2E-8	–	–
			LLI wall (6E+3)	–	–	–	8E-5	8E-4
		W, see ^{110}Sn	–	1E+4	5E-6	2E-8	–	–
50	Tin-123m[b/]	D, see ^{110}Sn	5E+4	1E+5	5E-5	2E-7	7E-4	7E-3
		W, see ^{110}Sn	–	1E+5	6E-5	2E-7	–	–
50	Tin-123	D, see ^{110}Sn	5E+2	6E+2	3E-7	9E-10	–	–
			LLI wall (6E+2)	–	–	–	9E-6	9E-5
		W, see ^{110}Sn	–	2E+2	7E-8	2E-10	–	–
50	Tin-125	D, see ^{110}Sn	4E+2	9E+2	4E-7	1E-9	–	–
			LLI wall (5E+2)	–	–	–	6E-6	6E-5
		W, see ^{110}Sn	–	4E+2	1E-7	5E-10	–	–
50	Tin-126	D, see ^{110}Sn	3E+2	6E+1	2E-8	8E-11	4E-6	4E-5
		W, see ^{110}Sn	–	7E+1	3E-8	9E-11	–	–
50	Tin-127	D, see ^{110}Sn	7E+3	2E+4	8E-6	3E-8	9E-5	9E-4
		W, see ^{110}Sn	–	2E+4	8E-6	3E-8	–	–
50	Tin-128[b/]	D, see ^{110}Sn	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
		W, see ^{110}Sn	–	4E+4	1E-5	5E-8	–	–
51	Antimony-115[b/]	D, all compounds except those given for W	8E+4	2E+5	1E-4	3E-7	1E-3	1E-2
		W, oxides, hydroxides, halides, sulfides, sulfates, and nitrates	–	3E+5	1E-4	4E-7	–	–
51	Antimony-116m[b/]	D, see ^{115}Sb	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
		W, see ^{115}Sb	–	1E+5	6E-5	2E-7	–	–
51	Antimony-116[b/]	D, see ^{115}Sb	7E+4	3E+5	1E-4	4E-7	–	–
			St wall (9E+4)	–	–	–	1E-3	1E-2
		W, see ^{115}Sb	–	3E+5	1E-4	5E-7	–	–
51	Antimony-117	D, see ^{115}Sb	7E+4	2E+5	9E-5	3E-7	9E-4	9E-3
		W, see ^{115}Sb	–	3E+5	1E-4	4E-7	–	–
51	Antimony-118m	D, see ^{115}Sb	6E+3	2E+4	8E-6	3E-8	7E-5	7E-4
		W, see ^{115}Sb	5E+3	2E+4	9E-6	3E-8	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	Inhalation				
			ALI (µCi)	ALI (µCi)	DAC (µCi/ml)	Air (µCi/ml)	Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
51	Antimony-119	D, see ^{115}Sb	2E+4	5E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{115}Sb	2E+4	3E+4	1E-5	4E-8	–	–
51	Antimony-120[b/] (16 min)	D, see ^{115}Sb	1E+5	4E+5	2E-4	6E-7	–	–
			St wall (2E+5)	–	–	–	2E-3	2E-2
		W, see ^{115}Sb	–	5E+5	2E-4	7E-7	–	–
51	Antimony-120 (5.76 d)	D, see ^{115}Sb	1E+3	2E+3	9E-7	3E-9	1E-5	1E-4
		W, see ^{115}Sb	9E+2	1E+3	5E-7	2E-9	–	–
51	Antimony-122	D, see ^{115}Sb	8E+2	2E+3	1E-6	3E-9	–	–
			LLI wall (8E+2)	–	–	–	1E-5	1E-4
		W, see ^{115}Sb	7E+2	1E+3	4E-7	2E-9	–	–
51	Antimony-124m[b/]	D, see ^{115}Sb	3E+5	8E+5	4E-4	1E-6	3E-3	3E-2
		W, see ^{115}Sb	2E+5	6E+5	2E-4	8E-7	–	–
51	Antimony-124	D, see ^{115}Sb	6E+2	9E+2	4E-7	1E-9	7E-6	7E-5
		W, see ^{115}Sb	5E+2	2E+2	1E-7	3E-10	–	–
51	Antimony-125	D, see ^{115}Sb	2E+3	2E+3	1E-6	3E-9	3E-5	3E-4
		W, see ^{115}Sb	–	5E+2	2E-7	7E-10	–	–
51	Antimony-126m[b/]	D, see ^{115}Sb	5E+4	2E+5	8E-5	3E-7	–	–
			St wall (7E+4)	–	–	–	9E-4	9E-3
		W, see ^{115}Sb	–	2E+5	8E-5	3E-7	–	–
51	Antimony-126	D, see ^{115}Sb	6E+2	1E+3	5E-7	2E-9	7E-6	7E-5
		W, see ^{115}Sb	5E+2	5E+2	2E-7	7E-10	–	–
51	Antimony-127	D, see ^{115}Sb	8E+2	2E+3	9E-7	3E-9	–	–
			LLI wall (8E+2)	–	–	–	1E-5	1E-4
		W, see ^{115}Sb	7E+2	9E+2	4E-7	1E-9	–	–
51	Antimony-128[b/] (10.4 min)	D, see ^{115}Sb	8E+4	4E+5	2E-4	5E-7	–	–
			St wall (1E+5)	–	–	–	1E-3	1E-2
		W, see ^{115}Sb	–	4E+5	2E-4	6E-7	–	–
51	Antimony-128 (9.01 h)	D, see ^{115}Sb	1E+3	4E+3	2E-6	6E-9	2E-5	2E-4
		W, see ^{115}Sb	–	3E+3	1E-6	5E-9	–	–
51	Antimony-129	D, see ^{115}Sb	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		W, see ^{115}Sb	–	9E+3	4E-6	1E-8	–	–
51	Antimony-130[b/]	D, see ^{115}Sb	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
		W, see ^{115}Sb	–	8E+4	3E-5	1E-7	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	Inhalation				
			ALI (µCi)	ALI (µCi)	DAC (µCi/ml)	Air (µCi/ml)	Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
51	Antimony-131[b/]	D, see ^{115}Sb	1E+4	2E+4	1E-5	–	–	–
			Thyroid	Thyroid				
			(2E+4)	(4E+4)	–	6E-8	2E-4	2E-3
		W, see ^{115}Sb	-	2E+4	1E-5	–	–	–
				Thyroid				
			-	(4E+4)	–	6E-8	–	–
52	Tellurium-116	D, all compounds except those given for W	8E+3	2E+4	9E-6	3E-8	1E-4	1E-3
		W, oxides, hydroxides, and nitrates	-	3E+4	1E-5	4E-8	–	–
52	Tellurium-121m	D, see ^{116}Te	5E+2	2E+2	8E-8	–	–	–
			Bone surf	Bone surf				
			(7E+2)	(4E+2)	–	5E-10	1E-5	1E-4
		W, see ^{116}Te	–	4E+2	2E-7	6E-10	–	–
52	Tellurium-121	D, see ^{116}Te	3E+3	4E+3	2E-6	6E-9	4E-5	4E-4
		W, see ^{116}Te	–	3E+3	1E-6	4E-9	–	–
52	Tellurium-123m	D, see ^{116}Te	6E+2	2E+2	9E-8	–	–	–
			Bone surf	Bone surf				
			(1E+3)	(5E+2)	–	8E-10	1E-5	1E-4
		W, see ^{116}Te	–	5E+2	2E-7	8E-10	–	–
52	Tellurium-123	D, see ^{116}Te	5E+2	2E+2	8E-8	–	–	–
			Bone surf	Bone surf				
			(1E+3)	(5E+2)	–	7E-10	2E-5	2E-4
		W, see ^{116}Te	–	4E+2	2E-7	–	–	–
				Bone surf				
			–	(1E+3)	–	2E-9	–	–
52	Tellurium-125m	D, see ^{116}Te	1E+3	4E+2	2E-7	–	–	–
			Bone surf	Bone surf				
			(1E+3)	(1E+3)	–	1E-9	2E-5	2E-4
		W, see ^{116}Te	–	7E+2	3E-7	1E-9	–	–
52	Tellurium-127m	D, see ^{116}Te	6E+2	3E+2	1E-7	–	9E-6	9E-5
				Bone surf				
			–	(4E+2)	–	6E-10	–	–
		W, see ^{116}Te	–	3E+2	1E-7	4E-10	–	–
52	Tellurium-127	D, see ^{116}Te	7E+3	2E+4	9E-6	3E-8	1E-4	1E-3
		W, see ^{116}Te	–	2E+4	7E-6	2E-8	–	–
52	Tellurium-129m	D, see ^{116}Te	5E+2	6E+2	3E-7	9E-10	7E-6	7E-5
		W, see ^{116}Te	–	2E+2	1E-7	3E-10	–	–
52	Tellurium-129[b/]	D, see ^{116}Te	3E+4	6E+4	3E-5	9E-8	4E-4	4E-3
		W, see ^{116}Te	–	7E+4	3E-5	1E-7	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	Inhalation				
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
52	Tellurium-131m	D, see ^{116}Te	3E+2 Thyroid (6E+2)	4E+2 Thyroid (1E+3)	2E-7 –	– 2E-9	– 8E-6	– 8E-5
		W, see ^{116}Te	– –	4E+2 Thyroid (9E+2)	2E-7 –	– 1E-9	– –	– –
52	Tellurium-131[b/]	D, see ^{116}Te	3E+3 Thyroid (6E+3)	5E+3 Thyroid (1E+4)	2E-6 –	– 2E-8	– 8E-5	– 8E-4
		W, see ^{116}Te	– –	5E+3 Thyroid (1E+4)	2E-6 –	– 2E-8	– –	– –
52	Tellurium-132	D, see ^{116}Te	2E+2 Thyroid (7E+2)	2E+2 Thyroid (8E+2)	9E-8 –	– 1E-9	– 9E-6	– 9E-5
		W, see ^{116}Te	– –	2E+2 Thyroid (6E+2)	9E-8 –	– 9E-10	– –	– –
52	Tellurium-133m[b/]	D, see ^{116}Te	3E+3 Thyroid (6E+3)	5E+3 Thyroid (1E+4)	2E-6 –	– 2E-8	– 9E-5	– 9E-4
		W, see ^{116}Te	– –	5E+3 Thyroid (1E+4)	2E-6 –	– 2E-8	– –	– –
52	Tellurium-133[b/]	D, see ^{116}Te	1E+4 Thyroid (3E+4)	2E+4 Thyroid (6E+4)	9E-6 –	– 8E-8	– 4E-4	– 4E-3
		W, see ^{116}Te	– –	2E+4 Thyroid (6E+4)	9E-6 –	– 8E-8	– –	– –
52	Tellurium-134[b/]	D, see ^{116}Te	2E+4 Thyroid (2E+4)	2E+4 Thyroid (5E+4)	1E-5 –	– 7E-8	– 3E-4	– 3E-3
		W, see ^{116}Te	– –	2E+4 Thyroid (5E+4)	1E-5 –	– 7E-8	– –	– –
53	Iodine-120m[b/]	D, all compounds	1E+4 Thyroid (1E+4)	2E+4 –	9E-6 –	3E-8 –	– 2E-4	– 2E-3
53	Iodine-120[b/]	D, all compounds	4E+3 Thyroid (8E+3)	9E+3 Thyroid (1E+4)	4E-6 –	– 2E-8	– 1E-4	– 1E-3

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	Inhalation				
			ALI (µCi)	ALI (µCi)	DAC (µCi/ml)	Air (µCi/ml)	Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
53	Iodine-121	D, all compounds	1E+4 Thyroid (3E+4)	2E+4 Thyroid (5E+4)	8E-6 –	7E-8	4E-4	4E-3
53	Iodine-123	D, all compounds	3E+3 Thyroid (1E+4)	6E+3 Thyroid (2E+4)	3E-6 –	2E-8	1E-4	1E-3
53	Iodine-124	D, all compounds	5E+1 Thyroid (2E+2)	8E+1 Thyroid (3E+2)	3E-8 –	4E-10	2E-6	2E-5
53	Iodine-125	D, all compounds	4E+1 Thyroid (1E+2)	6E+1 Thyroid (2E+2)	3E-8 –	3E-10	2E-6	2E-5
53	Iodine-126	D, all compounds	2E+1 Thyroid (7E+1)	4E+1 Thyroid (1E+2)	1E-8 –	2E-10	1E-6	1E-5
53	Iodine-128[b/]	D, all compounds	4E+4 St wall (6E+4)	1E+5 –	5E-5 –	2E-7 –	– 8E-4	– 8E-3
53	Iodine-129	D, all compounds	5E+0 Thyroid (2E+1)	9E+0 Thyroid (3E+1)	4E-9 –	4E-11	2E-7	2E-6
53	Iodine-130	D, all compounds	4E+2 Thyroid (1E+3)	7E+2 Thyroid (2E+3)	3E-7 –	3E-9	2E-5	2E-4
53	Iodine-131	D, all compounds	3E+1 Thyroid (9E+1)	5E+1 Thyroid (2E+2)	2E-8 –	2E-10	1E-6	1E-5
53	Iodine-132m[b/]	D, all compounds	4E+3 Thyroid (1E+4)	8E+3 Thyroid (2E+4)	4E-6 –	3E-8	1E-4	1E-3
53	Iodine-132	D, all compounds	4E+3 Thyroid (9E+3)	8E+3 Thyroid (1E+4)	3E-6 –	2E-8	1E-4	1E-3
53	Iodine-133	D, all compounds	1E+2 Thyroid (5E+2)	3E+2 Thyroid (9E+2)	1E-7 –	1E-9	7E-6	7E-5
53	Iodine-134[b/]	D, all compounds	2E+4 Thyroid (3E+4)	5E+4 –	2E-5 –	6E-8 –	– 4E-4	– 4E-3

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	Inhalation				
			ALI (µCi)	ALI (µCi)	DAC (µCi/ml)	Air (µCi/ml)	Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
53	Iodine-135	D, all compounds	8E+2 Thyroid (3E+3)	2E+3 Thyroid (4E+3)	7E-7 –	– 6E-9	– 3E-5	– 3E-4
54	Xenon-120[b/]	Submersion[a/]	–	–	1E-5	4E-8	–	–
54	Xenon-121[b/]	Submersion[a/]	–	–	2E-6	1E-8	–	–
54	Xenon-122	Submersion[a/]	–	–	7E-5	3E-7	–	–
54	Xenon-123	Submersion[a/]	–	–	6E-6	3E-8	–	–
54	Xenon-125	Submersion[a/]	–	–	2E-5	7E-8	–	–
54	Xenon-127	Submersion[a/]	–	–	1E-5	6E-8	–	–
54	Xenon-129m	Submersion[a/]	–	–	2E-4	9E-7	–	–
54	Xenon-131m	Submersion[a/]	–	–	4E-4	2E-6	–	–
54	Xenon-133m	Submersion[a/]	–	–	1E-4	6E-7	–	–
54	Xenon-133	Submersion[a/]	–	–	1E-4	5E-7	–	–
54	Xenon-135m[b/]	Submersion[a/]	–	–	9E-6	4E-8	–	–
54	Xenon-135	Submersion[a/]	–	–	1E-5	7E-8	–	–
54	Xenon-138[b/]	Submersion[a/]	–	–	4E-6	2E-8	–	–
55	Cesium-125[b/]	D, all compounds	5E+4 St wall (9E+4)	1E+5 –	6E-5 –	2E-7 –	– 1E-3	– 1E-2
55	Cesium-127	D, all compounds	6E+4	9E+4	4E-5	1E-7	9E-4	9E-3
55	Cesium-129	D, all compounds	2E+4	3E+4	1E-5	5E-8	3E-4	3E-3
55	Cesium-130[b/]	D, all compounds	6E+4 St wall (1E+5)	2E+5 –	8E-5 –	3E-7 –	– 1E-3	– 1E-2
55	Cesium-131	D, all compounds	2E+4	3E+4	1E-5	4E-8	3E-4	3E-3
55	Cesium-132	D, all compounds	3E+3	4E+3	2E-6	6E-9	4E-5	4E-4
55	Cesium-134m	D, all compounds	1E+5 St wall (1E+5)	1E+5 –	6E-5 –	2E-7 –	– 2E-3	– 2E-2
55	Cesium-134	D, all compounds	7E+1	1E+2	4E-8	2E-10	9E-7	9E-6

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	Inhalation				
			ALI (µCi)	ALI (µCi)	DAC (µCi/ml)	Air (µCi/ml)	Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
55	Cesium-135m[b/]	D, all compounds	1E+5	2E+5	8E-5	3E-7	1E-3	1E-2
55	Cesium-135	D, all compounds	7E+2	1E+3	5E-7	2E-9	1E-5	1E-4
55	Cesium-136	D, all compounds	4E+2	7E+2	3E-7	9E-10	6E-6	6E-5
55	Cesium-137	D, all compounds	1E+2	2E+2	6E-8	2E-10	1E-6	1E-5
55	Cesium-138[b/]	D, all compounds	2E+4	6E+4	2E-5	8E-8	–	–
			St wall (3E+4)	–	–	–	4E-4	4E-3
56	Barium-126[b/]	D, all compounds	6E+3	2E+4	6E-6	2E-8	8E-5	8E-4
56	Barium-128	D, all compounds	5E+2	2E+3	7E-7	2E-9	7E-6	7E-5
56	Barium-131m[b/]	D, all compounds	4E+5	1E+6	6E-4	2E-6	–	–
			St wall (5E+5)	–	–	–	7E-3	7E-2
56	Barium-131	D, all compounds	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
56	Barium-133m	D, all compounds	2E+3	9E+3	4E-6	1E-8	–	–
			LLI wall (3E+3)	–	–	–	4E-5	4E-4
56	Barium-133	D, all compounds	2E+3	7E+2	3E-7	9E-10	2E-5	2E-4
56	Barium-135m	D, all compounds	3E+3	1E+4	5E-6	2E-8	4E-5	4E-4
56	Barium-139[b/]	D, all compounds	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
56	Barium-140	D, all compounds	5E+2	1E+3	6E-7	2E-9	–	–
			LLI wall (6E+2)	–	–	–	8E-6	8E-5
56	Barium-141[b/]	D, all compounds	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
56	Barium-142[b/]	D, all compounds	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
57	Lanthanum-131[b/]	D, all compounds except those given for W	5E+4	1E+5	5E-5	2E-7	6E-4	6E-3
		W, oxides and hydroxides	–	2E+5	7E-5	2E-7	–	–
57	Lanthanum-132	D, see ^{131}La	3E+3	1E+4	4E-6	1E-8	4E-5	4E-4
		W, see ^{131}La	–	1E+4	5E-6	2E-8	–	–
57	Lanthanum-135	D, see ^{131}La	4E+4	1E+5	4E-5	1E-7	5E-4	5E-3
		W, see ^{131}La	–	9E+4	4E-5	1E-7	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	Inhalation				
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
57	Lanthanum-137	D, see ^{131}La	1E+4	6E+1	3E-8	–	2E-4	2E-3
			–	Liver (7E+1)	–	1E-10	–	–
		W, see ^{131}La	–	3E+2	1E-7	–	–	–
			–	Liver (3E+2)	–	4E-10	–	–
57	Lanthanum-138	D, see ^{131}La	9E+2	4E+0	1E-9	5E-12	1E-5	1E-4
		W, see ^{131}La	–	1E+1	6E-9	2E-11	–	–
57	Lanthanum-140	D, see ^{131}La	6E+2	1E+3	6E-7	2E-9	9E-6	9E-5
		W, see ^{131}La	–	1E+3	5E-7	2E-9	–	–
57	Lanthanum-141	D, see ^{131}La	4E+3	9E+3	4E-6	1E-8	5E-5	5E-4
		W, see ^{131}La	–	1E+4	5E-6	2E-8	–	–
57	Lanthanum-142[b]	D, see ^{131}La	8E+3	2E+4	9E-6	3E-8	1E-4	1E-3
		W, see ^{131}La	–	3E+4	1E-5	5E-8	–	–
57	Lanthanum-143[b]	D, see ^{131}La	4E+4	1E+5	4E-5	1E-7	–	–
			St wall (4E+4)	–	–	–	5E-4	5E-3
		W, see ^{131}La	–	9E+4	4E-5	1E-7	–	–
58	Cerium-134	W, all compounds except those given for Y	5E+2	7E+2	3E-7	1E-9	–	–
			LLI wall (6E+2)	–	–	–	8E-6	8E-5
		Y, oxides, hydroxides, and fluorides	–	7E+2	3E-7	9E-10	–	–
58	Cerium-135	W, see ^{134}Ce	2E+3	4E+3	2E-6	5E-9	2E-5	2E-4
		Y, see ^{134}Ce	–	4E+3	1E-6	5E-9	–	–
58	Cerium-137m	W, see ^{134}Ce	2E+3	4E+3	2E-6	6E-9	–	–
			LLI wall (2E+3)	–	–	–	3E-5	3E-4
		Y, see ^{134}Ce	–	4E+3	2E-6	5E-9	–	–
58	Cerium-137	W, see ^{134}Ce	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
		Y, see ^{134}Ce	–	1E+5	5E-5	2E-7	–	–
58	Cerium-139	W, see ^{134}Ce	5E+3	8E+2	3E-7	1E-9	7E-5	7E-4
		Y, see ^{134}Ce	–	7E+2	3E-7	9E-10	–	–
58	Cerium-141	W, see ^{134}Ce	2E+3	7E+2	3E-7	1E-9	–	–
			LLI wall (2E+3)	–	–	–	3E-5	3E-4
		Y, see ^{134}Ce	–	6E+2	2E-7	8E-10	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	Inhalation				
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
58	Cerium-143	W, see ^{134}Ce	1E+3	2E+3	8E-7	3E-9	–	–
			LLI wall (1E+3)	–	–	–	2E-5	2E-4
		Y, see ^{134}Ce	–	2E+3	7E-7	2E-9	–	–
58	Cerium-144	W, see ^{134}Ce	2E+2	3E+1	1E-8	4E-11	–	–
			LLI wall (3E+2)	–	–	–	3E-6	3E-5
		Y, see ^{134}Ce	–	1E+1	6E-9	2E-11	–	–
59	Praseodymium-136[b/]	W, all compounds except those given for Y	5E+4	2E+5	1E-4	3E-7	–	–
			St wall (7E+4)	–	–	–	1E-3	1E-2
		Y, oxides, hydroxides, carbides, and fluorides	–	2E+5	9E-5	3E-7	–	–
59	Praseodymium-137[b/]	W, see ^{136}Pr	4E+4	2E+5	6E-5	2E-7	5E-4	5E-3
		Y, see ^{136}Pr	–	1E+5	6E-5	2E-7	–	–
59	Praseodymium-138m	W, see ^{136}Pr	1E+4	5E+4	2E-5	8E-8	1E-4	1E-3
		Y, see ^{136}Pr	–	4E+4	2E-5	6E-8	–	–
59	Praseodymium-139	W, see ^{136}Pr	4E+4	1E+5	5E-5	2E-7	6E-4	6E-3
		Y, see ^{136}Pr	–	1E+5	5E-5	2E-7	–	–
59	Praseodymium-142m[b/]	W, see ^{136}Pr	8E+4	2E+5	7E-5	2E-7	1E-3	1E-2
		Y, see ^{136}Pr	–	1E+5	6E-5	2E-7	–	–
59	Praseodymium-142	W, see ^{136}Pr	1E+3	2E+3	9E-7	3E-9	1E-5	1E-4
		Y, see ^{136}Pr	–	2E+3	8E-7	3E-9	–	–
59	Praseodymium-143	W, see ^{136}Pr	9E+2	8E+2	3E-7	1E-9	–	–
			LLI wall (1E+3)	–	–	–	2E-5	2E-4
		Y, see ^{136}Pr	–	7E+2	3E-7	9E-10	–	–
59	Praseodymium-144[b/]	W, see ^{136}Pr	3E+4	1E+5	5E-5	2E-7	–	–
			St wall (4E+4)	–	–	–	6E-4	6E-3
		Y, see ^{136}Pr	–	1E+5	5E-5	2E-7	–	–
59	Praseodymium-145	W, see ^{136}Pr	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		Y, see ^{136}Pr	–	8E+3	3E-6	1E-8	–	–
59	Praseodymium-147[b/]	W, see ^{136}Pr	5E+4	2E+5	8E-5	3E-7	–	–
			St wall (8E+4)	–	–	–	1E-3	1E-2
		Y, see ^{136}Pr	–	2E+5	8E-5	3E-7	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation	Col. 3	Col. 1	Col. 2	
			ALI (µCi)	ALI (µCi)	DAC (µCi/ml)	Air (µCi/ml)	Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
60	Neodymium-136[b/]	W, all compounds except those given for Y	1E+4	6E+4	2E-5	8E-8	2E-4	2E-3
		Y, oxides, hydroxides, carbides, and fluorides	–	5E+4	2E-5	8E-8	–	–
60	Neodymium-138	W, see ^{136}Nd	2E+3	6E+3	3E-6	9E-9	3E-5	3E-4
		Y, see ^{136}Nd	-	5E+3	2E-6	7E-9	-	-
60	Neodymium-139m	W, see ^{136}Nd	5E+3	2E+4	7E-6	2E-8	7E-5	7E-4
		Y, see ^{136}Nd	–	1E+4	6E-6	2E-8	–	–
60	Neodymium-139[b/]	W, see ^{136}Nd	9E+4	3E+5	1E-4	5E-7	1E-3	1E-2
		Y, see ^{136}Nd	–	3E+5	1E-4	4E-7	–	–
60	Neodymium-141	W, see ^{136}Nd	2E+5	7E+5	3E-4	1E-6	2E-3	2E-2
		Y, see ^{136}Nd	–	6E+5	3E-4	9E-7	–	–
60	Neodymium-147	W, see ^{136}Nd	1E+3	9E+2	4E-7	1E-9	–	–
			LLI wall (1E+3)	–	–	–	2E-5	2E-4
		Y, see ^{136}Nd	–	8E+2	4E-7	1E-9	–	–
60	Neodymium-149[b/]	W, see ^{136}Nd	1E+4	3E+4	1E-5	4E-8	1E-4	1E-3
		Y, see ^{136}Nd	–	2E+4	1E-5	3E-8	–	–
60	Neodymium-151[b/]	W, see ^{136}Nd	7E+4	2E+5	8E-5	3E-7	9E-4	9E-3
		Y, see ^{136}Nd	–	2E+5	8E-5	3E-7	–	–
61	Promethium-141[b/]	W, all compounds except those given for Y	5E+4	2E+5	8E-5	3E-7	–	–
			St wall (6E+4)	–	–	–	8E-4	8E-3
		Y, oxides, hydroxides, carbides, and fluorides	–	2E+5	7E-5	2E-7	–	–
61	Promethium-143	W, see ^{141}Pm	5E+3	6E+2	2E-7	8E-10	7E-5	7E-4
		Y, see ^{141}Pm	–	7E+2	3E-7	1E-9	–	–
61	Promethium-144	W, see ^{141}Pm	1E+3	1E+2	5E-8	2E-10	2E-5	2E-4
		Y, see ^{141}Pm	–	1E+2	5E-8	2E-10	–	–
61	Promethium-145	W, see ^{141}Pm	1E+4	2E+2	7E-8	–	1E-4	1E-3
			–	Bone surf (2E+2)	–	3E-10	–	–
		Y, see ^{141}Pm	–	2E+2	8E-8	3E-10	–	–
61	Promethium-146	W, see ^{141}Pm	2E+3	5E+1	2E-8	7E-11	2E-5	2E-4
		Y, see ^{141}Pm	–	4E+1	2E-8	6E-11	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	Inhalation				
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
61	Promethium-147	W, see ^{141}Pm	4E+3	1E+2	5E-8	–	–	–
			LLI wall	Bone surf				
			(5E+3)	(2E+2)	–	3E-10	7E-5	7E-4
		Y, see ^{141}Pm	–	1E+2	6E-8	2E-10	–	–
61	Promethium-148m	W, see ^{141}Pm	7E+2	3E+2	1E-7	4E-10	1E-5	1E-4
		Y, see ^{141}Pm	–	3E+2	1E-7	5E-10	–	–
61	Promethium-148	W, see ^{141}Pm	4E+2	5E+2	2E-7	8E-10	–	–
			LLI wall					
			(5E+2)	–	–	–	7E-6	7E-5
		Y, see ^{141}Pm	–	5E+2	2E-7	7E-10	–	–
61	Promethium-149	W, see ^{141}Pm	1E+3	2E+3	8E-7	3E-9	–	–
			LLI wall					
			(1E+3)	–	–	–	2E-5	2E-4
		Y, see ^{141}Pm	–	2E+3	8E-7	2E-9	–	–
61	Promethium-150	W, see ^{141}Pm	5E+3	2E+4	8E-6	3E-8	7E-5	7E-4
		Y, see ^{141}Pm	–	2E+4	7E-6	2E-8	–	–
61	Promethium-151	W, see ^{141}Pm	2E+3	4E+3	1E-6	5E-9	2E-5	2E-4
		Y, see ^{141}Pm	–	3E+3	1E-6	4E-9	–	–
62	Samarium-141m[b/]	W, all compounds	3E+4	1E+5	4E-5	1E-7	4E-4	4E-3
62	Samarium-141[b/]	W, all compounds	5E+4	2E+5	8E-5	2E-7	–	–
			St wall					
			(6E+4)	–	–	–	8E-4	8E-3
62	Samarium-142[b/]	W, all compounds	8E+3	3E+4	1E-5	4E-8	1E-4	1E-3
62	Samarium-145	W, all compounds	6E+3	5E+2	2E-7	7E-10	8E-5	8E-4
62	Samarium-146	W, all compounds	1E+1	4E-2	1E-11	–	–	–
			Bone surf	Bone surf				
			(3E+1)	(6E-2)	–	9E-14	3E-7	3E-6
62	Samarium-147	W, all compounds	2E+1	4E-2	2E-11	–	–	–
			Bone surf	Bone surf				
			(3E+1)	(7E-2)	–	1E-13	4E-7	4E-6
62	Samarium-151	W, all compounds	1E+4	1E+2	4E-8	–	–	–
			LLI wall	Bone surf				
			(1E+4)	(2E+2)	–	2E-10	2E-4	2E-3
62	Samarium-153	W, all compounds	2E+3	3E+3	1E-6	4E-9	–	–
			LLI wall					
			(2E+3)	–	–	–	3E-5	3E-4

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation		Col. 1	Col. 2	
			ALI (µCi)	ALI (µCi)	DAC (µCi/ml)	Air (µCi/ml)	Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
62	Samarium-155[b/]	W, all compounds	6E+4	2E+5	9E-5	3E-7	–	–
			St wall (8E+4)	–	–	–	1E-3	1E-2
62	Samarium-156	W, all compounds	5E+3	9E+3	4E-6	1E-8	7E-5	7E-4
63	Europium-145	W, all compounds	2E+3	2E+3	8E-7	3E-9	2E-5	2E-4
63	Europium-146	W, all compounds	1E+3	1E+3	5E-7	2E-9	1E-5	1E-4
63	Europium-147	W, all compounds	3E+3	2E+3	7E-7	2E-9	4E-5	4E-4
63	Europium-148	W, all compounds	1E+3	4E+2	1E-7	5E-10	1E-5	1E-4
63	Europium-149	W, all compounds	1E+4	3E+3	1E-6	4E-9	2E-4	2E-3
63	Europium-150 (12.62 h)	W, all compounds	3E+3	8E+3	4E-6	1E-8	4E-5	4E-4
63	Europium-150 (34.2 y)	W, all compounds	8E+2	2E+1	8E-9	3E-11	1E-5	1E-4
63	Europium-152m	W, all compounds	3E+3	6E+3	3E-6	9E-9	4E-5	4E-4
63	Europium-152	W, all compounds	8E+2	2E+1	1E-8	3E-11	1E-5	1E-4
63	Europium-154	W, all compounds	5E+2	2E+1	8E-9	3E-11	7E-6	7E-5
63	Europium-155	W, all compounds	4E+3	9E+1	4E-8	–	5E-5	5E-4
			–	Bone surf (1E+2)	–	2E-10	–	–
63	Europium-156	W, all compounds	6E+2	5E+2	2E-7	6E-10	8E-6	8E-5
63	Europium-157	W, all compounds	2E+3	5E+3	2E-6	7E-9	3E-5	3E-4
63	Europium-158[b/]	W, all compounds	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
64	Gadolinium-145[b/]	D, all compounds except those given for W	5E+4	2E+5	6E-5	2E-7	–	–
			St wall (5E+4)	–	–	–	6E-4	6E-3
		W, oxides, hydroxides, and fluorides	–	2E+5	7E-5	2E-7	–	–
64	Gadolinium-146	D, see ^{145}Gd	1E+3	1E+2	5E-8	2E-10	2E-5	2E-4
		W, see ^{145}Gd	–	3E+2	1E-7	4E-10	–	–
64	Gadolinium-147	D, see ^{145}Gd	2E+3	4E+3	2E-6	6E-9	3E-5	3E-4
		W, see ^{145}Gd	–	4E+3	1E-6	5E-9	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	Inhalation				
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
64	Gadolinium-148	D, see ^{145}Gd	1E+1	8E+3	3E-12	–	–	–
			Bone surf (2E+1)	Bone surf (2E-2)	–	2E-14	3E-7	3E-6
		W, see ^{145}Gd	–	3E-2	1E-11	–	–	–
			–	Bone surf (6E-2)	–	8E-14	–	–
64	Gadolinium-149	D, see ^{145}Gd	3E+3	2E+3	9E-7	3E-9	4E-5	4E-4
		W, see ^{145}Gd	–	2E+3	1E-6	3E-9	–	–
64	Gadolinium-151	D, see ^{145}Gd	6E+3	4E+2	2E-7	–	9E-5	9E-4
			–	Bone surf (6E+2)	–	9E-10	–	–
		W, see ^{145}Gd	–	1E+3	5E-7	2E-9	–	–
64	Gadolinium-152	D, see ^{145}Gd	2E+1	1E-2	4E-12	–	–	–
			Bone surf (3E+1)	Bone surf (2E-2)	–	3E-14	4E-7	4E-6
		W, see ^{145}Gd	–	4E-2	2E-11	–	–	–
			–	Bone surf (8E-2)	–	1E-13	–	–
64	Gadolinium-153	D, see ^{145}Gd	5E+3	1E+2	6E-8	–	6E-5	6E-4
			–	Bone surf (2E+2)	–	3E-10	–	–
		W, see ^{145}Gd	–	6E+2	2E-7	8E-10	–	–
64	Gadolinium-159	D, see ^{145}Gd	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
		W, see ^{145}Gd	–	6E+3	2E-6	8E-9	–	–
65	Terbium-147[b]	W, all compounds	9E+3	3E+4	1E-5	5E-8	1E-4	1E-3
65	Terbium-149	W, all compounds	5E+3	7E+2	3E-7	1E-9	7E-5	7E-4
65	Terbium-150	W, all compounds	5E+3	2E+4	9E-6	3E-8	7E-5	7E-4
65	Terbium-151	W, all compounds	4E+3	9E+3	4E-6	1E-8	5E-5	5E-4
65	Terbium-153	W, all compounds	5E+3	7E+3	3E-6	1E-8	7E-5	7E-4
65	Terbium-154	W, all compounds	2E+3	4E+3	2E-6	6E-9	2E-5	2E-4
65	Terbium-155	W, all compounds	6E+3	8E+3	3E-6	1E-8	8E-5	8E-4
65	Terbium-156m (5.0 h)	W, all compounds	2E+4	3E+4	1E-5	4E-8	2E-4	2E-3
65	Terbium-156m (24.4 h)	W, all compounds	7E+3	8E+3	3E-6	1E-8	1E-4	1E-3
65	Terbium-156	W, all compounds	1E+3	1E+3	6E-7	2E-9	1E-5	1E-4

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	Inhalation				
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
65	Terbium-157	W, all compounds	5E+4	3E+2	1E-7	–	–	–
			LLI wall (5E+4)	Bone surf (6E+2)	–	8E-10	7E-4	7E-3
65	Terbium-158	W, all compounds	1E+3	2E+1	8E-9	3E-11	2E-5	2E-4
65	Terbium-160	W, all compounds	8E+2	2E+2	9E-8	3E-10	1E-5	1E-4
65	Terbium-161	W, all compounds	2E+3	2E+3	7E-7	2E-9	–	–
			LLI wall (2E+3)	–	–	–	3E-5	3E-4
66	Dysprosium-155	W, all compounds	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
66	Dysprosium-157	W, all compounds	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
66	Dysprosium-159	W, all compounds	1E+4	2E+3	1E-6	3E-9	2E-4	2E-3
66	Dysprosium-165	W, all compounds	1E+4	5E+4	2E-5	6E-8	2E-4	2E-3
66	Dysprosium-166	W, all compounds	6E+2	7E+2	3E-7	1E-9	–	–
			LLI wall (8E+2)	–	–	–	1E-5	1E-4
67	Holmium-155[b]	W, all compounds	4E+4	2E+5	6E-5	2E-7	6E-4	6E-3
67	Holmium-157[b]	W, all compounds	3E+5	1E+6	6E-4	2E-6	4E-3	4E-2
67	Holmium-159[b]	W, all compounds	2E+5	1E+6	4E-4	1E-6	3E-3	3E-2
67	Holmium-161	W, all compounds	1E+5	4E+5	2E-4	6E-7	1E-3	1E-2
67	Holmium-162m[b]	W, all compounds	5E+4	3E+5	1E-4	4E-7	7E-4	7E-3
67	Holmium-162[b]	W, all compounds	5E+5	2E+6	1E-3	3E-6	–	–
			St wall (8E+5)	–	–	–	1E-2	1E-1
67	Holmium-164m[b]	W, all compounds	1E+5	3E+5	1E-4	4E-7	1E-3	1E-2
67	Holmium-164[b]	W, all compounds	2E+5	6E+5	3E-4	9E-7	–	–
			St wall (2E+5)	–	–	–	3E-3	3E-2
67	Holmium-166m	W, all compounds	6E+2	7E+0	3E-9	9E-12	9E-6	9E-5
67	Holmium-166	W, all compounds	9E+2	2E+3	7E-7	2E-9	–	–
			LLI wall (9E+2)	–	–	–	1E-5	1E-4
67	Holmium-167	W, all compounds	2E+4	6E+4	2E-5	8E-8	2E-4	2E-3

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation	Col. 3	Col. 1	Col. 2	
			ALI (µCi)	ALI (µCi)	DAC (µCi/ml)	Air (µCi/ml)	Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
68	Erbium-161	W, all compounds	2E+4	6E+4	3E-5	9E-8	2E-4	2E-3
68	Erbium-165	W, all compounds	6E+4	2E+5	8E-5	3E-7	9E-4	9E-3
68	Erbium-169	W, all compounds	3E+3	3E+3	1E-6	4E-9	–	-
			LLI wall (4E+3)	–	–	–	5E-5	5E-4
68	Erbium-171	W, all compounds	4E+3	1E+4	4E-6	1E-8	5E-5	5E-4
68	Erbium-172	W, all compounds	1E+3	1E+3	6E-7	2E-9	–	-
			LLI wall (1E+3)	–	–	–	2E-5	2E-4
69	Thulium-162[b/]	W, all compounds	7E+4	3E+5	1E-4	4E-7	–	-
			St wall (7E+4)	–	–	–	1E-3	1E-2
69	Thulium-166	W, all compounds	4E+3	1E+4	6E-6	2E-8	6E-5	6E-4
69	Thulium-167	W, all compounds	2E+3	2E+3	8E-7	3E-9	–	-
			LLI wall (2E+3)	–	–	–	3E-5	3E-4
69	Thulium-170	W, all compounds	8E+2	2E+2	9E-8	3E-10	–	-
			LLI wall (1E+3)	–	–	–	1E-5	1E-4
69	Thulium-171	W, all compounds	1E+4	3E+2	1E-7	–	–	-
			LLI wall (1E+4)	Bone surf (6E+2)	–	8E-10	2E-4	2E-3
69	Thulium-172	W, all compounds	7E+2	1E+3	5E-7	2E-9	–	-
			LLI wall (8E+2)	–	–	–	1E-5	1E-4
69	Thulium-173	W, all compounds	4E+3	1E+4	5E-6	2E-8	6E-5	6E-4
69	Thulium-175[b/]	W, all compounds	7E+4	3E+5	1E-4	4E-7	–	-
			St wall (9E+4)	–	–	–	1E-3	1E-2
70	Ytterbium-162[b/]	W, all compounds except those given for Y	7E+4	3E+5	1E-4	4E-7	1E-3	1E-2
		Y, oxides, hydroxides, and fluorides	–	3E+5	1E-4	4E-7	–	-
70	Ytterbium-166	W, see ^{162}Yb	1E+3	2E+3	8E-7	3E-9	2E-5	2E-4
		Y, see ^{162}Yb	–	2E+3	8E-7	3E-9	–	-

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation		Col. 1	Col. 2	
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
70	Ytterbium-167[b/]	W, see ^{162}Yb	3E+5	8E+5	3E-4	1E-6	4E-3	4E-2
		Y, see ^{162}Yb	–	7E+5	3E-4	1E-6	–	–
70	Ytterbium-169	W, see ^{162}Yb	2E+3	8E+2	4E-7	1E-9	2E-5	2E-4
		Y, see ^{162}Yb	–	7E+2	3E-7	1E-9	–	–
70	Ytterbium-175	W, see ^{162}Yb	3E+3	4E+3	1E-6	5E-9	–	–
			LLI wall (3E+3)	–	–	–	4E-5	4E-4
		Y, see ^{162}Yb	–	3E+3	1E-6	5E-9	–	–
70	Ytterbium-177[b/]	W, see ^{162}Yb	2E+4	5E+4	2E-5	7E-8	2E-4	2E-3
		Y, see ^{162}Yb	–	5E+4	2E-5	6E-8	–	–
70	Ytterbium-178[b/]	W, see ^{162}Yb	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		Y, see ^{162}Yb	–	4E+4	2E-5	5E-8	–	–
71	Lutetium-169	W, all compounds except those given for Y	3E+3	4E+3	2E-6	6E-9	3E-5	3E-4
		Y, oxides, hydroxides, and fluorides	–	4E+3	2E-6	6E-9	–	–
71	Lutetium-170	W, see ^{169}Lu	1E+3	2E+3	9E-7	3E-9	2E-5	2E-4
		Y, see ^{169}Lu	–	2E+3	8E-7	3E-9	–	–
71	Lutetium-171	W, see ^{169}Lu	2E+3	2E+3	8E-7	3E-9	3E-5	3E-4
		Y, see ^{169}Lu	–	2E+3	8E-7	3E-9	–	–
71	Lutetium-172	W, see ^{169}Lu	1E+3	1E+3	5E-7	2E-9	1E-5	1E-4
		Y, see ^{169}Lu	–	1E+3	5E-7	2E-9	–	–
71	Lutetium-173	W, see ^{169}Lu	5E+3	3E+2 Bone surf	1E-7	–	7E-5	7E-4
			–	(5E+2)	-	6E-10	–	–
		Y, see ^{169}Lu	–	3E+2	1E-7	4E-10	–	–
71	Lutetium-174m	W, see ^{169}Lu	2E+3	2E+2	1E-7	–	–	–
			LLI wall (3E+3)	Bone surf (3E+2)	–	5E-10	4E-5	4E-4
		Y, see ^{169}Lu	–	2E+2	9E-8	3E-10	–	–
71	Lutetium-174	W, see ^{169}Lu	5E+3	1E+2 Bone surf	5E-8	–	7E-5	7E-4
			–	(2E+2)	–	3E-10	–	–
		Y, see ^{169}Lu	–	2E+2	6E-8	2E-10	–	–
71	Lutetium-176m	W, see ^{169}Lu	8E+3	3E+4	1E-5	3E-8	1E-4	1E-3
		Y, see ^{169}Lu	–	2E+4	9E-6	3E-8	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	Inhalation				
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
71	Lutetium-176	W, see ^{169}Lu	7E+2	5E+0 Bone surf	2E-9	–	1E-5	1E-4
			–	(1E+1)	–	2E-11	–	–
		Y, see ^{169}Lu	–	8E+0	3E-9	1E-11	–	–
71	Lutetium-177m	W, see ^{169}Lu	7E+2	1E+2 Bone surf	5E-8	–	1E-5	1E-4
			–	(1E+2)	–	2E-10	–	–
		Y, see ^{169}Lu	–	8E+1	3E-8	1E-10	–	–
71	Lutetium-177	W, see ^{169}Lu	2E+3	2E+3	9E-7	3E-9	–	–
			LLI wall (3E+3)	–	–	–	4E-5	4E-4
		Y, see ^{169}Lu	–	2E+3	9E-7	3E-9	–	–
71	Lutetium-178m[b]	W, see ^{169}Lu	5E+4	2E+5	8E-5	3E-7	–	–
			St wall (6E+4)	–	–	–	8E-4	8E-3
		Y, see ^{169}Lu	–	2E+5	7E-5	2E-7	–	–
71	Lutetium-178[b]	W, see ^{169}Lu	4E+4	1E+5	5E-5	2E-7	–	–
			St wall (4E+4)	–	–	–	6E-4	6E-3
		Y, see ^{169}Lu	–	1E+5	5E-5	2E-7	–	–
71	Lutetium-179	W, see ^{169}Lu	6E+3	2E+4	8E-6	3E-8	9E-5	9E-4
		Y, see ^{169}Lu	–	2E+4	6E-6	3E-8	–	–
72	Hafnium-170	D, all compounds except those given for W	3E+3	6E+3	2E-6	8E-9	4E-5	4E-4
		W, oxides, hydroxides, carbides, and nitrates	–	5E+3	2E-6	6E-9	–	–
72	Hafnium-172	D, see ^{170}Hf	1E+3	9E+0 Bone surf	4E-9	–	2E-5	2E-4
			–	(2E+1)	–	3E-11	–	–
		W, see ^{170}Hf	–	4E+1 Bone surf	2E-8	–	–	–
			–	(6E+1)	–	8E-11	–	–
72	Hafnium-173	D, see ^{170}Hf	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
		W, see ^{170}Hf	–	1E+4	5E-6	2E-8	–	–
72	Hafnium-175	D, see ^{170}Hf	3E+3	9E+2 Bone surf	4E-7	–	4E-5	4E-4
			–	(1E+3)	–	1E-9	–	–
		W, see ^{170}Hf	–	1E+3	5E-7	2E-9	–	–
72	Hafnium-177m[b]	D, see ^{170}Hf	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
		W, see ^{170}Hf	–	9E+4	4E-5	1E-7	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values: Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values: Col. 2 Inhalation ALI (µCi)	Table I Occupational Values: Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentrations: Col. 1 Air (µCi/ml)	Table II Effluent Concentrations: Col. 2 Water (µCi/ml)	Table III Releases to Sewers: Monthly Average Concentration (µCi/ml)
72	Hafnium-178m	D, see ^{170}Hf	3E+2	1E+0 Bone surf	5E-10	–	3E-6	3E-5
			–	(2E+0)	–	3E-12	–	–
		W, see ^{170}Hf	–	5E+0 Bone surf	2E-9	–	–	–
			–	(9E+0)	–	1E-11	–	–
72	Hafnium-179m	D, see ^{170}Hf	1E+3	3E+2 Bone surf	1E-7	–	1E-5	1E-4
			–	(6E+2)	–	8E-10	–	–
		W, see ^{170}Hf	–	6E+2	3E-7	8E-10	–	–
72	Hafnium-180m	D, see ^{170}Hf	7E+3	2E+4	9E-6	3E-8	1E-4	1E-3
		W, see ^{170}Hf	–	3E+4	1E-5	4E-8	–	–
72	Hafnium-181	D, see ^{170}Hf	1E+3	2E+2 Bone surf	7E-8	–	2E-5	2E-4
			–	(4E+2)	–	6E-10	–	–
		W, see ^{170}Hf	–	4E+2	2E-7	6E-10	–	–
72	Hafnium-182m[b/]	D, see ^{170}Hf	4E+4	9E+4	4E-5	1E-7	5E-4	5E-3
		W, see ^{170}Hf	–	1E+5	6E-5	2E-7	–	–
72	Hafnium-182	D, see ^{170}Hf	2E+2 Bone surf (4E+2)	8E-1 Bone surf (2E+0)	3E-10 –	–	–	–
						2E-12	5E-6	5E-5
		W, see ^{170}Hf	–	3E+0 Bone surf	1E-9	–	–	–
			–	(7E+0)	–	1E-11	–	–
72	Hafnium-183[b/]	D, see ^{170}Hf	2E+4	5E+4	2E-5	6E-8	3E-4	3E-3
		W, see ^{170}Hf	–	6E+4	2E-5	8E-8	–	–
72	Hafnium-184	D, see ^{170}Hf	2E+3	8E+3	3E-6	1E-8	3E-5	3E-4
		W, see ^{170}Hf	–	6E+3	3E-6	9E-9	–	–
73	Tantalum-172[b/]	W, all compounds except those given for Y	4E+4	1E+5	5E-5	2E-7	5E-4	5E-3
		Y, elemental Ta, oxides, hydroxides, halides, carbides, nitrates, and nitrides	–	1E+5	4E-5	1E-7	–	–
73	Tantalum-173	W, see ^{172}Ta	7E+3	2E+4	8E-6	3E-8	9E-5	9E-4
		Y, see ^{172}Ta	–	2E+4	7E-6	2E-8	–	–
73	Tantalum-174[b/]	W, see ^{172}Ta	3E+4	1E+5	4E-5	1E-7	4E-4	4E-3
		Y, see ^{172}Ta	–	9E+4	4E-5	1E-7	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	Inhalation				
			ALI (µCi)	ALI (µCi)	DAC (µCi/ml)	Air (µCi/ml)	Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
73	Tantalum-175	W, see ^{172}Ta	6E+3	2E+4	7E-6	2E-8	8E-5	8E-4
		Y, see ^{172}Ta	–	1E+4	6E-6	2E-8	–	–
73	Tantalum-176	W, see ^{172}Ta	4E+3	1E+4	5E-6	2E-8	5E-5	5E-4
		Y, see ^{172}Ta	–	1E+4	5E-6	2E-8	–	–
73	Tantalum-177	W, see ^{172}Ta	1E+4	2E+4	8E-6	3E-8	2E-4	2E-3
		Y, see ^{172}Ta	–	2E+4	7E-6	2E-8	–	–
73	Tantalum-178	W, see ^{172}Ta	2E+4	9E+4	4E-5	1E-7	2E-4	2E-3
		Y, see ^{172}Ta	–	7E+4	3E-5	1E-7	–	–
73	Tantalum-179	W, see ^{172}Ta	2E+4	5E+3	2E-6	8E-9	3E-4	3E-3
		Y, see ^{172}Ta	–	9E+2	4E-7	1E-9	–	–
73	Tantalum-180m	W, see ^{172}Ta	2E+4	7E+4	3E-5	9E-8	3E-4	3E-3
		Y, see ^{172}Ta	–	6E+4	2E-5	8E-8	–	–
73	Tantalum-180	W, see ^{172}Ta	1E+3	4E+2	2E-7	6E-10	2E-5	2E-4
		Y, see ^{172}Ta	–	2E+1	1E-8	3E-11	–	–
73	Tantalum-182m[b/]	W, see ^{172}Ta	2E+5	5E+5	2E-4	8E-7	–	–
			St wall (2E+5)	–	–	–	3E-3	3E-2
		Y, see ^{172}Ta	–	4E+5	2E-4	6E-7	–	–
73	Tantalum-182	W, see ^{172}Ta	8E+2	3E+2	1E-7	5E-10	1E-5	1E-4
		Y, see ^{172}Ta	–	1E+2	6E-8	2E-10	–	–
73	Tantalum-183	W, see ^{172}Ta	9E+2	1E+3	5E-7	2E-9	–	–
			LLI wall (1E+3)	–	–	–	2E-5	2E-4
		Y, see ^{172}Ta	–	1E+3	4E-7	1E-9	–	–
73	Tantalum-184	W, see ^{172}Ta	2E+3	5E+3	2E-6	8E-9	3E-5	3E-4
		Y, see ^{172}Ta	–	5E+3	2E-6	7E-9	–	–
73	Tantalum-185[b/]	W, see ^{172}Ta	3E+4	7E+4	3E-5	1E-7	4E-4	4E-3
		Y, see ^{172}Ta	–	6E+4	3E-5	9E-8	–	–
73	Tantalum-186[b/]	W, see ^{172}Ta	5E+4	2E+5	1E-4	3E-7	–	–
			St wall (7E+4)	–	–	–	1E-3	1E-2
		Y, see ^{172}Ta	–	2E+5	9E-5	3E-7	–	–
74	Tungsten-176	D, all compounds	1E+4	5E+4	2E-5	7E-8	1E-4	1E-3
74	Tungsten-177	D, all compounds	2E+4	9E+4	4E-5	1E-7	3E-4	3E-3
74	Tungsten-178	D, all compounds	5E+3	2E+4	8E-6	3E-8	7E-5	7E-4

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	Inhalation				
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
74	Tungsten-179[b/]	D, all compounds	5E+5	2E+6	7E-4	2E-6	7E-3	7E-2
74	Tungsten-181	D, all compounds	2E+4	3E+4	1E-5	5E-8	2E-4	2E-3
74	Tungsten-185	D, all compounds	2E+3	7E+3	3E-6	9E-9	–	–
			LLI wall (3E+3)	–	–	–	4E-5	4E-4
74	Tungsten-187	D, all compounds	2E+3	9E+3	4E-6	1E-8	3E-5	3E-4
74	Tungsten-188	D, all compounds	4E+2	1E+3	5E-7	2E-9	–	–
			LLI wall (5E+2)	–	–	–	7E-6	7E-5
75	Rhenium-177[b/]	D, all compounds except those given for W	9E+4	3E+5	1E-4	4E-7	–	–
			St wall (1E+5)	–	–	–	2E-3	2E-2
		W, oxides, hydroxides, and nitrates	–	4E+5	1E-4	5E-7	–	–
75	Rhenium-178[b/]	D, see ^{177}Re	7E+4	3E+5	1E-4	4E-7	–	–
			St wall (1E+5)	–	–	–	1E-3	1E-2
		W, see ^{177}Re	–	3E+5	1E-4	4E-7	–	–
75	Rhenium-181	D, see ^{177}Re	5E+3	9E+3	4E-6	1E-8	7E-5	7E-4
		W, see ^{177}Re	–	9E+3	4E-6	1E-8	–	–
75	Rhenium-182 (12.7 h)	D, see ^{177}Re	7E+3	1E+4	5E-6	2E-8	9E-5	9E-4
		W, see ^{177}Re	–	2E+4	6E-6	2E-8	–	–
75	Rhenium-182 (64.0 h)	D, see ^{177}Re	1E+3	2E+3	1E-6	3E-9	2E-5	2E-4
		W, see ^{177}Re	–	2E+3	9E-7	3E-9	–	–
75	Rhenium-184m	D, see ^{177}Re	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
		W, see ^{177}Re	–	4E+2	2E-7	6E-10	–	–
75	Rhenium-184	D, see ^{177}Re	2E+3	4E+3	1E-6	5E-9	3E-5	3E-4
		W, see ^{177}Re	–	1E+3	6E-7	2E-9	–	–
75	Rhenium-186m	D, see ^{177}Re	1E+3	2E+3	7E-7	–	–	–
			St wall (2E+3)	St wall (2E+3)	–	3E-9	2E-5	2E-4
		W, see ^{177}Re	–	2E+2	6E-8	2E-10	–	–
75	Rhenium-186	D, see ^{177}Re	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
		W, see ^{177}Re	–	2E+3	7E-7	2E-9	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation	Col. 3	Col. 1	Col. 2	
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
75	Rhenium-187	D, see ^{177}Re	6E+5	8E+5 St wall	4E-4	–	8E-3	8E-2
			–	(9E+5)	–	1E-6	–	–
		W, see ^{177}Re	–	1E+5	4E-5	1E-7	–	–
75	Rhenium-188m[b/]	D, see ^{177}Re	8E+4	1E+5	6E-5	2E-7	1E-3	1E-2
		W, see ^{177}Re	–	1E+5	6E-5	2E-7	–	–
75	Rhenium-188	D, see ^{177}Re	2E+3	3E+3	1E-6	4E-9	2E-5	2E-4
		W, see ^{177}Re	–	3E+3	1E-6	4E-9	–	–
75	Rhenium-189	D, see ^{177}Re	3E+3	5E+3	2E-6	7E-9	4E-5	4E-4
		W, see ^{177}Re	–	4E+3	2E-6	6E-9	–	–
76	Osmium-180[b/]	D, all compounds except those given for W and Y	1E+5	4E+5	2E-4	5E-7	1E-3	1E-2
		W, halides and nitrates	–	5E+5	2E-4	7E-7	–	–
		Y, oxides and hydroxides	–	5E+5	2E-4	6E-7	–	–
76	Osmium-181[b/]	D, see ^{180}Os	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{180}Os	–	5E+4	2E-5	6E-8	–	–
		Y, see ^{180}Os	–	4E+4	2E-5	6E-8	–	–
76	Osmium-182	D, see ^{180}Os	2E+3	6E+3	2E-6	8E-9	3E-5	3E-4
		W, see ^{180}Os	–	4E+3	2E-6	6E-9	–	–
		Y, see ^{180}Os	–	4E+3	2E-6	6E-9	–	–
76	Osmium-185	D, see ^{180}Os	2E+3	5E+2	2E-7	7E-10	3E-5	3E-4
		W, see ^{180}Os	–	8E+2	3E-7	1E-9	–	–
		Y, see ^{180}Os	–	8E+2	3E-7	1E-9	–	–
76	Osmium-189m	D, see ^{180}Os	8E+4	2E+5	1E-4	3E-7	1E-3	1E-2
		W, see ^{180}Os	–	2E+5	9E-5	3E-7	–	–
		Y, see ^{180}Os	–	2E+5	7E-5	2E-7	–	–
76	Osmium-191m	D, see ^{180}Os	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
		W, see ^{180}Os	–	2E+4	8E-6	3E-8	–	–
		Y, see ^{180}Os	–	2E+4	7E-6	2E-8	–	–
76	Osmium-191	D, see ^{180}Os	2E+3 LLI wall	2E+3	9E-7	3E-9	–	–
			(3E+3)	–	–	–	3E-5	3E-4
		W, see ^{180}Os	–	2E+3	7E-7	2E-9	–	–
		Y, see ^{180}Os	–	1E+3	6E-7	2E-9	–	–
76	Osmium-193	D, see ^{180}Os	2E+3 LLI wall	5E+3	2E-6	6E-9	–	–
			(2E+3)	–	–	–	2E-5	2E-4
		W, see ^{180}Os	–	3E+3	1E-6	4E-9	–	–
		Y, see ^{180}Os	–	3E+3	1E-6	4E-9	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation	Col. 3 Inhalation	Col. 1	Col. 2	
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
76	Osmium-194	D, see ^{180}Os	4E+2	4E+1	2E-8	6E-11	–	–
			LLI wall (6E+2)	–	–	–	8E-6	8E-5
		W, see ^{180}Os	–	6E+1	2E-8	8E-11	–	–
		Y, see ^{180}Os	–	8E+0	3E-9	1E-11	–	–
77	Iridium-182[b/]	D, all compounds except those given for W and Y	4E+4	1E+5	6E-5	2E-7	–	–
			St wall (4E+4)	–	–	–	6E-4	6E-3
		W, halides, nitrates, and metallic iridium	–	2E+5	6E-5	2E-7	–	–
		Y, oxides and hydroxides	–	1E+5	5E-5	2E-7	–	–
77	Iridium-184	D, see ^{182}Ir	8E+3	2E+4	1E-5	3E-8	1E-4	1E-3
		W, see ^{182}Ir	–	3E+4	1E-5	5E-8	–	–
		Y, see ^{182}Ir	–	3E+4	1E-5	4E-8	–	–
77	Iridium-185	D, see ^{182}Ir	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
		W, see ^{182}Ir	–	1E+4	5E-6	2E-8	–	–
		Y, see ^{182}Ir	–	1E+4	4E-6	1E-8	–	–
77	Iridium-186	D, see ^{182}Ir	2E+3	8E+3	3E-6	1E-8	3E-5	3E-4
		W, see ^{182}Ir	–	6E+3	3E-6	9E-9	–	–
		Y, see ^{182}Ir	–	6E+3	2E-6	8E-9	–	–
77	Iridium-187	D, see ^{182}Ir	1E+4	3E+4	1E-5	5E-8	1E-4	1E-3
		W, see ^{182}Ir	–	3E+4	1E-5	4E-8	–	–
		Y, see ^{182}Ir	–	3E+4	1E-5	4E-8	–	–
77	Iridium-188	D, see ^{182}Ir	2E+3	5E+3	2E-6	6E-9	3E-5	3E-4
		W, see ^{182}Ir	–	4E+3	1E-6	5E-9	–	–
		Y, see ^{182}Ir	–	3E+3	1E-6	5E-9	–	–
77	Iridium-189	D, see ^{182}Ir	5E+3	5E+3	2E-6	7E-9	–	–
			LLI wall (5E+3)	–	–	–	7E-5	7E-4
		W, see ^{182}Ir	–	4E+3	2E-6	5E-9	–	–
		Y, see ^{182}Ir	–	4E+3	1E-6	5E-9	–	–
77	Iridium-190m[b/]	D, see ^{182}Ir	2E+5	2E+5	8E-5	3E-7	2E-3	2E-2
		W, see ^{182}Ir	–	2E+5	9E-5	3E-7	–	–
		Y, see ^{182}Ir	–	2E+5	8E-5	3E-7	–	–
77	Iridium-190	D, see ^{182}Ir	1E+3	9E+2	4E-7	1E-9	1E-5	1E-4
		W, see ^{182}Ir	–	1E+3	4E-7	1E-9	–	–
		Y, see ^{182}Ir	–	9E+2	4E-7	1E-9	–	–
77	Iridium-192m	D, see ^{182}Ir	3E+3	9E+1	4E-8	1E-10	4E-5	4E-4
		W, see ^{182}Ir	–	2E+2	9E-8	3E-10	–	–
		Y, see ^{182}Ir	–	2E+1	6E-9	2E-11	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	Inhalation				
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
77	Iridium-192	D, see ^{182}Ir	9E+2	3E+2	1E-7	4E-10	1E-5	1E-4
		W, see ^{182}Ir	–	4E+2	2E-7	6E-10	–	–
		Y, see ^{182}Ir	–	2E+2	9E-8	3E-10	–	–
77	Iridium-194m	D, see ^{182}Ir	6E+2	9E+1	4E-8	1E-10	9E-6	9E-5
		W, see ^{182}Ir	–	2E+2	7E-8	2E-10	–	–
		Y, see ^{182}Ir	–	1E+2	4E-8	1E-10	–	–
77	Iridium-194	D, see ^{182}Ir	1E+3	3E+3	1E-6	4E-9	1E-5	1E-4
		W, see ^{182}Ir	–	2E+3	9E-7	3E-9	–	–
		Y, see ^{182}Ir	–	2E+3	8E-7	3E-9	–	–
77	Iridium-195m	D, see ^{182}Ir	8E+3	2E+4	1E-5	3E-8	1E-4	1E-3
		W, see ^{182}Ir	–	3E+4	1E-5	4E-8	–	–
		Y, see ^{182}Ir	–	2E+4	9E-6	3E-8	–	–
77	Iridium-195	D, see ^{182}Ir	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{182}Ir	–	5E+4	2E-5	7E-8	–	–
		Y, see ^{182}Ir	–	4E+4	2E-5	6E-8	–	–
78	Platinum-186	D, all compounds	1E+4	4E+4	2E-5	5E-8	2E-4	2E-3
78	Platinum-188	D, all compounds	2E+3	2E+3	7E-7	2E-9	2E-5	2E-4
78	Platinum-189	D, all compounds	1E+4	3E+4	1E-5	4E-8	1E-4	1E-3
78	Platinum-191	D, all compounds	4E+3	8E+3	4E-6	1E-8	5E-5	5E-4
78	Platinum-193m	D, all compounds	3E+3	6E+3	3E-6	8E-9	–	–
			LLI wall (3E+4)	–	–	–	4E-5	4E-4
78	Platinum-193	D, all compounds	4E+4	2E+4	1E-5	3E-8	–	–
			LLI wall (5E+4)	–	–	–	6E-4	6E-3
78	Platinum-195m	D, all compounds	2E+3	4E+3	2E-6	6E-9	–	–
			LLI wall (2E+3)	–	–	–	3E-5	3E-4
78	Platinum-197m[b]	D, all compounds	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
78	Platinum-197	D, all compounds	3E+3	1E+4	4E-6	1E-8	4E-5	4E-4
78	Platinum-199[b]	D, all compounds	5E+4	1E+5	6E-5	2E-7	7E-4	7E-3
78	Platinum-200	D, all compounds	1E+3	3E+3	1E-6	5E-9	2E-5	2E-4

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	Inhalation				
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
79	Gold-193	D, all compounds except those given for W and Y	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
		W, halides and nitrates	–	2E+4	9E-6	3E-8	–	–
		Y, oxides and hydroxides	–	2E+4	8E-6	3E-8	–	–
79	Gold-194	D, see ^{193}Au	3E+3	8E+3	3E-6	1E-8	4E-5	4E-4
		W, see ^{193}Au	–	5E+3	2E-6	8E-9	–	–
		Y, see ^{193}Au	–	5E+3	2E-6	7E-9	–	–
79	Gold-195	D, see ^{193}Au	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
		W, see ^{193}Au	–	1E+3	6E-7	2E-9	–	–
		Y, see ^{193}Au	–	4E+2	2E-7	6E-10	–	–
79	Gold-198m	D, see ^{193}Au	1E+3	3E+3	1E-6	4E-9	1E-5	1E-4
		W, see ^{193}Au	–	1E+3	5E-7	2E-9	–	–
		Y, see ^{193}Au	–	1E+3	5E-7	2E-9	–	–
79	Gold-198	D, see ^{193}Au	1E+3	4E+3	2E-6	5E-9	2E-5	2E-4
		W, see ^{193}Au	–	2E+3	8E-7	3E-9	–	–
		Y, see ^{193}Au	–	2E+3	7E-7	2E-9	–	–
79	Gold-199	D, see ^{193}Au	3E+3	9E+3	4E-6	1E-8	–	–
			LLI wall (3E+3)	–	–	–	4E-5	4E-4
		W, see ^{193}Au	–	4E+3	2E-6	6E-9	–	–
		Y, see ^{193}Au	–	4E+3	2E-6	5E-9	–	–
79	Gold-200m	D, see ^{193}Au	1E+3	4E+3	1E-6	5E-9	2E-5	2E-4
		W, see ^{193}Au	–	3E+3	1E-6	4E-9	–	–
		Y, see ^{193}Au	–	2E+4	1E-6	3E-9	–	–
79	Gold-200[b/]	D, see ^{193}Au	3E+4	6E+4	3E-5	9E-8	4E-4	4E-3
		W, see ^{193}Au	–	8E+4	3E-5	1E-7	–	–
		Y, see ^{193}Au	–	7E+4	3E-5	1E-7	–	–
79	Gold-201[b/]	D, see ^{193}Au	7E+4	2E+5	9E-5	3E-7	–	–
			St wall (9E+4)	–	–	–	1E-3	1E-2
		W, see ^{193}Au	–	2E+5	1E-4	3E-7	–	–
		Y, see ^{193}Au	–	2E+5	9E-5	3E-7	–	–
80	Mercury-193m	Vapor	–	8E+3	4E-6	1E-8	–	–
		Organic D	4E+3	1E+4	5E-6	2E-8	6E-5	6E-4
		D, sulfates	3E+3	9E+3	4E-6	1E-8	4E-5	4E-4
		W, oxides, hydroxides, halides, nitrates, and sulfides	–	8E+3	3E-6	1E-8	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	Inhalation				
			ALI (µCi)	ALI (µCi)	DAC (µCi/ml)	Air (µCi/ml)	Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
80	Mercury-193	Vapor	–	3E+4	1E-5	4E-8	–	–
		Organic D	2E+4	6E+4	3E-5	9E-8	3E-4	3E-3
		D, see ^{193m}Hg	2E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{193m}Hg	–	4E+4	2E-5	6E-8	–	–
80	Mercury-194	Vapor	–	3E+1	1E-8	4E-11	–	–
		Organic D	2E+1	3E+1	1E-8	4E-11	2E-7	2E-6
		D, see ^{193m}Hg	8E+2	4E+1	2E-8	6E-11	1E-5	1E-4
		W, see ^{193m}Hg	–	1E+2	5E-8	2E-10	–	–
80	Mercury-195m	Vapor	–	4E+3	2E-6	6E-9	–	–
		Organic D	3E+3	6E+3	3E-6	8E-9	4E-5	4E-4
		D, see ^{193m}Hg	2E+3	5E+3	2E-6	7E-9	3E-5	3E-4
		W, see ^{193m}Hg	–	4E+3	2E-6	5E-9	–	–
80	Mercury-195	Vapor	–	3E+4	1E-5	4E-8	–	–
		Organic D	2E+4	5E+4	2E-5	6E-8	2E-4	2E-3
		D, see ^{193m}Hg	1E+4	4E+4	1E-5	5E-8	2E-4	2E-3
		W, see ^{193m}Hg	–	3E+4	1E-5	5E-8	–	–
80	Mercury-197m	Vapor	–	5E+3	2E-6	7E-9	–	–
		Organic D	4E+3	9E+3	4E-6	1E-8	5E-5	5E-4
		D, see ^{193m}Hg	3E+3	7E+3	3E-6	1E-8	4E-5	4E-4
		W, see ^{193m}Hg	–	5E+3	2E-6	7E-9	–	–
80	Mercury-197	Vapor	–	8E+3	4E-6	1E-8	–	–
		Organic D	7E+3	1E+4	6E-6	2E-8	9E-5	9E-4
		D, see ^{193m}Hg	6E+3	1E+4	5E-6	2E-8	8E-5	8E-4
		W, see ^{193m}Hg	–	9E+3	4E-6	1E-8	–	–
80	Mercury-199m[b/]	Vapor	–	8E+4	3E-5	1E-7	–	–
		Organic D	6E+4	2E+5	7E-5	2E-7	–	–
			St wall (1E+5)	–	–	–	1E-3	1E-2
		D, see ^{193m}Hg	6E+4	1E+5	6E-5	2E-7	8E-4	8E-3
		W, see ^{193m}Hg	–	2E+5	7E-5	2E-7	–	–
80	Mercury-203	Vapor	–	8E+2	4E-7	1E-9	–	–
		Organic D	5E+2	8E+2	3E-7	1E-9	7E-6	7E-5
		D, see ^{193m}Hg	2E+3	1E+3	5E-7	2E-9	3E-5	3E-4
		W, see ^{193m}Hg	–	1E+3	5E-7	2E-9	–	–
81	Thallium-194m[b/]	D, all compounds	5E+4	2E+5	6E-5	2E-7	–	–
			St wall (7E+4)	–	–	–	1E-3	1E-2
81	Thallium-194[b/]	D, all compounds	3E+5	6E+5	2E-4	8E-7	–	–
			St wall (3E+5)	–	–	–	4E-3	4E-2
81	Thallium-195[b/]	D, all compounds	6E+4	1E+5	5E-5	2E-7	9E-4	9E-3

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	Inhalation				
			ALI (µCi)	ALI (µCi)	DAC (µCi/ml)	Air (µCi/ml)	Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
81	Thallium-197	D, all compounds	7E+4	1E+5	5E-5	2E-7	1E-3	1E-2
81	Thallium-198m[b/]	D, all compounds	3E+4	5E+4	2E-5	8E-8	4E-4	4E-3
81	Thallium-198	D, all compounds	2E+4	3E+4	1E-5	5E-8	3E-4	3E-3
81	Thallium-199	D, all compounds	6E+4	8E+4	4E-5	1E-7	9E-4	9E-3
81	Thallium-200	D, all compounds	8E+3	1E+4	5E-6	2E-8	1E-4	1E-3
81	Thallium-201	D, all compounds	2E+4	2E+4	9E-6	3E-8	2E-4	2E-3
81	Thallium-202	D, all compounds	4E+3	5E+3	2E-6	7E-9	5E-5	5E-4
81	Thallium-204	D, all compounds	2E+3	2E+3	9E-7	3E-9	2E-5	2E-4
82	Lead-195m[b/]	D, all compounds	6E+4	2E+5	8E-5	3E-7	8E-4	8E-3
82	Lead-198	D, all compounds	3E+4	6E+4	3E-5	9E-8	4E-4	4E-3
82	Lead-199[b/]	D, all compounds	2E+4	7E+4	3E-5	1E-7	3E-4	3E-3
82	Lead-200	D, all compounds	3E+3	6E+3	3E-6	9E-9	4E-5	4E-4
82	Lead-201	D, all compounds	7E+3	2E+4	8E-6	3E-8	1E-4	1E-3
82	Lead-202m	D, all compounds	9E+3	3E+4	1E-5	4E-8	1E-4	1E-3
82	Lead-202	D, all compounds	1E+2	5E+1	2E-8	7E-11	2E-6	2E-5
82	Lead-203	D, all compounds	5E+3	9E+3	4E-6	1E-8	7E-5	7E-4
82	Lead-205	D, all compounds	4E+3	1E+3	6E-7	2E-9	5E-5	5E-4
82	Lead-209	D, all compounds	2E+4	6E+4	2E-5	8E-8	3E-4	3E-3
82	Lead-210	D, all compounds	6E-1	2E-1	1E-10	–	–	–
			Bone surf (1E+0)	Bone surf (4E-1)	–	6E-13	1E-8	1E-7
82	Lead-211[b/]	D, all compounds	1E+4	6E+2	3E-7	9E-10	2E-4	2E-3
82	Lead-212	D, all compounds	8E+1	3E+1	1E-8	5E-11	–	–
			Bone surf (1E+2)	–	–	–	2E-6	2E-5
82	Lead-214[b/]	D, all compounds	9E+3	8E+2	3E-7	1E-9	1E-4	1E-3
83	Bismuth-200[b/]	D, nitrates	3E+4	8E+4	4E-5	1E-7	4E-4	4E-3
		W, all other compounds	–	1E+5	4E-5	1E-7	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	Inhalation				
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
83	Bismuth-201[b/]	D, see ^{200}Bi	1E+4	3E+4	1E-5	4E-8	2E-4	2E-3
		W, see ^{200}Bi	–	4E+4	2E-5	5E-8	–	–
83	Bismuth-202[b/]	D, see ^{200}Bi	1E+4	4E+4	2E-5	6E-8	2E-4	2E-3
		W, see ^{200}Bi	–	8E+4	3E-5	1E-7	–	–
83	Bismuth-203	D, see ^{200}Bi	2E+3	7E+3	3E-6	9E-9	3E-5	3E-4
		W, see ^{200}Bi	–	6E+3	3E-6	9E-9	–	–
83	Bismuth-205	D, see ^{200}Bi	1E+3	3E+3	1E-6	3E-9	2E-5	2E-4
		W, see ^{200}Bi	–	1E+3	5E-7	2E-9	–	–
83	Bismuth-206	D, see ^{200}Bi	6E+2	1E+3	6E-7	2E-9	9E-6	9E-5
		W, see ^{200}Bi	–	9E+2	4E-7	1E-9	–	–
83	Bismuth-207	D, see ^{200}Bi	1E+3	2E+3	7E-7	2E-9	1E-5	1E-4
		W, see ^{200}Bi	–	4E+2	1E-7	5E-10	–	–
83	Bismuth-210m	D, see ^{200}Bi	4E+1	5E+0	2E-9	–	–	–
			Kidneys	Kidneys				
			(6E+1)	(6E+0)	–	9E-12	8E-7	8E-6
		W, see ^{200}Bi	–	7E-1	3E-10	9E-13	–	–
83	Bismuth-210	D, see ^{200}Bi	8E+2	2E+2	1E-7	–	1E-5	1E-4
			–	Kidneys				
			–	(4E+2)	–	5E-10	–	–
		W, see ^{200}Bi	–	3E+1	1E-8	4E-11	–	–
83	Bismuth-212[b/]	D, see ^{200}Bi	5E+3	2E+2	1E-7	3E-10	7E-5	7E-4
		W, see ^{200}Bi	–	3E+2	1E-7	4E-10	–	–
83	Bismuth-213[b/]	D, see ^{200}Bi	7E+3	3E+2	1E-7	4E-10	1E-4	1E-3
		W, see ^{200}Bi	–	4E+2	1E-7	5E-10	–	–
83	Bismuth-214[b/]	D, see ^{200}Bi	2E+4	8E+2	3E-7	1E-9	–	–
			St wall					
			(2E+4)	–	–	–	3E-4	3E-3
		W, see ^{200}Bi	–	9E-2	4E-7	1E-9	–	–
84	Polonium-203[b/]	D, all compounds except those given for W	3E+4	6E+4	3E-5	9E-8	3E-4	3E-3
		W, oxides, hydroxides, and nitrates	–	9E+4	4E-5	1E-7	–	–
84	Polonium-205[b/]	D, see ^{203}Po	2E+4	4E+4	2E-5	5E-8	3E-4	3E-3
		W, see ^{203}Po	–	7E+4	3E-5	1E-7	–	–
84	Polonium-207	D, see ^{203}Po	8E+3	3E+4	1E-5	3E-8	1E-4	1E-3
		W, see ^{203}Po	–	3E+4	1E-5	4E-8	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	Inhalation				
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
84	Polonium-210	D, see ^{203}Po	3E+0	6E-1	3E-10	9E-13	4E-8	4E-7
		W, see ^{203}Po	–	6E-1	3E-10	9E-13	–	–
85	Astatine-207[b/]	D, halides	6E+3	3E+3	1E-6	4E-9	8E-5	8E-4
		W	–	2E+3	9E-7	3E-9	–	–
85	Astatine-211	D, halides	1E+2	8E+1	3E-8	1E-10	2E-6	2E-5
		W	–	5E+1	2E-8	8E-11	–	–
86	Radon-220	With daughters removed	–	2E+4	7E-6	2E-8	–	–
		With daughters present	–	2E+1 (or 12 WLM)	9E-9 (or 1.0 WL)	3E-11	–	–
86	Radon-222	With daughters removed	–	1E+4	4E-6	1E-8	–	–
		With daughters present	–	1E+2 (or 4 WLM)	3E-8 (or 0.33 WL)	1E-10	–	–
87	Francium-222[b/]	D, all compounds	2E+3	5E+2	2E-7	6E-10	3E-5	3E-4
87	Francium-223[b/]	D, all compounds	6E+2	8E+2	3E-7	1E-9	8E-6	8E-5
88	Radium-223	W, all compounds	5E+0 Bone surf (9E+0)	7E-1	3E-10	9E-13	–	–
				–	–	–	1E-7	1E-6
88	Radium-224	W, all compounds	8E+0 Bone surf (2E+1)	2E+0	7E-10	2E-12	–	–
				–	–	–	2E-7	2E-6
88	Radium-225	W, all compounds	8E+0 Bone surf (2E+1)	7E-1	3E-10	9E-13	–	–
				–	–	–	2E-7	2E-6
88	Radium-226	W, all compounds	2E+0 Bone surf (5E+0)	6E-1	3E-10	9E-13	–	–
				–	–	–	6E-8	6E-7
88	Radium-227[b/]	W, all compounds	2E+4 Bone surf (2E+4)	1E+4 Bone surf (2E+4)	6E-6	–	–	–
					–	3E-8	3E-4	3E-3
88	Radium-228	W, all compounds	2E+0 Bone surf (4E+0)	1E+0	5E-10	2E-12	–	–
				–	–	–	6E-8	6E-7

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values: Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values: Col. 2 Inhalation ALI (µCi)	Table I Occupational Values: Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentrations: Col. 1 Air (µCi/ml)	Table II Effluent Concentrations: Col. 2 Water (µCi/ml)	Table III Releases to Sewers: Monthly Average Concentration (µCi/ml)
89	Actinium-224	D, all compounds except those given for W and Y	2E+3	3E+1	1E-8	–	–	–
			LLI wall (2E+3)	Bone surf (4E+1)	–	5E-11	3E-5	3E-4
		W, halides and nitrates	–	5E+1	2E-8	7E-11	–	–
		Y, oxides and hydroxides	–	5E+1	2E-8	6E-11	–	–
89	Actinium-225	D, see ^{224}Ac	5E+1	3E-1	1E-10	–	–	–
			LLI wall (5E+1)	Bone surf (5E-1)	-	7E-13	7E-7	7E-6
		W, see ^{224}Ac	–	6E-1	3E-10	9E-13	–	–
		Y, see ^{224}Ac	–	6E-1	3E-10	9E-13	–	–
89	Actinium-226	D, see ^{224}Ac	1E+2	3E+0	1E-9	–	–	–
			LLI wall (1E+2)	Bone surf (4E+0)	–	5E-12	2E-6	2E-5
		W, see ^{224}Ac	–	5E+0	2E-9	7E-12	–	–
		Y, see ^{224}Ac	–	5E+0	2E-9	6E-12	–	–
89	Actinium-227	D, see ^{224}Ac	2E-1	4E-4	2E-13	–	–	–
			Bone surf (4E-1)	Bone surf (8E-4)	–	1E-15	5E-9	5E-8
		W, see ^{224}Ac	–	2E-3	7E-13	–	–	–
				Bone surf				
			–	(3E-3)	–	4E-15	–	–
		Y, see ^{224}Ac	–	4E-3	2E-12	6E-15	–	–
89	Actinium-228	D, see ^{224}Ac	2E+3	9E+0	4E-9	–	3E-5	3E-4
				Bone surf				
			–	(2E+1)	–	2E-11	–	–
		W, see ^{224}Ac	–	4E+1	2E-8	–	–	–
				Bone surf				
			–	(6E+1)	–	8E-11	–	–
		Y, see ^{224}Ac	–	4E+1	2E-8	6E-11	–	–
90	Thorium-226[b]	W, all compounds except those given for Y	5E+3	2E+2	6E-8	2E-10	–	–
			St wall (5E+3)	–	–	–	7E-5	7E-4
		Y, oxides and hydroxides	–	1E+2	6E-8	2E-10	–	–
90	Thorium-227	W, see ^{226}Th	1E+2	3E-1	1E-10	5E-13	2E-6	2E-5
		Y, see ^{226}Th	–	3E-1	1E-10	5E-13	–	–
90	Thorium-228	W, see ^{226}Th	6E+0	1E-2	4E-12	–	–	–
			Bone surf (1E+1)	Bone surf (2E-2)	–	3E-14	2E-7	2E-6
		Y, see ^{226}Th	–	2E-2	7E-12	2E-14	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation		Col. 1	Col. 2	
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
90	Thorium-229	W, see ^{226}Th	6E-1 Bone surf (1E+0)	9E-4 Bone surf (2E-3)	4E-13 –	– 3E-15	– 2E-8	– 2E-7
		Y, see ^{226}Th	– –	2E-3 Bone surf (3E-3)	1E-12 –	– 4E-15	– –	– –
90	Thorium-230	W, see ^{226}Th	4E+0 Bone surf (9E+0)	6E-3 Bone surf (2E-2)	3E-12 –	– 2E-14	– 1E-7	– 1E-6
		Y, see ^{226}Th	– –	2E-2 Bone surf (2E-2)	6E-12 –	– 3E-14	– –	– –
90	Thorium-231	W, see ^{226}Th	4E+3	6E+3	3E-6	9E-9	5E-5	5E-4
		Y, see ^{226}Th	–	6E+3	3E-6	9E-9	–	–
90	Thorium-232	W, see ^{226}Th	7E-1 Bone surf (2E+0)	1E-3 Bone surf (3E-3)	5E-13 –	– 4E-15	– 3E-8	– 3E-7
		Y, see ^{226}Th	– –	3E-3 Bone sur (4E-3)	1E-12 –	– 6E-15	– –	– –
90	Thorium-234	W, see ^{226}Th	3E+2 LLI wall (4E+2)	2E+2 –	8E-8 –	3E-10 –	– 5E-6	– 5E-5
		Y, see ^{226}Th	–	2E+2	6E-8	2E-10	–	–
91	Protactinium-227[b/]	W, all compounds except those given for Y	4E+3	1E+2	5E-8	2E-10	5E-5	5E-4
		Y, oxides and hydroxides	–	1E+2	4E-8	1E-10	–	–
91	Protactinium-228	W, see ^{227}Pa	1E+3	1E+1 Bone surf (2E+1)	5E-9 –	– 3E-11	2E-5 –	2E-4 –
		Y, see ^{227}Pa	–	1E+1	5E-9	2E-11	–	–
91	Protactinium-230	W, see ^{227}Pa	6E+2 Bone surf (9E+2)	5E+0 –	2E-9 –	7E-12 –	– 1E-5	– 1E-4
		Y, see ^{227}Pa	–	4E+0	1E-9	5E-12	–	–
91	Protactinium-231	W, see ^{227}Pa	2E-1 Bone surf (5E-1)	2E-3 Bone surf (4E-3)	6E-13 –	– 6E-15	– 6E-9	– 6E-8
		Y, see ^{227}Pa	– –	4E-3 Bone surf (6E-3)	2E-12 –	– 8E-15	– –	– –

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation		Col. 1	Col. 2	
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
91	Protactinium-232	W, see ^{227}Pa	1E+3	2E+1 Bone surf	9E-9	–	2E-5	2E-4
			–	(6E+1)	–	8E-11	–	–
		Y, see ^{227}Pa	–	6E+1 Bone surf	2E-8	–	–	–
			–	(7E+1)	–	1E-10	–	–
91	Protactinium-233	W, see ^{227}Pa	1E+3 LLI wall	7E+2	3E-7	1E-9	–	–
			(2E+3)	–	–	–	2E-5	2E-4
		Y, see ^{227}Pa	–	6E+2	2E-7	8E-10	–	–
91	Protactinium-234	W, see ^{227}Pa	2E+3	8E+3	3E-6	1E-8	3E-5	3E-4
		Y, see ^{227}Pa	–	7E+3	3E-6	9E-9	–	–
92	Uranium-230	D, UF_6, UO_2F_2, $UO_2(NO_3)_2$	4E+0 Bone surf	4E-1 Bone surf	2E-10	–	–	–
			(6E+0)	(6E-1)	–	8E-13	8E-8	8E-7
		W, UO_3, UF_4, UCl_4	–	4E-1	1E-10	5E-13	–	–
		Y, UO_2, U_3O_8	–	3E-1	1E-10	4E-13	–	–
92	Uranium-231	D, see ^{230}U	5E+3 LLI wall	8E+3	3E-6	1E-8	–	–
			(4E+3)	–	–	–	6E-5	6E-4
		W, see ^{230}U	–	6E+3	2E-6	8E-9	–	–
		Y, see ^{230}U	–	5E+3	2E-6	6E-9	–	–
92	Uranium-232	D, see ^{230}U	2E+0 Bone surf	2E-1 Bone surf	9E-11	–	–	–
			(4E+0)	(4E-1)	–	6E-13	6E-8	6E-7
		W, see ^{230}U	–	4E-1	2E-10	5E-13	–	–
		Y, see ^{230}U	–	8E-3	3E-12	1E-14	–	–
92	Uranium-233	D, see ^{230}U	1E+1 Bone surf	1E+0 Bone surf	5E-10	–	–	–
			(2E+1)	(2E+0)	–	3E-12	3E-7	3E-6
		W, see ^{230}U	–	7E-1	3E-10	1E-12	–	–
		Y, see ^{230}U	–	4E-2	2E-11	5E-14	–	–
92	Uranium-234[c]	D, see ^{230}U	1E+1 Bone surf	1E+0 Bone surf	5E-10	–	–	–
			(2E+1)	(2E+0)	–	3E-12	3E-7	3E-6
		W, see ^{230}U	–	7E-1	3E-10	1E-12	–	–
		Y, see ^{230}U	–	4E-2	2E-11	5E-14	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation		Col. 1	Col. 2	
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
92	Uranium-235[a/]	D, see ^{230}U	1E+1 Bone surf (2E+1)	1E+0 Bone surf (2E+0)	6E-10 –	– 3E-12	– 3E-7	– 3E-6
		W, see ^{230}U	–	8E-1	3E-10	1E-12	–	–
		Y, see ^{230}U	–	4E-2	2E-11	6E-14	–	–
92	Uranium-236	D, see ^{230}U	1E+1 Bone surf (2E+1)	1E+0 Bone surf (2E+0)	5E-10 –	– 3E-12	– 3E-7	– 3E-6
		W, see ^{230}U	–	8E-1	3E-10	1E-12	–	–
		Y, see ^{230}U	–	4E-2	2E-11	6E-14	–	–
92	Uranium-237	D, see ^{230}U	2E+3 LLI wall (2E+3)	3E+3 –	1E-6 –	4E-9 -	– 3E-5	– 3E-4
		W, see ^{230}U	–	2E+3	7E-7	2E-9	–	–
		Y, see ^{230}U	–	2E+3	6E-7	2E-9	–	–
92	Uranium-238[a/]	D, see ^{230}U	1E+1 Bone surf (2E+1)	1E+0 Bone surf (2E+0)	6E-10 –	– 3E-12	– 3E-7	– 3E-6
		W, see ^{230}U	–	8E-1	3E-10	1E-12	–	–
		Y, see ^{230}U	–	4E-2	2E-11	6E-14	–	–
92	Uranium-239[b/]	D, see ^{230}U	7E+4	2E+5	8E-5	3E-7	9E-4	9E-3
		W, see ^{230}U	–	2E+5	7E-5	2E-7	–	–
		Y, see ^{230}U	–	2E+5	6E-5	2E-7	–	–
92	Uranium-240	D, see ^{230}U	1E+3	4E+3	2E-6	5E-9	2E-5	2E-4
		W, see ^{230}U	–	3E+3	1E-6	4E-9	–	–
		Y, see ^{230}U	–	2E+3	1E-6	3E-9	–	–
92	Uranium-natural[g/]	D, see ^{230}U	1E+1 Bone surf (2E+1)	1E+0 Bone surf (2E+0)	5E-10 –	– 3E-12	– 3E-7	– 3E-6
		W, see ^{230}U	–	8E-1	3E-10	9E-13	–	–
		Y, see ^{230}U	–	5E-2	2E-11	9E-14	–	–
93	Neptunium-232[b/]	W, all compounds	1E+5	2E+3 Bone surf	7E-7	–	2E-3	2E-2
			–	(5E+2)	–	6E-9	–	–
93	Neptunium-233[b/]	W, all compounds	8E+5	3E+6	1E-3	4E-6	1E-2	1E-1
93	Neptunium-234	W, all compounds	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4
93	Neptunium-235	W, all compounds	2E+4 LLI wall (2E+4)	8E+2 Bone surf (1E+3)	3E-7 –	– 2E-9	– 3E-4	– 3E-3

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation		Col. 1	Col. 2	
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
93	Neptunium-236 (1.15E+5 y)	W, all compounds	3E+0	2E-2	9E-12	–	–	–
			Bone surf (6E+0)	Bone surf (5E-2)	–	8E-14	9E-8	9E-7
93	Neptunium-236 (22.5 h)	W, all compounds	3E+3	3E+1	1E-8	–	–	–
			Bone surf (4E+3)	Bone surf (7E+1)	–	1E-10	5E-5	5E-4
93	Neptunium-237	W, all compounds	5E-1	4E-3	2E-12	–	–	–
			Bone surf (1E+0)	Bone surf (1E-2)	–	1E-14	2E-8	2E-7
93	Neptunium-238	W, all compounds	1E+3	6E+1	3E-8	–	2E-5	2E-4
				Bone surf				
			–	(2E+2)	–	2E-10	–	–
93	Neptunium-239	W, all compounds	2E+3	2E+3	9E-7	3E-9	–	–
			LLI wall (2E+3)	–	–	–	2E-5	2E-4
93	Neptunium-240[b/]	W, all compounds	2E+4	8E+4	3E-5	1E-7	3E-4	3E-3
94	Plutonium-234	W, all compounds except PuO_2	8E+3	2E+2	9E-8	3E-10	1E-4	1E-3
		Y, PuO_2	–	2E+2	8E-8	3E-10	–	–
94	Plutonium-235[b/]	W, see ^{234}Pu	9E+5	3E+6	1E-3	4E-6	1E-2	1E-1
		Y, see ^{234}Pu	–	3E+6	1E-3	3E-6	–	–
94	Plutonium-236	W, see ^{234}Pu	2E+0	2E-2	8E-12	–	–	–
			Bone surf (4E+0)	Bone surf (4E-2)	–	5E-14	6E-8	6E-7
		Y, see ^{234}Pu	–	4E-2	2E-11	6E-14	–	–
94	Plutonium-237	W, see ^{234}Pu	1E+4	3E+3	1E-6	5E-9	2E-4	2E-3
		Y, see ^{234}Pu	–	3E+3	1E-6	4E-9	–	–
94	Plutonium-238	W, see ^{234}Pu	9E-1	7E-3	3E-12	–	–	–
			Bone surf (2E+0)	Bone surf (1E-2)	–	2E-14	2E-8	2E-7
		Y, see ^{234}Pu	–	2E-2	8E-12	2E-14	–	–
94	Plutonium-239	W, see ^{234}Pu	8E-1	6E-3	3E-12	–	–	–
			Bone surf (1E+0)	Bone surf (1E-2)	–	2E-14	2E-8	2E-7
		Y, see ^{234}Pu	–	2E-2	7E-12	–	–	–
			–	Bone surf (2E-2)	–	2E-14	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values: Col. 1 Oral Ingestion ALI (µCi)	Table I Occupational Values: Col. 2 Inhalation ALI (µCi)	Table I Occupational Values: Col. 3 Inhalation DAC (µCi/ml)	Table II Effluent Concentrations: Col. 1 Air (µCi/ml)	Table II Effluent Concentrations: Col. 2 Water (µCi/ml)	Table III Releases to Sewers: Monthly Average Concentration (µCi/ml)
94	Plutonium-240	W, see ^{234}Pu	8E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 –	– 2E-14	– 2E-8	– 2E-7
		Y, see ^{234}Pu	– –	2E-2 Bone surf (2E-2)	7E-12 –	– 2E-14	– –	– –
94	Plutonium-241	W, see ^{234}Pu	4E+1 Bone surf (7E+1)	3E-1 Bone surf (6E-1)	1E-10 –	– 8E-13	– 1E-6	– 1E-5
		Y, see ^{234}Pu	– –	8E-1 Bone surf (1E+0)	3E-10 –	– 1E-12	– –	– –
94	Plutonium-242	W, see ^{234}Pu	8E-1 Bone surf (1E+0)	7E-3 Bone surf (1E-2)	3E-12 –	– 2E-14	– 2E-8	– 2E-7
		Y, see ^{234}Pu	– –	2E-2 Bone surf (2E-2)	7E-12 –	– 2E-14	– –	– –
94	Plutonium-243	W, see ^{234}Pu	2E+4	4E+4	2E-5	5E-8	2E-4	2E-3
		Y, see ^{234}Pu	–	4E+4	2E-5	5E-8	–	–
94	Plutonium-244	W, see ^{234}Pu	8E-1 Bone surf (2E+0)	7E-3 Bone surf (1E-2)	3E-12 –	– 2E-14	– 2E-8	– 2E-7
		Y, see ^{234}Pu	– –	2E-2 Bone surf (2E-2)	7E-12 –	– 2E-14	– –	– –
94	Plutonium-245	W, see ^{234}Pu	2E+3	5E+3	2E-6	6E-9	3E-5	3E-4
		Y, see ^{234}Pu	–	4E+3	2E-6	6E-9	–	–
94	Plutonium-246	W, see ^{234}Pu	4E+2 LLI wall (4E+2)	3E+2 –	1E-7 –	4E-10 –	– 6E-6	– 6E-5
		Y, see ^{234}Pu	–	3E+2	1E-7	4E-10	–	–
95	Americium-237[b/]	W, all compounds	8E+4	3E+5	1E-4	4E-7	1E-3	1E-2
95	Americium-238[b/]	W, all compounds	4E+4 –	3E+3 Bone surf (6E+3)	1E-6 –	– 9E-9	5E-4 –	5E-3 –
95	Americium-239	W, all compounds	5E+3	1E+4	5E-6	2E-8	7E-5	7E-4
95	Americium-240	W, all compounds	2E+3	3E+3	1E-6	4E-9	3E-5	3E-4

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
			Oral Ingestion	Inhalation				
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
95	Americium-241	W, all compounds	8E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 –	– 2E-14	– 2E-8	– 2E-7
95	Americium-242m	W, all compounds	8E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 –	– 2E-14	– 2E-8	– 2E-7
95	Americium-242	W, all compounds	4E+3 –	8E+1 Bone surf (9E+1)	4E-8 –	– 1E-10	5E-5 –	5E-4 –
95	Americium-243	W, all compounds	8E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 –	– 2E-14	– 2E-8	– 2E-7
95	Americium-244m[b]	W, all compounds	6E+4 St wall (8E+4)	4E+3 Bone surf (7E+3)	2E-6 –	– 1E-8	– 1E-3	– 1E-2
95	Americium-244	W, all compounds	3E+3 –	2E+2 Bone surf (3E+2)	8E-8 –	– 4E-10	4E-5 –	4E-4 –
95	Americium-245	W, all compounds	3E+4	8E+4	3E-5	1E-7	4E-4	4E-3
95	Americium-246m[b]	W, all compounds	5E+4 St wall (6E+4)	2E+5 –	8E-5 –	3E-7 –	– 8E-4	– 8E-3
95	Americium-246[b]	W, all compounds	3E+4	1E+5	4E-5	1E-7	4E-4	4E-3
96	Curium-238	W, all compounds	2E+4	1E+3	5E-7	2E-9	2E-4	2E-3
96	Curium-240	W, all compounds	6E+1 Bone surf (8E+1)	6E-1 Bone surf (6E-1)	2E-10 –	– 9E-13	– 1E-6	– 1E-5
96	Curium-241	W, all compounds	1E+3 –	3E+1 Bone surf (4E+1)	1E-8 –	– 5E-11	2E-5 –	2E-4 –
96	Curium-242	W, all compounds	3E+1 Bone surf (5E+1)	3E-1 Bone surf (3E-1)	1E-10 –	– 4E-13	– 7E-7	– 7E-6
96	Curium-243	W, all compounds	1E+0 Bone surf (2E+0)	9E-3 Bone surf (2E-2)	4E-12 –	– 2E-14	– 3E-8	– 3E-7

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation		Col. 1	Col. 2	
			ALI (µCi)	ALI (µCi)	DAC (µCi/ml)	Air (µCi/ml)	Water (µCi/ml)	Monthly Average Concentration (µCi/ml)
96	Curium-244	W, all compounds	1E+0 Bone surf (3E+0)	1E-2 Bone surf (2E-2)	5E-12 –	– 3E-14	– 3E-8	– 3E-7
96	Curium-245	W, all compounds	7E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 –	– 2E-14	– 2E-8	– 2E-7
96	Curium-246	W, all compounds	7E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 –	– 2E-14	– 2E-8	– 2E-7
96	Curium-247	W, all compounds	8E-1 Bone surf (1E+0)	6E-3 Bone surf (1E-2)	3E-12 –	– 2E-14	– 2E-8	– 2E-7
96	Curium-248	W, all compounds	2E-1 Bone surf (4E-1)	2E-3 Bone surf (3E-3)	7E-13 –	– 4E-15	– 5E-9	– 5E-8
96	Curium-249[b/]	W, all compounds	5E+4 –	2E+4 Bone surf (3E+4)	7E-6 –	– 4E-8	7E-4 –	7E-3 –
96	Curium-250	W, all compounds	4E-2 Bone surf (6E-2)	3E-4 Bone surf (5E-4)	1E-13 –	– 8E-16	– 9E-10	– 9E-9
97	Berkelium-245	W, all compounds	2E+3	1E+3	5E-7	2E-9	3E-5	3E-4
97	Berkelium-246	W, all compounds	3E+3	3E+3	1E-6	4E-9	4E-5	4E-4
97	Berkelium-247	W, all compounds	5E-1 Bone surf (1E+0)	4E-3 Bone surf (9E-3)	2E-12 –	– 1E-14	– 2E-8	– 2E-7
97	Berkelium-249	W, all compounds	2E+2 Bone surf (5E+2)	2E+0 Bone surf (4E+0)	7E-10 –	– 5E-12	– 6E-6	– 6E-5
97	Berkelium-250	W, all compounds	9E+3 –	3E+2 Bone surf (7E+2)	1E-7 –	– 1E-9	1E-4 –	1E-3 –
98	Californium-244[b/]	W, all compounds except those given for Y	3E+4 St wall (3E+4)	6E+2 –	2E-7 –	8E-10 –	– 4E-4	– 4E-3
		Y, oxides and hydroxides	–	6E+2	2E-7	8E-10	–	–

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation		Col. 1	Col. 2	
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
98	Californium-246	W, see ^{244}Cf	4E+2	9E+0	4E-9	1E-11	5E-6	5E-5
		Y, see ^{244}Cf	–	9E+0	4E-9	1E-11	–	–
98	Californium-248	W, see ^{244}Cf	8E+0 Bone surf	6E-2 Bone surf	3E-11	–	–	–
			(2E+1)	(1E-1)	–	2E-13	2E-7	2E-6
		Y, see ^{244}Cf	–	1E-1	4E-11	1E-13	–	–
98	Californium-249	W, see ^{244}Cf	5E-1 Bone surf	4E-3 Bone surf	2E-12	–	–	–
			(1E+0)	(9E-3)	–	1E-14	2E-8	2E-7
		Y, see ^{244}Cf	–	1E-2 Bone surf	4E-12	–	–	–
			–	(1E-2)	–	2E-14	–	–
98	Californium-250	W, see ^{244}Cf	1E+0 Bone surf	9E-3 Bone surf	4E-12	–	–	–
			(2E+0)	(2E-2)	–	3E-14	3E-8	3E-7
		Y, see ^{244}Cf	–	3E-2	1E-11	4E-14	–	–
98	Californium-251	W, see ^{244}Cf	5E-1 Bone surf	4E-3 Bone surf	2E-12	–	–	–
			(1E+0)	(9E-3)	–	1E-14	2E-8	2E-7
		Y, see ^{244}Cf	–	1E-2 Bone surf	4E-12	–	–	–
			–	(1E-2)	–	2E-14	–	–
98	Californium-252	W, see ^{244}Cf	2E+0 Bone surf	2E-2 Bone surf	8E-12	–	–	–
			(5E+0)	(4E-2)	–	5E-14	7E-8	7E-7
		Y, see ^{244}Cf	–	3E-2	1E-11	5E-14	–	–
98	Californium-253	W, see ^{244}Cf	2E+2 Bone surf	2E+0	8E-10	3E-12	–	–
			(4E+2)	–	–	–	5E-6	5E-5
		Y, see ^{244}Cf	–	2E+0	7E-10	2E-12	–	–
98	Californium-254	W, see ^{244}Cf	2E+0	2E-2	9E-12	3E-14	3E-8	3E-7
		Y, see ^{244}Cf	–	2E-2	7E-12	2E-14	–	–
99	Einsteinium-250	W, all compounds	4E+4	5E+2 Bone surf	2E-7	–	6E-4	6E-3
			–	(1E+3)	–	2E-9	–	–
99	Einsteinium-251	W, all compounds	7E+3	9E+2 Bone surf	4E-7	–	1E-4	1E-3
			–	(1E+3)	–	2E-9	–	–
99	Einsteinium-253	W, all compounds	2E+2	1E+0	6E-10	2E-12	2E-6	2E-5

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (*continued*)

Atomic No.	Radionuclide	Class	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
			Col. 1 Oral Ingestion	Col. 2 Inhalation		Col. 1	Col. 2	
			ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
99	Einsteinium-254m	W, all compounds	3E+2	1E+1	4E-9	1E-11	–	–
			LLI wall (3E+2)	–	–	–	4E-6	4E-5
99	Einsteinium-254	W, all compounds	8E+0	7E-2	3E-11	–	–	–
			Bone surf (2E+1)	Bone surf (1E-1)	–	2E-13	2E-7	2E-6
100	Fermium-252	W, all compounds	5E+2	1E+1	5E-9	2E-11	6E-6	6E-5
100	Fermium-253	W, all compounds	1E+3	1E+1	4E-9	1E-11	1E-5	1E-4
100	Fermium-254	W, all compounds	3E+3	9E+1	4E-8	1E-10	4E-5	4E-4
100	Fermium-255	W, all compounds	5E+2	2E+1	9E-9	3E-11	7E-6	7E-5
100	Fermium-257	W, all compounds	2E+1	2E-1	7E-11	–	–	–
			Bone surf (4E+1)	Bone surf (2E-1)	–	3E-13	5E-7	5E-6
101	Mendelevium-257	W, all compounds	7E+3	8E+1	4E-8	–	1E-4	1E-3
			–	Bone surf (9E+1)	–	1E-10	–	–
101	Mendelevium-258	W, all compounds	3E+1	2E-1	1E-10	–	–	–
			Bone surf (5E+1)	Bone surf (3E-1)	–	5E-13	6E-7	6E-6
- Any single radionuclide not listed above with decay mode other than alpha emission or spontaneous fission and with radioactive half-life less than 2 hours		Submersion[a/]	–	2E+2	1E-7	1E-9	–	–
- Any single radionuclide not listed above with decay mode other than alpha emission or spontaneous fission and with radioactive half-life greater than 2 hours		. . . .	–	2E-1	1E-10	1E-12	1E-8	1E-7
- Any single radionuclide not listed above that decays by alpha emission or spontaneous fission, or any mixture for which either the identity or the concentration of any radionuclide in the mixture is not known		. . . .	–	4E-4	2E-13	1E-15	2E-9	2E-8

Footnotes for Appendix G to Section 3:

[a/] "Submersion" means that values given are for submersion in a hemispherical semi-infinite cloud of airborne material.

[b/] These radionuclides have radiological half-lives of less than 2 hours. The total effective dose equivalent received during operations with these radionuclides might include a significant contribution from external exposure. The DAC values for all radionuclides, other than those designated Class "Submersion," are based upon the committed effective dose equivalent due to the intake of the radionuclide into the body and do NOT include potentially significant contributions to dose equivalent from external exposures. The licensee may substitute 1E-7 μCi/ml for the listed DAC to account for the submersion dose prospectively, but should use individual monitoring devices or other radiation measuring instruments that measure external exposure to demonstrate compliance with the limits. (See RH-1202.)

[c/] For soluble mixtures of U-238, U-234, and U-235 in air, chemical toxicity may be the limiting factor. (See RH-1200.e.) If the percent by weight (enrichment) of U-235 is not greater than 5, the concentration value for a 40-hour workweek is 0.2 milligrams uranium per cubic meter of air average. For any enrichment, the product of the average concentration and time of exposure during a 40-hour workweek shall not exceed 8E-3 (SA) μCi-hr/ml, where SA is the specific activity of the uranium inhaled. The specific activity for natural uranium is 6.77E-7 curies per gram U. The specific activity for other mixtures of U-238, U-235, and U-234, if not known, shall be:

SA = 3.6E-7 curies/gram U U-depleted

$SA = [0.4 + 0.38 (enrichment) + 0.0034 (enrichment)^2] E-6$, enrichment ≥ 0.72

where enrichment is the percentage by weight of U-235, expressed as percent.

Note:

1. If the identity of each radionuclide in a mixture is known but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.

2. If the identity of each radionuclide in the mixture is not known, but it is known that certain radionuclides specified in this appendix are not present in the mixture, the inhalation ALI, DAC, and effluent and sewage concentrations for the mixture are the lowest values specified in this appendix for any radionuclide that is not known to be absent from the mixture; or

~~Footnotes for Appendix G to Section 3 (Cont'd)~~

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage

	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
	Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
	Oral Ingestion	Inhalation				
Radionuclide	ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
If it is known that Ac-227-D and Cm-250-W are not present	–	7E-4	3E-13	–	–	–
If, in addition, it is known that Ac-227-W,Y, Th-229-W,Y, Th-230-W, Th-232-W,Y, Pa-231-W,Y, Np-237-W, Pu-239-W, Pu-240-W, Pu-242-W, Am-241-W, Am-242m-W, Am-243-W, Cm-245-W, Cm-246-W, Cm-247-W, Cm-248-W, Bk-247-W, Cf-249-W, and Cf-251-W are not present	–	7E-3	3E-12	–	–	–
If, in addition, it is known that Sm-146-W, Sm-147-W, Gd-148-D,W, Gd-152-D,W, Th-228-W,Y, Th-230-Y, U-232-Y, U-233-Y, U-234-Y, U-235-Y, U-236-Y, U-238-Y, Np-236-W, Pu-236-W,Y, Pu-238-W,Y, Pu-239-Y, Pu-240-Y, Pu-242-Y, Pu-244-W,Y, Cm-243-W, Cm-244-W, Cf-248-W, Cf-249-Y, Cf-250-W,Y, Cf-251-Y, Cf-252-W,Y, and Cf-254-W,Y are not present	–	7E-2	3E-11	–	–	–
If, in addition, it is known that Pb-210-D, Bi-210m-W, Po-210-D,W, Ra-223-W, Ra-225-W, Ra-226-W, Ac-225-D,W,Y, Th-227-W,Y, U-230-D,W,Y, U-232-D,W, Pu-241-W, Cm-240-W, Cm-242-W, Cf-248-Y, Es-254-W, Fm-257-W, and Md-258-W are not present	–	7E-1	3E-10	–	–	–
If, in addition, it is known that Si-32-Y, Ti-44-Y, Fe-60-D, Sr-90-Y, Zr-93-D, Cd-113m-D, Cd-113-D, In-115-D,W, La-138-D, Lu-176-W, Hf-178m-D,W, Hf-182-D,W, Bi-210m-D, Ra-224-W, Ra-228-W, Ac-226-D,W,Y, Pa-230-W,Y, U-233-D,W, U-234-D,W, U-235-D,W, U-236-D,W, U-238-D,W, Pu-241-Y, Bk-249-W, Cf-253-W,Y, and Es-253-W are not present	–	7E+0	3E-9	–	–	–
If it is known that Ac-227-D,W,Y, Th-229-W,Y, Th-232-W,Y, Pa-231-W,Y, Cm-248-W, and Cm-250-W are not present	–	–	–	1E-14	–	–
If, in addition, it is known that Sm-146-W, Gd-148-D,W, Gd-152-D, Th-228-W,Y, Th-230-W,Y, U-232-Y, U-233-Y, U-234-Y, U-235-Y, U-236-Y, U-238-Y, U-Nat-Y, Np-236-W, Np-237-W, Pu-236-W,Y, Pu-238-W,Y, Pu-239-W,Y, Pu-240-W,Y, Pu-242-W,Y, Pu-244-W,Y, Am-241-W, Am-242m-W, Am-243-W, Cm-243-W, Cm-244-W, Cm-245-W, Cm-246-W, Cm-247-W, Bk-247-W, Cf-249-W,Y, Cf-250-W,Y, Cf-251-W,Y, Cf-252-W,Y, and Cf-254-W,Y are not present	–	–	–	1E-13	–	–

Footnotes for Appendix G to Section 3 (Cont'd)

Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage (continued)

	Table I Occupational Values			Table II Effluent Concentrations		Table III Releases to Sewers
	Col. 1	Col. 2	Col. 3	Col. 1	Col. 2	
	Oral Ingestion	Inhalation				
Radionuclide	ALI (μCi)	ALI (μCi)	DAC (μCi/ml)	Air (μCi/ml)	Water (μCi/ml)	Monthly Average Concentration (μCi/ml)
If, in addition, it is known that Sm-147-W, Gd-152-W, Pb-210-D, Bi-210m-W, Po-210-D,W, Ra-223-W, Ra-225-W, Ra-226-W, Ac-225-D,W,Y, Th-227-W,Y, U-230-D,W,Y, U-232-D,W, U-Nat-W, Pu-241-W, Cm-240-W, Cm-242-W, Cf-248-W,Y, Es-254-W, Fm-257-W, and Md-258-W are not present	–	–	–	1E-12	–	–
If, in addition it is known that Fe-60, Sr-90, Cd-113m, Cd-113, In-115, I-129, Cs-134, Sm-145, Sm-147, Gd-148, Gd-152, Hg-194 (organic), Bi-210m, Ra-223, Ra-224, Ra-225, Ac-225, Th-228, Th-230, U-233, U-234, U-235, U-236, U-238, U-Nat, Cm-242, Cf-248, Es-254, Fm-257, and Md-258 are not present	–	–	–	–	1E-6	1E-5

Note (Cont'd):

3. If a mixture of radionuclides consists of uranium and its daughters in ore dust (10 μm AMAD particle distribution assumed) prior to chemical separation of the uranium from the ore, the following values may be used for the DAC of the mixture:- 6E-11 μCi of gross alpha activity from uranium-238, uranium-234, thorium-230, and radium-226 per milliliter of air; 3E-11 μCi of natural uranium per milliliter of air; or 45 micrograms of natural uranium per cubic meter of air.

4. If the identity and concentration of each radionuclide in a mixture are known, the limiting values should be derived as follows:- determine, for each radionuclide in the mixture, the ratio between the concentration present in the mixture and the concentration otherwise established in Appendix G to Section 3 for the specific radionuclide when not in a mixture. -The sum of such ratios for all of the radionuclides in the mixture may not exceed "1" (i.e., "unity").

   Example:- If radionuclides "A," "B," and "C" are present in concentrations C_A, C_B, and C_C, and if the applicable DACs are DAC_A, DAC_B, and DAC_C, respectively, then the concentrations shall be limited so that the following relationship exists:

$$\frac{C_A}{DAC_A} + \frac{C_B}{DAC_B} + \frac{C_C}{DAC_C} < 1$$

APPENDIX H TO SECTION 3

QUANTITIES[a/] OF LICENSED MATERIAL REQUIRING LABELING

(In order of atomic number)

Radionuclide	Quantity (μCi)[b/]	Radionuclide	Quantity (μCi)[b/]
Hydrogen-3	1,000	Vanadium-47	1,000
Beryllium-7	1,000	Vanadium-48	100
Beryllium-10	1	Vanadium-49	1,000
Carbon-11	1,000	Chromium-48	1,000
Carbon-14	100	Chromium-49	1,000
Fluorine-18	1,000	Chromium-51	1,000
Sodium-22	10	Manganese-51	1,000
Sodium-24	100	Manganese-52m	1,000
Magnesium-28	100	Manganese-52	100
Aluminum-26	10	Manganese-53	1,000
Silicon-31	1,000	Manganese-54	100
Silicon-32	1	Manganese-56	1,000
Phosphorus-32	10	Iron-52	100
Phosphorus-33	100	Iron-55	100
Sulfur-35	100	Iron-59	10
Chlorine-36	10	Iron-60	1
Chlorine-38	1,000	Cobalt-55	100
Chlorine-39	1,000	Cobalt-56	10
Argon-39	1,000	Cobalt-57	100
Argon-41	1,000	Cobalt-58m	1,000
Potassium-40	100	Cobalt-58	100
Potassium-42	1,000	Cobalt-60m	1,000
Potassium-43	1,000	Cobalt-60	1
Potassium-44	1,000	Cobalt-61	1,000
Potassium-45	1,000	Cobalt-62m	1,000
Calcium-41	100	Nickel-56	100
Calcium-45	100	Nickel-57	100
Calcium-47	100	Nickel-59	100
Scandium-43	1,000	Nickel-63	100
Scandium-44m	100	Nickel-65	1,000
Scandium-44	100	Nickel-66	10
Scandium-46	10	Copper-60	1,000
Scandium-47	100	Copper-61	1,000
Scandium-48	100	Copper-64	1,000
Scandium-49	1,000	Copper-67	1,000
Titanium-44	1	Zinc-62	100
Titanium-45	1,000	Zinc-63	1,000

APPENDIX H TO SECTION 3

QUANTITIES[a/] OF LICENSED MATERIAL REQUIRING LABELING

(In order of atomic number)

Radionuclide	Quantity (µCi)[b/]	Radionuclide	Quantity (µCi)[b/]
Zinc-65	10	Bromine-74	1,000
Zinc-69m	100	Bromine-75	1,000
Zinc-69	1,000	Bromine-76	100
Zinc-71m	1,000	Bromine-77	1,000
Zinc-72	100	Bromine-80m	1,000
Gallium-65	1,000	Bromine-80	1,000
Gallium-66	100	Bromine-82	100
Gallium-67	1,000	Bromine-83	1,000
Gallium-68	1,000	Bromine-84	1,000
Gallium-70	1,000	Krypton-74	1,000
Gallium-72	100	Krypton-76	1,000
Gallium-73	1,000	Krypton-77	1,000
Germanium-66	1,000	Krypton-79	1,000
Germanium-67	1,000	Krypton-81	1,000
Germanium-68	10	Krypton-83m	1,000
Germanium-69	1,000	Krypton-85m	1,000
Germanium-71	1,000	Krypton-85	1,000
Germanium-75	1,000	Krypton-87	1,000
Germanium-77	1,000	Krypton-88	1,000
Germanium-78	1,000	Rubidium-79	1,000
Arsenic-69	1,000	Rubidium-81m	1,000
Arsenic-70	1,000	Rubidium-81	1,000
Arsenic-71	100	Rubidium-82m	1,000
Arsenic-72	100	Rubidium-83	100
Arsenic-73	100	Rubidium-84	100
Arsenic-74	100	Rubidium-86	100
Arsenic-76	100	Rubidium-87	100
Arsenic-77	100	Rubidium-88	1,000
Arsenic-78	1,000	Rubidium-89	1,000
Selenium-70	1,000	Strontium-80	100
Selenium-73m	1,000	Strontium-81	1,000
Selenium-73	100	Strontium-83	100
Selenium-75	100	Strontium-85m	1,000
Selenium-79	100	Strontium-85	100
Selenium-81m	1,000	Strontium-87m	1,000
Selenium-81	1,000	Strontium-89	10
Selenium-83	1,000	Strontium-90	0.1
Bromine-74m	1,000	Strontium-91	100

APPENDIX H TO SECTION 3

QUANTITIES[a/] OF LICENSED MATERIAL REQUIRING LABELING

(In order of atomic number)

Radionuclide	Quantity (μCi)[b/]	Radionuclide	Quantity (μCi)[b/]
Strontium-92	100	Technetium-94	1,000
Yttrium-86m	1,000	Technetium-96m	1,000
Yttrium-86	100	Technetium-96	100
Yttrium-87	100	Technetium-97m	100
Yttrium-88	10	Technetium-97	1,000
Yttrium-90m	1,000	Technetium-98	10
Yttrium-90	10	Technetium-99m	1,000
Yttrium-91m	1,000	Technetium-99	100
Yttrium-91	10	Technetium-101	1,000
Yttrium-92	100	Technetium-104	1,000
Yttrium-93	100	Ruthenium-94	1,000
Yttrium-94	1,000	Ruthenium-97	1,000
Yttrium-95	1,000	Ruthenium-103	100
Zirconium-86	100	Ruthenium-105	1,000
Zirconium-88	10	Ruthenium-106	1
Zirconium-89	100	Rhodium-99m	1,000
Zirconium-93	1	Rhodium-99	100
Zirconium-95	10	Rhodium-100	100
Zirconium-97	100	Rhodium-101m	1,000
Niobium-88	1,000	Rhodium-101	10
Niobium-89m (66 min)	1,000	Rhodium-102m	10
Niobium-89 (122 min)	1,000	Rhodium-102	10
Niobium-90	100	Rhodium-103m	1,000
Niobium-93m	10	Rhodium-105	100
Niobium-94	1	Rhodium-106m	1,000
Niobium-95m	100	Rhodium-107	1,000
Niobium-95	100	Palladium-100	100
Niobium-96	100	Palladium-101	1,000
Niobium-97	1,000	Palladium-103	100
Niobium-98	1,000	Palladium-107	10
Molybdenum-90	100	Palladium-109	100
Molybdenum-93m	100	Silver-102	1,000
Molybdenum-93	10	Silver-103	1,000
Molybdenum-99	100	Silver-104m	1,000
Molybdenum-101	1,000	Silver-104	1,000
Technetium-93m	1,000	Silver-105	100
Technetium-93	1,000	Silver-106m	100
Technetium-94m	1,000	Silver-106	1,000

APPENDIX H TO SECTION 3

QUANTITIES[a/] OF LICENSED MATERIAL REQUIRING LABELING

(In order of atomic number)

Radionuclide	Quantity (µCi)[b/]	Radionuclide	Quantity (µCi)[b/]
Silver-108m	1	Tin-127	1,000
Silver-110m	10	Tin-128	1,000
Silver-111	100	Antimony-115	1,000
Silver-112	100	Antimony-116m	1,000
Silver-115	1,000	Antimony-116	1,000
Cadmium-104	1,000	Antimony-117	1,000
Cadmium-107	1,000	Antimony-118m	1,000
Cadmium-109	1	Antimony-119	1,000
Cadmium-113m	0.1	Antimony-120 (16 min)	1,000
Cadmium-113	100	Antimony-120 (5.76 d)	100
Cadmium-115m	10	Antimony-122	100
Cadmium-115	100	Antimony-124m	1,000
Cadmium-117m	1,000	Antimony-124	10
Cadmium-117	1,000	Antimony-125	100
Indium-109	1,000	Antimony-126m	1,000
Indium-110 (69.1 min)	1,000	Antimony-126	100
Indium-110 (4.9 h)	1,000	Antimony-127	100
Indium-111	100	Antimony-128 (10.4 min)	1,000
Indium-112	1,000	Antimony-128 (9.01 h)	100
Indium-113m	1,000	Antimony-129	100
Indium-114m	10	Antimony-130	1,000
Indium-115m	1,000	Antimony-131	1,000
Indium-115	100	Tellurium-116	1,000
Indium-116m	1,000	Tellurium-121m	10
Indium-117m	1,000	Tellurium-121	100
Indium-117	1,000	Tellurium-123m	10
Indium-119m	1,000	Tellurium-123	100
Tin-110	100	Tellurium-125m	10
Tin-111	1,000	Tellurium-127m	10
Tin-113	100	Tellurium-127	1,000
Tin-117m	100	Tellurium-129m	10
Tin-119m	100	Tellurium-129	1,000
Tin-121m	100	Tellurium-131m	10
Tin-121	1,000	Tellurium-131	100
Tin-123m	1,000	Tellurium-132	10
Tin-123	10	Tellurium-133m	100
Tin-125	10	Tellurium-133	1,000
Tin-126	10	Tellurium-134	1,000

APPENDIX H TO SECTION 3

QUANTITIES[a/] OF LICENSED MATERIAL REQUIRING LABELING
(In order of atomic number)

Radionuclide	Quantity (µCi)[b/]	Radionuclide	Quantity (µCi)[b/]
Iodine-120m	1,000	Cesium-135	100
Iodine-120	100	Cesium-136	10
Iodine-121	1,000	Cesium-137	10
Iodine-123	100	Cesium-138	1,000
Iodine-124	10	Barium-126	1,000
Iodine-125	1	Barium-128	100
Iodine-126	1	Barium-131m	1,000
Iodine-128	1,000	Barium-131	100
Iodine-129	1	Barium-133m	100
Iodine-130	10	Barium-133	100
Iodine-131	1	Barium-135m	100
Iodine-132m	100	Barium-139	1,000
Iodine-132	100	Barium-140	100
Iodine-133	10	Barium-141	1,000
Iodine-134	1,000	Barium-142	1,000
Iodine-135	100	Lanthanum-131	1,000
Xenon-120	1,000	Lanthanum-132	100
Xenon-121	1,000	Lanthanum-135	1,000
Xenon-122	1,000	Lanthanum-137	10
Xenon-123	1,000	Lanthanum-138	100
Xenon-125	1,000	Lanthanum-140	100
Xenon-127	1,000	Lanthanum-141	100
Xenon-129m	1,000	Lanthanum-142	1,000
Xenon-131m	1,000	Lanthanum-143	1,000
Xenon-133m	1,000	Cerium-134	100
Xenon-133	1,000	Cerium-135	100
Xenon-135m	1,000	Cerium-137m	100
Xenon-135	1,000	Cerium-137	1,000
Xenon-138	1,000	Cerium-139	100
Cesium-125	1,000	Cerium-141	100
Cesium-127	1,000	Cerium-143	100
Cesium-129	1,000	Cerium-144	1
Cesium-130	1,000	Praseodymium-136	1,000
Cesium-131	1,000	Praseodymium-137	1,000
Cesium-132	100	Praseodymium-138m	1,000
Cesium-134m	1,000	Praseodymium-139	1,000
Cesium-134	10	Praseodymium-142m	1,000
Cesium-135m	1,000	Praseodymium-142	100

APPENDIX H TO SECTION 3

QUANTITIES[a/] OF LICENSED MATERIAL REQUIRING LABELING
(In order of atomic number)

Radionuclide	Quantity (µCi)[b/]	Radionuclide	Quantity (µCi)[b/]
Praseodymium-143	100	Europium-150 (12.62 h)	100
Praseodymium-144	1,000	Europium-150 (34.2 y)	1
Praseodymium-145	100	Europium-152m	100
Praseodymium-147	1,000	Europium-152	1
Neodymium-136	1,000	Europium-154	1
Neodymium-138	100	Europium-155	10
Neodymium-139m	1,000	Europium-156	100
Neodymium-139	1,000	Europium-157	100
Neodymium-141	1,000	Europium-158	1,000
Neodymium-147	100	Gadolinium-145	1,000
Neodymium-149	1,000	Gadolinium-146	10
Neodymium-151	1,000	Gadolinium-147	100
Promethium-141	1,000	Gadolinium-148	0.001
Promethium-143	100	Gadolinium-149	100
Promethium-144	10	Gadolinium-151	10
Promethium-145	10	Gadolinium-152	100
Promethium-146	1	Gadolinium-153	10
Promethium-147	10	Gadolinium-159	100
Promethium-148m	10	Terbium-147	1,000
Promethium-148	10	Terbium-149	100
Promethium-149	100	Terbium-150	1,000
Promethium-150	1,000	Terbium-151	100
Promethium-151	100	Terbium-153	1,000
Samarium-141m	1,000	Terbium-154	100
Samarium-141	1,000	Terbium-155	1,000
Samarium-142	1,000	Terbium-156m (5.0 h)	1,000
Samarium-145	100	Terbium-156m (24.4 h)	1,000
Samarium-146	1	Terbium-156	100
Samarium-147	100	Terbium-157	10
Samarium-151	10	Terbium-158	1
Samarium-153	100	Terbium-160	10
Samarium-155	1,000	Terbium-161	100
Samarium-156	1,000	Dysprosium-155	1,000
Europium-145	100	Dysprosium-157	1,000
Europium-146	100	Dysprosium-159	100
Europium-147	100	Dysprosium-165	1,000
Europium-148	10	Dysprosium-166	100
Europium-149	100	Holmium-155	1,000

APPENDIX H TO SECTION 3

QUANTITIES[a/] OF LICENSED MATERIAL REQUIRING LABELING

(In order of atomic number)

Radionuclide	Quantity (µCi)[b/]	Radionuclide	Quantity (µCi)[b/]
Holmium-157	1,000	Lutetium-176	100
Holmium-159	1,000	Lutetium-177m	10
Holmium-161	1,000	Lutetium-177	100
Holmium-162m	1,000	Lutetium-178m	1,000
Holmium-162	1,000	Lutetium-178	1,000
Holmium-164m	1,000	Lutetium-179	1,000
Holmium-164	1,000	Hafnium-170	100
Holmium-166m	1	Hafnium-172	1
Holmium-166	100	Hafnium-173	1,000
Holmium-167	1,000	Hafnium-175	100
Erbium-161	1,000	Hafnium-177m	1,000
Erbium-165	1,000	Hafnium-178m	0.1
Erbium-169	100	Hafnium-179m	10
Erbium-171	100	Hafnium-180m	1,000
Erbium-172	100	Hafnium-181	10
Thulium-162	1,000	Hafnium-182m	1,000
Thulium-166	100	Hafnium-182	0.1
Thulium-167	100	Hafnium-183	1,000
Thulium-170	10	Hafnium-184	100
Thulium-171	10	Tantalum-172	1,000
Thulium-172	100	Tantalum-173	1,000
Thulium-173	100	Tantalum-174	1,000
Thulium-175	1,000	Tantalum-175	1,000
Ytterbium-162	1,000	Tantalum-176	100
Ytterbium-166	100	Tantalum-177	1,000
Ytterbium-167	1,000	Tantalum-178	1,000
Ytterbium-169	100	Tantalum-179	100
Ytterbium-175	100	Tantalum-180m	1,000
Ytterbium-177	1,000	Tantalum-180	100
Ytterbium-178	1,000	Tantalum-182m	1,000
Lutetium-169	100	Tantalum-182	10
Lutetium-170	100	Tantalum-183	100
Lutetium-171	100	Tantalum-184	100
Lutetium-172	100	Tantalum-185	1,000
Lutetium-173	10	Tantalum-186	1,000
Lutetium-174m	10	Tungsten-176	1,000
Lutetium-174	10	Tungsten-177	1,000
Lutetium-176m	1,000	Tungsten-178	1,000

APPENDIX H TO SECTION 3

QUANTITIES[a/] OF LICENSED MATERIAL REQUIRING LABELING

(In order of atomic number)

Radionuclide	Quantity (µCi)[b/]	Radionuclide	Quantity (µCi)[b/]
Tungsten-179	1,000	Iridium-194m	10
Tungsten-181	1,000	Iridium-194	100
Tungsten-185	100	Iridium-195m	1,000
Tungsten-187	100	Iridium-195	1,000
Tungsten-188	10	Platinum-186	1,000
Rhenium-177	1,000	Platinum-188	100
Rhenium-178	1,000	Platinum-189	1,000
Rhenium-181	1,000	Platinum-191	100
Rhenium-182 (12.7 h)	1,000	Platinum-193m	100
Rhenium-182 (64.0 h)	100	Platinum-193	1,000
Rhenium-184m	10	Platinum-195m	100
Rhenium-184	100	Platinum-197m	1,000
Rhenium-186m	10	Platinum-197	100
Rhenium-186	100	Platinum-199	1,000
Rhenium-187	1,000	Platinum-200	100
Rhenium-188m	1,000	Gold-193	1,000
Rhenium-188	100	Gold-194	100
Rhenium-189	100	Gold-195	10
Osmium-180	1,000	Gold-198m	100
Osmium-181	1,000	Gold-198	100
Osmium-182	100	Gold-199	100
Osmium-185	100	Gold-200m	100
Osmium-189m	1,000	Gold-200	1,000
Osmium-191m	1,000	Gold-201	1,000
Osmium-191	100	Mercury-193m	100
Osmium-193	100	Mercury-193	1,000
Osmium-194	1	Mercury-194	1
Iridium-182	1,000	Mercury-195m	100
Iridium-184	1,000	Mercury-195	1,000
Iridium-185	1,000	Mercury-197m	100
Iridium-186	100	Mercury-197	1,000
Iridium-187	1,000	Mercury-199m	1,000
Iridium-188	100	Mercury-203	100
Iridium-189	100	Thallium-194m	1,000
Iridium-190m	1,000	Thallium-194	1,000
Iridium-190	100	Thallium-195	1,000
Iridium-192m (1.4 min)	10	Thallium-197	1,000
Iridium-192 (73.8 d)	1	Thallium-198m	1,000

APPENDIX H TO SECTION 3

QUANTITIES[a/] OF LICENSED MATERIAL REQUIRING LABELING

(In order of atomic number)

Radionuclide	Quantity (μCi)[b/]	Radionuclide	Quantity (μCi)[b/]
Thallium-198	1,000	Radon-220	1
Thallium-199	1,000	Radon-222	1
Thallium-200	1,000	Francium-222	100
Thallium-201	1,000	Francium-223	100
Thallium-202	100	Radium-223	0.1
Thallium-204	100	Radium-224	0.1
Lead-195m	1,000	Radium-225	0.1
Lead-198	1,000	Radium-226	0.1
Lead-199	1,000	Radium-227	1,000
Lead-200	100	Radium-228	0.1
Lead-201	1,000	Actinium-224	1
Lead-202m	1,000	Actinium-225	0.01
Lead-202	10	Actinium-226	0.1
Lead-203	1,000	Actinium-227	0.001
Lead-205	100	Actinium-228	1
Lead-209	1,000	Thorium-226	10
Lead-210	0.01	Thorium-227	0.01
Lead-211	100	Thorium-228	0.001
Lead-212	1	Thorium-229	0.001
Lead-214	100	Thorium-230	0.001
Bismuth-200	1,000	Thorium-231	100
Bismuth-201	1,000	Thorium-232	100
Bismuth-202	1,000	Thorium-234	10
Bismuth-203	100	Thorium-natural	100
Bismuth-205	100	Protactinium-227	10
Bismuth-206	100	Protactinium-228	1
Bismuth-207	10	Protactinium-230	0.1
Bismuth-210m	0.1	Protactinium-231	0.001
Bismuth-210	1	Protactinium-232	1
Bismuth-212	10	Protactinium-233	100
Bismuth-213	10	Protactinium-234	100
Bismuth-214	100	Uranium-230	0.01
Polonium-203	1,000	Uranium-231	100
Polonium-205	1,000	Uranium-232	0.001
Polonium-207	1,000	Uranium-233	0.001
Polonium-210	0.1	Uranium-234	0.001
Astatine-207	100	Uranium-235	0.001
Astatine-211	10	Uranium-236	0.001

APPENDIX H TO SECTION 3

QUANTITIES[a/] OF LICENSED MATERIAL REQUIRING LABELING

(In order of atomic number)

Radionuclide	Quantity (µCi)[b/]	Radionuclide	Quantity (µCi)[b/]
Uranium-237	100	Americium-246m	1,000
Uranium-238	100	Americium-246	1,000
Uranium-239	1,000	Curium-238	100
Uranium-240	100	Curium-240	0.1
Uranium-natural	100	Curium-241	1
Neptunium-232	100	Curium-242	0.01
Neptunium-233	1,000	Curium-243	0.001
Neptunium-234	100	Curium-244	0.001
Neptunium-235	100	Curium-245	0.001
Neptunium-236 (1.15E+5 y)	0.001	Curium-246	0.001
Neptunium-236 (22.5 h)	1	Curium-247	0.001
Neptunium-237	0.001	Curium-248	0.001
Neptunium-238	10	Curium-249	1,000
Neptunium-239	100	Berkelium-245	100
Neptunium-240	1,000	Berkelium-246	100
Plutonium-234	10	Berkelium-247	0.001
Plutonium-235	1,000	Berkelium-249	0.1
Plutonium-236	0.001	Berkelium-250	10
Plutonium-237	100	Californium-244	100
Plutonium-238	0.001	Californium-246	1
Plutonium-239	0.001	Californium-248	0.01
Plutonium-240	0.001	Californium-249	0.001
Plutonium-241	0.01	Californium-250	0.001
Plutonium-242	0.001	Californium-251	0.001
Plutonium-243	1,000	Californium-252	0.001
Plutonium-244	0.001	Californium-253	0.1
Plutonium-245	100	Californium-254	0.001
Americium-237	1,000	Einsteinium-250	100
Americium-238	100	Einsteinium-251	100
Americium-239	1,000	Einsteinium-253	0.1
Americium-240	100	Einsteinium-254m	1
Americium-241	0.001	Einsteinium-254	0.01
Americium-242m	0.001	Fermium-252	1
Americium-242	10	Fermium-253	1
Americium-243	0.001	Fermium-254	10
Americium-244m	100	Fermium-255	1
Americium-244	10	Fermium-257	0.01
Americium-245	1,000	Mendelevium-257	10

APPENDIX H TO SECTION 3

QUANTITIES[a/] OF LICENSED MATERIAL REQUIRING LABELING

(In order of atomic number)

Radionuclide	Quantity (µCi)[b/]	Radionuclide	Quantity (µCi)[b/]
Mendelevium-258	0.01		
Any alpha emitting radionuclide not listed above or mixtures of alpha emitters of unknown composition	0.001	Any radionuclide other than alpha emitting radionuclides not listed above, or mixtures of beta emitters of unknown composition	0.01

Note:

For purposes of RH-1310.a. and RH-1501.c. where there is involved a combination of radionuclides in known amounts, the limit for the combination shall be derived as follows: determine, for each radionuclide in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific radionuclide when not in combination. The sum of such ratios for all radionuclides in the combination may not exceed "1" -- that is, unity.

Footnotes for Appendix H to Section 3:

[a/] The quantities listed above were derived by taking 1/10th of the most restrictive ALI listed in Table I, Columns 1 and 2, of Appendix G to Section 3, rounding to the nearest factor of 10, and constraining the values listed between 37 Bq and 37 MBq (0.001 and 1,000 µCi). Values of 3.7 MBq (100 µCi) have been assigned for radionuclides having a radioactive half-life in excess of E+9 years, except rhenium, 37 MBq (1,000 µCi), to take into account their low specific activity.

[b/] To convert µCi to kBq, multiply the µCi value by 37.

FOOTNOTES TO SECTION 3

1/ An organ or tissue is deemed to be significantly irradiated if, for that organ or tissue, the product of the weighting factors, W_T, and the committed dose equivalent, $H_{T,50}$, per unit intake is greater than ten percent (10%) of the maximum weighted value of $H_{T,50}$ (i.e., $W_T H_{T,50}$) per unit intake for any organ or tissue. \ $H_{T,50}$ was H_{50}.

~~2/ This section applies to radiation from byproduct, source, or special nuclear materials that are used in sealed sources in non-self-shielded irradiators. This section does not apply to radioactive sources that are used in teletherapy, in industrial radiography, or in completely self-shielded irradiators in which the source is both stored and operated within the same shielding radiation barrier and, in the designed configuration of the irradiator cannot create high levels of radiation in an area that is accessible to any individual. This section also does not apply to sources from which the radiation is incidental to some other use or to nuclear reactor-generated radiation.~~

~~3~~2/ Deleted.

~~4~~3/ Labeled with a Radioactive White I, Yellow II, or Yellow III label as specified in U. S. Department of Transportation regulations, 49 CFR 172.403 and 172.436-440.

~~5~~4/ Labeling of packages containing radioactive materials is required by the Department of Transportation (DOT) if the amount and type of radioactive material exceeds the limits for an excepted quantity or article as defined and limited by DOT regulations 49 CFR 173.403 and 173.421-426.

~~6~~5/ Licensees are not required to partition historical dose between external dose equivalent(s) and internal committed dose equivalent(s). \\ Further, occupational exposure histories obtained and recorded on RC FORM 111 (formerly known as Department Form Z or Department Form RH-1), or equivalent, before January 1, 1994, might not have included effective dose equivalent, but may be used in the absence of specific information on the intake of radionuclides by the individual.

~~7~~6/ Assessments of dose equivalent and records made using units in effect before the licensee's adoption of this Section need not be changed.

~~8~~7/ A previous RH-1403. permitted certain burials of small quantities of licensed materials in soil before January 1, 1983, without specific Department authorization. \ As of January 1, 1983, these burials had to receive specific approval by the Department, in accordance with the revised RH-1403. \ Disposal by burial in soil came to be regulated under RH-1401.

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~~FOOTNOTES TO SECTION 3~~ ~~*(Continued)*~~

~~9~~8/ With respect to the limit for the embryo/fetus (RH-1207), the identifiers should be those of the declared pregnant woman.

~~10~~9/ Deleted.

~~11~~10/ The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent (99%) minimum aluminum, 0.12 percent copper.

~~12~~11/ Deleted.

~~13~~12/ Deleted.

~~14~~13/ An example of a suggested plaque is shown at the end of this Part.

~~15~~14/ Appropriate warnings may include:

a. "Do not drill below plug back depth";

b. "Do not enlarge casing"; or

c. "Do not re-enter the hole," followed by the words, "before contacting the Arkansas Department of Health."

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SECTION 4.
TRANSPORTATION OF RADIOACTIVE MATERIALS

PART A.
GENERAL

RH-3000. **Authority**. Act 8 of Second Extraordinary Session of 1961, as amended.

RH-3001. **Effective Date**. The provisions of these Rules shall become operative on the effective date of an agreement executed by the State of Arkansas and the Federal Government under the provisions of Section 274 of the Atomic Energy Act of 1954 as amended (73 STAT. 689).

RH-3002. **Purpose and Scope**.

a. This Section establishes requirements for packaging, preparation for shipment, and transportation of licensed material.

b. The packaging and transport of licensed material are also subject to the regulations of other agencies (e.g., the U.S. Department of Transportation, the U.S. Nuclear Regulatory Commission, and the U.S. Postal Service) having jurisdiction over means of transport. The requirements of this Section are in addition to, and not in substitution for, other requirements.

c. The rules in this Section apply to any licensee authorized by specific or general license issued by the Department to receive, possess, use, or transfer licensed material, if the licensee delivers that material to a carrier for transport, transports the material outside the site of usage as specified in the Department license, or transports that material on public highways. No provision of this Section authorizes the possession of licensed material.

d. 1. Exemptions from Section 4 requirements are specified in Part C of this Section. General licenses for which no NRC package approval is required are issued in RH-3304. through RH-3306. The general license in RH-3301. requires that an NRC Certificate of Compliance or other package approval be issued for the package to be used under this general license.

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~~RH-3002.d. (Cont'd)~~

2. A licensee transporting licensed material, or delivering licensed material to a carrier for transport, shall comply with the operating control requirements of Part F; the quality assurance requirements of Part G; and the general provisions of Part A, including referenced U.S. Department of Transportation regulations.

RH-3003. **Communications and Records**.

a. where otherwise specified, all communications concerning these Rules may be addressed to the Arkansas Department of Health, Radiation Control Section, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

b. Each record required by this section must be legible throughout the retention period specified by each Department rule. The record may be the original, a reproduced copy, or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

RH-3004. **Requirement for License**.

Except as authorized in a general license or a specific license issued by the Department, or as exempted in this Section, no licensee may:

a. Deliver licensed material to a carrier for transport; or

b. Transport licensed material.

RH-3005. **Transportation of Radioactive Material**.

a. Each licensee who transports licensed material outside the site of usage, as specified in the Department license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of the DOT regulations in 49 CFR parts 107, 171 through 180, and 390 through 397, appropriate to the mode of transport.

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~~RH 3005.a. (Cont'd)~~

1. The licensee shall particularly note DOT regulations in the following areas:

   A. Packaging--49 CFR part 173: Subparts A, B, and I.

   B. Marking and labeling--49 CFR part 172: Subpart D; and §§ 172.400 through 172.407 and §§ 172.436 through 172.441 of Subpart E.

   C. Placarding--49 CFR part 172: Subpart F, especially §§ 172.500 through 172.519 and 172.556; and appendices B and C.

   D. Accident reporting--49 CFR part 171: §§ 171.15 and 171.16.

   E. Shipping papers and emergency information--49 CFR part 172: Subparts C and G.

   F. Hazardous material employee training--49 CFR part 172: Subpart H.

   G. Security plans--49 CFR part 172: Subpart I.

   H. Hazardous material shipper/carrier registration--49 CFR part 107: Subpart G.

2. The licensee shall also note DOT regulations pertaining to the following modes of transportation:

   A. Rail--49 CFR part 174: Subparts A through D and K.

   B. Air--49 CFR part 175.

   C. Vessel--49 CFR part 176: Subparts A through F and M.

   D. Public Highway--49 CFR part 177 and parts 390 through 397.

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b. If DOT regulations are not applicable to a shipment of licensed material, the licensee shall conform to the standards and requirements of the DOT specified in RH-3005.a. of this section to the same extent as if the shipment or transportation were subject to DOT regulations. A request for modification, waiver, or exemption from those requirements, and any notification referred to in those requirements, must be filed with, or made to, the Arkansas Department of Health, Radiation Control Section, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

RH-3006. **Interpretations**.

Except as specifically authorized by the Department in writing, no interpretations of the meaning of the rules in this Section by an officer or employee of the Department other than a written interpretation by the Department Director or designee will be recognized as binding upon the Department.

RH-3007.- RH-3099. Reserved.

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PART B.

DEFINITIONS

RH-3100. **Definitions**.

The following terms are as defined for the purpose of this Section. To ensure compatibility with international transportation standards, all limits in this Section are given in terms of dual units: The International System of Units (SI) followed or preceded by U.S. standard or customary units. The U.S. customary units are not exact equivalents, but rounded to a convenient value, providing a functionally equivalent unit. For the purpose of this Section, either unit may be used.

A_1 - Maximum activity of special form of radioactive material permitted in a Type A package. These values are either listed in Table A-1 of Appendix A to this Section or may be derived in accordance with the procedure prescribed in Appendix A.

A_2 - Maximum activity of radioactive material, other than special form, LSA and SCO material, permitted in a Type A package. These values are either listed in Table A-1 of Appendix A to this Section or may be derived in accordance with the procedure prescribed in Appendix A.

Act - Act 8 of Second Extraordinary Session of 1961, as amended.

Carrier - A person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft.

Certificate Holder – a person who has been issued a Certificate of Compliance or other package approval by the U.S. Nuclear Regulatory Commission.

Certificate of Compliance (CoC) - the certificate issued by the U.S. Nuclear Regulatory Commission which approves the design of a package for the transportation of radioactive material.

CFR - Code of Federal Regulations.

Close reflection by water - immediate contact by water of sufficient thickness for maximum reflection of neutrons.

Consignment - Each shipment of a package or groups of packages or load of radioactive material offered by a shipper for transport.

Containment system - the assembly of components of the packaging intended to retain the radioactive material during transport.

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Contamination - The presence of a radioactive substance on a surface in quantities in excess of 0.4 Bq/cm^2 (1 x 10^{-5} µCi/cm^2) for beta and gamma emitters and low toxicity alpha emitters, or 0.04 Bq/cm^2 (1 x 10^{-6} µCi/cm^2) for all other alpha emitters.

1. **Fixed contamination** - Contamination that cannot be removed from a surface during normal conditions of transport.

2. **Non-fixed contamination** - Contamination that can be removed from a surface during normal conditions of transport.

Conveyance -

1. For transport by public highway or rail, any transport vehicle or large freight container;

2. For transport by water, any vessel, or any hold, compartment, or defined deck area of a vessel including any transport vehicle on board the vessel; and

3. For transport by any aircraft.

Criticality Safety Index (CSI) - The dimensionless number (rounded up to the next tenth) assigned to and placed on the label of a fissile material package, to designate the degree of control of accumulation of packages, overpacks, or freight containers containing fissile material during transportation. Determination of the criticality safety index is described in RH-3305., RH-3306., and in 10 CFR 71.59. The criticality safety index for an overpack, freight container, consignment, or conveyance containing fissile material packages is the arithmetic sum of the criticality safety indices of all the fissile material packages contained within the overpack, freight container, consignment, or conveyance.

Deuterium - For the purposes of RH-3203. and RH-3305., deuterium and any deuterium compounds, including heavy water, in which the ratio of deuterium atoms to hydrogen atoms exceeds 1:5000.

DOT - The U.S. Department of Transportation.

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Exclusive use (also referred to in other regulations as "sole") - The sole use of a conveyance by a single consignor of a conveyance for which all initial, intermediate, and final loading and unloading are carried out in accordance with the direction of the consignor or consignee. The consignor and the carrier must ensure that any loading or unloading is performed by personnel having radiological training and resources appropriate for safe handling of the consignment. The consignor must issue specific instructions, in writing, for maintenance of exclusive use shipment controls, and include them with the shipping paper information provided by the consignor.

Fissile material - The radionuclides uranium-233, uranium-235, plutonium-239, and plutonium-241, or any combination of these radionuclides. Fissile material means the fissile nuclides themselves, not material containing fissile nuclides. Unirradiated natural uranium and depleted uranium, that has been irradiated in thermal reactors only, are not included in this definition. Certain exclusions from fissile material controls are provided in RH-3203.

Graphite - For the purposes of RH-3203 and RH-3305, graphite with a boron equivalent content less than five (5) parts per million and density greater than 1.5 grams per cubic centimeter.

Indian Tribe - An Indian or Alaska native Tribe, band, nation, pueblo, village, or community that the Secretary of the Interior acknowledges to exist as an Indian Tribe pursuant to the Federally Recognized Indian Tribe List Act of 1994, 25 U.S.C. 479a.

Licensed material - Radioactive material received, possessed, used, or transferred under a general or specific license issued by the Department pursuant to these Rules.

Low Specific Activity (LSA) - Radioactive material with limited specific activity which is nonfissile or is excepted under RH-3203. and which satisfies the descriptions and limits set forth below. Shielding materials surrounding the LSA material may not be considered in determining the estimated average specific activity of the package contents. The LSA material must be in one of three groups:

1. **LSA-I**:

   A. Uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing naturally occurring radioactive

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radionuclides that are intended to be processed for the use of these radionuclides;

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B. Natural uranium, depleted uranium, natural thorium, or their compounds or mixtures, provided they are unirradiated and in solid or liquid form;

C. Radioactive material other than fissile material, for which the A_2 value is unlimited; or

D. Other radioactive material in which the activity is distributed throughout and the estimated average specific activity does not exceed 30 times the value for exempt material activity concentration determined in accordance with Appendix A to Section 4.

2. **LSA-II**:

A. Water with tritium concentration up to 0.8 TBq/liter (20.0 Ci/liter); or

B. Other radioactive material in which the activity is distributed throughout and the estimated average specific activity does not exceed 10^{-4} A_2/g -for solid and gases, and 10^{-5} A_2/g for liquids.

3. **LSA-III**:

Solids (e.g., consolidated wastes, activated materials), excluding powders, that satisfy the requirements of 10 CFR 71.77, in which:

A. The radioactive material is distributed throughout a solid or a collection of solid objects, or is essentially uniformly distributed in a solid compact binding agent (such as concrete, bitumen, ceramic, etc.);

B. The radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that even under loss of packaging, the loss of radioactive material per package by leaching when placed in water for seven (7) days will not exceed 0.1 A_2.; and

C. The estimated average specific activity of the solid, excluding any shielding material, does not exceed 2 x $10^{-3}$$A_2$/g.

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Low toxicity alpha emitters - natural uranium, depleted uranium, natural thorium; uranium-235, uranium-238, thorium-232, thorium-228, or thorium-230 when contained in ores or physical or chemical concentrates or tailings; or alpha emitters with a half-life of less than ten (10) days.

Maximum normal operating pressure - the maximum gauge pressure that would develop in the containment system in a period of one (1) year under the heat condition specified in 10 CFR 71.71(c)(1) in the absence of venting, external cooling by an ancillary system, or operational controls during transport.

Natural thorium - Thorium with the naturally occurring distribution of thorium isotopes (essentially 100 weight percent thorium-232).

Normal form radioactive material - Radioactive material that has not been demonstrated to qualify as "special form radioactive material."

Optimum interspersed hydrogenous moderation - The presence of hydrogenous material between packages to such an extent that the maximum nuclear reactivity results.

Package - Packaging together with its radioactive contents as presented for transport.

1. **Fissile material package or Type AF package, Type BF package, Type B(U)F package, or Type B(M)F package** - A fissile material packaging together with its fissile material contents.

2. **Type A package** - A Type A packaging together with its radioactive contents. A Type A package is defined and must comply with the DOT regulations in 49 CFR Part 173.

3. **Type B package** - A Type B packaging together with its radioactive contents. On approval, a Type B package design is designated by NRC as B(U) unless the package has a maximum normal operating pressure of more than 700 kilopascal (100 lb/in²) gauge or a pressure relief device which would allow the release of radioactive material to the environment under the tests specified in 10 CFR 71.73 (hypothetical accident conditions), in which case it will receive a designation B(M). B(U) refers to the need for unilateral approval of international shipments; B(M) refers to the need for multilateral approval of international shipments.

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There is no distinction made in how packages with these designations may be used in domestic transportation. To determine their distinction for international transportation, see DOT regulations in 49 CFR Part 173. A

Type B package approved prior to September 6, 1983, was designated only as Type B. Limitations on its use are specified in 10 CFR 71.19.

Packaging - Assembly of components necessary to ensure compliance with the packaging requirements of this Section. It may consist of one or more receptacles, absorbent materials, spacing structures, thermal insulation, radiation shielding, and devices for cooling or absorbing mechanical shocks. The vehicle, tie-down system, and auxiliary equipment may be designated as part of the packaging.

Special form radioactive material - Radioactive material that satisfies the following conditions:

1. It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;

2. The piece or capsule has at least one dimension not less than five (5) millimeters (0.2 inch); and

3. It satisfies the requirements of 10 CFR 71.75. A special form encapsulation designed in accordance with the requirements of 10 CFR 71.4 in effect on June 30, 1983 (see 10 CFR Part 71, revised as of January 1, 1983), and constructed before July 1, 1985; a special form encapsulation designed in accordance with the requirements of 10 CFR 71.4 in effect on March 31, 1996 (see 10 CFR Part 71, revised as of January 1, 1996), and constructed before April 1, 1998; and special form material that was successfully tested before September 10, 2015, in accordance with the requirements of 10 CFR 71.75(d) in effect before September 10, 2015, may continue to be used. Any other special form encapsulation must meet the specifications of this definition.

Specific activity of a radionuclide - The radioactivity of the radionuclide per unit mass of that nuclide. The specific activity of a material in which the radionuclide is essentially uniformly distributed is the radioactivity per unit mass of the material.

Spent nuclear fuel or Spent fuel -- Fuel that has been withdrawn from a nuclear reactor following irradiation, has undergone at least one (1) year's decay since being used as a source of energy in a power reactor, and has not been chemically separated into its constituent elements by reprocessing. Spent fuel includes the

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special nuclear material, byproduct material, source material, and other radioactive materials associated with fuel assemblies.

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State - A State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

Surface Contaminated Object (SCO) - A solid object that is not itself classed as radioactive material, but which has radioactive material distributed on any of its surfaces. SCO must be in one of two (2) groups with surface activity not exceeding the following limits:

1. **SCO-I**: A solid object on which:

   A. The non-fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 10^{-4} microcurie/cm^2 (4 Bq/cm^2) for beta and gamma and low toxicity alpha emitters, or 10^{-5} microcurie/cm^2 (0.4 Bq/cm^2) for all other alpha emitters; and

   B. The fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 1.0 microcurie/cm^2 (4 x 10^4 Bq/cm^2) for beta and gamma and low toxicity alpha emitters, or 0.1 microcurie/cm^2 (4 x 10^3 Bq/cm) all other alpha emitters; and

   C. The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 1.0 microcurie/cm^2 (4 x 10^4 Bq/cm^2) for beta and gamma and low toxicity alpha emitters, or 0.1 microcurie/cm^2 (4 x 10^3 Bq/cm^2) all other alpha emitters.

2. **SCO-II**: A solid object on which the limits for SCO-1 are exceeded and on which:

   A. The non-fixed contamination on the accessible surface averaged over 300 cm^2 (or the area of the surface if less than 300 cm^2) does not exceed 10^{-2} microcurie/cm^2 (400 Bq/cm^2) for beta and gamma and low toxicity alpha emitters, or 10^{-3} microcurie/cm^2 (40 Bq/cm^2) for all other alpha emitters;

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B. The fixed contamination on the accessible surface averaged over 300 cm² (or the area of the surface if less than 300 cm²) does not exceed 20 microcurie/cm² (8 x 10^5 Bq/cm²) for beta and gamma and low toxicity alpha emitters, or 2 microcurie/cm² (8 x 10^4 Bq/cm²) for all other alpha emitters; and

~~RH-3100. (Cont'd)~~

C. The non-fixed contamination plus the fixed contamination on the inaccessible surface averaged over 300 cm² (or the area of the surface if less than 300 cm²) does not exceed 20 microcurie/cm² (8 x 10^5 Bq/cm²) for beta and gamma and low toxicity alpha emitters, or 2 microcurie/cm² (8 x 10^4 Bq/cm²) for all other alpha emitters.

Transport index - The dimensionless number (rounded up to the next tenth) placed on the label of a package, to designate the degree of control to be exercised by the carrier during transportation. ~~-~~(The transport index is the number determined by multiplying the maximum radiation level in millisievert (mSv) per hour at one (1) meter (3.3 ft) from the external surface of the package by 100 (equivalent to the maximum radiation level in millirem per hour at one (1) meter (3.3 ft)).

Tribal official - The highest ranking individual that represents Tribal leadership, such as the Chief, President, or Tribal Council leadership.

Type A quantity - A quantity of radioactive material, the aggregate radioactivity of which does not exceed A_1 for special form radioactive material or A_2 for normal form radioactive material, where A_1 and A_2 are given in Table A-1 of Appendix A to this Section or may be determined by procedures described in Appendix A to this Section.

Type B quantity - A quantity of radioactive material greater than a Type A quantity.

Unirradiated uranium - Uranium containing not more than 2 x 10^3 Bq of plutonium per gram of uranium-235, not more than 9 x 10^6 Bq of fission products per gram of uranium-235, and not more than 5 x 10^{-3} g of uranium-236 per gram of uranium-235.

Uranium - natural, depleted, enriched.

1. **Natural uranium** - Uranium (which may be chemically separated) with the naturally occurring distribution of uranium isotopes (approximately

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0.711 weight percent uranium-235 and the remainder by weight essentially uranium-238).

2. **Depleted uranium** - Uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.

3. **Enriched uranium** - Uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.

RH-3101.- RH-3199.– _Reserved.

PART C.
EXEMPTIONS

RH-3200. **Specific Exemptions**.

The Department may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the rules in this Section as it determines are authorized by law and will not result in undue hazard to public health and safety or property, and are otherwise in the public interest.

RH-3201. **Exemption of Physicians**.

Any physician, as defined in RH-200., licensed by the State of Arkansas to dispense drugs in the practice of medicine is exempt from RH-3005. with respect to transport by the physician of licensed material for use in the practice of medicine. -However, any physician operating under this exemption must be licensed by the Department under Section 9 of these Rules, U.S. Nuclear Regulatory Commission's 10 CFR Part 35 regulations or the equivalent Agreement State regulations.

RH-3202. **Exemption for Low-Level Radioactive Materials**.

A licensee is exempt from all the requirements of this Section with respect to shipment or carriage of the following low-level materials:

a. Natural material and ores containing naturally occurring radionuclides that are either in their natural state, or have only been processed for purposes other than for the extraction of the radionuclides, and which are not intended to be processed for use of these radionuclides, provided the activity concentration of the material does not exceed ten (10) times the applicable radionuclide activity concentration values specified in Table A-2 or Table A-3 of Appendix A to Section 4.

b. Materials for which the activity concentration is not greater than the activity concentration values specified in Table A-2 or Table A-3 of Appendix A to Section 4, or for which the consignment activity is not greater than the limit for an exempt consignment found in Table A-2 or Table A-3 of Appendix A to Section 4.

c. Non-radioactive solid objects with radioactive substances present on any surfaces in quantities not in excess of the levels cited in the definition of contamination in RH-3100.

RH-3203. **Exemption from Classification as Fissile Material**.

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Fissile material meeting the requirements of at least one of the paragraphs a. through f. of this section are exempt from classification as fissile material and from the fissile material package standards of 10 CFR 71.55 and 71.59, but are subject to all other requirements of this Section, except as noted.

a. Individual package containing two (2) grams or less fissile material.

b. Individual or bulk packaging containing 15 grams or less of fissile material provided the package has at least 200 grams of solid nonfissile material for every gram of fissile material. Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but must not be included in determining the required mass for solid nonfissile material.

c. 1. Low concentrations of solid fissile material commingled with solid nonfissile material, provided that:

A. There is at least 2000 grams of solid nonfissile material for every gram of fissile material, and

B. There is no more than 180 grams of fissile material distributed within 360 kg of contiguous nonfissile material.

2. Lead, beryllium, graphite, and hydrogenous material enriched in deuterium may be present in the package but must not be included in determining the required mass of solid nonfissile material.

d. Uranium enriched in uranium-235 to a maximum of one percent (1%) by weight, and with total plutonium and uranium-233 content of up to one percent (1%) of the mass of uranium-235, provided that the mass of any beryllium, graphite, and hydrogenous material enriched in deuterium constitutes less than five percent (5%) of the uranium mass, and that the fissile material is distributed homogenously and does not form a lattice arrangement within the package.

e. Liquid solutions of uranyl nitrate enriched in uranium-235 to a maximum of two percent (2%) by mass, with a total plutonium and uranium-233 content not exceeding 0.002 percent of the mass of uranium, and with a minimum nitrogen to uranium atomic ratio (N/U) of two (2). The material must be contained in at least a DOT Type A package.

~~RH-3203. (Cont'd)~~

f. Packages containing, individually, a total plutonium mass of not more than 1000 grams, of which not more than twenty percent (20%) by mass may

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consist of plutonium-239, plutonium-241, or any combination of these radionuclides.

RH-3204.- RH-3299.– _Reserved.

PART D.
GENERAL LICENSES

RH-3300. Reserved.

RH-3301. **General License for NRC-Approved Packages**.

a. A general license is hereby issued to any licensee of the Department to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, Certificate of Compliance (CoC), or other approval has been issued by the U.S. Nuclear Regulatory Commission.

b. This general license applies only to a licensee who has a quality assurance program approved by the Department as satisfying the provisions of Part G of this Section.

c. Each licensee issued a general license under paragraph a. of this section shall:

1. Maintain a copy of the CoC, or other approval of the package, and the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken before shipment;

2. Comply with the terms and conditions of the license, certificate, or other approval, as applicable, and the applicable requirements of Parts A, F, and G of this Section;

3. Submit in writing before the first use of the package to the U.S. Nuclear Regulatory Commission:- ATTN:- Document Control Desk, Director, Division of Fuel Management, Office of Nuclear Material Safety and Safeguards, using an appropriate method listed in 10 CFR 71.1(a), the licensee's name and license number and the package identification number specified in the package approval.

d. This general license applies only when the package approval authorizes use of the package under this general license.

e. For a Type B or fissile material package, the design of which was approved by the U.S. Nuclear Regulatory Commission before April 1, 1996, the general license is subject to the additional restrictions of 10 CFR 71.19.

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RH-3303. Reserved.

RH-3304. **General License for Use of Foreign Approved Package**.

a. A general license is hereby issued to any licensee of the Department to transport, or to deliver to a carrier for transport, licensed material in a package, the design of which has been approved in a foreign national competent authority certificate, that has been revalidated by the U.S. Department of Transportation as meeting the applicable requirements of 49 CFR 171.23.

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b. Except as otherwise provided in this section, the general license applies only to a licensee who has a quality assurance program approved by the Department as satisfying the applicable provisions of Part G of this Section.

c. This general license applies only to shipments made to or from locations outside the United States.

d. Each licensee issued a general license under paragraph a. of this section shall:

1. Maintain a copy of the applicable certificate, the revalidation, and the drawings and other documents referenced in the certificate, relating to the use and maintenance of the packaging and to the actions to be taken before shipment; and

2. Comply with the terms and conditions of the certificate and revalidation, and with the applicable requirements of Parts A, F, and G of this Section.

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RH-3305. **General License: Fissile Material**.

a. A general license is issued to any licensee of the Department to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped in accordance with this section. The fissile material need not be contained in a package which meets the standards of Part E of this Section and 10 CFR Part 71, Subparts E and F; however, the material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 49 CFR 173.417(a).

b. The general license applies only to a licensee who has a quality assurance program approved by the Department as satisfying the provisions of Part G of this Section.

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c. The general license applies only when a package's contents:

~~RH-3305.e. (Cont'd)~~

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1. Contain no more than a Type A quantity of radioactive material; and

2. Contain less than 500 total grams of beryllium, graphite, or hydrogenous material enriched in deuterium.

d. The general license applies only to packages containing fissile material that are labeled with a CSI which:

1. Has been determined in accordance with paragraph (e) of this section;

2. Has a value less than or equal to 10; and

3. For a shipment of multiple packages containing fissile material, the sum of the CSIs must be less than or equal to 50 (for shipment on a nonexclusive use conveyance) and less than or equal to 100 (for shipment on an exclusive use conveyance).

e. 1. The value for the CSI must be greater than or equal to the number calculated by the following equation:

$$CSI = 10 \left[\frac{\text{grams of } ^{235}U}{X} + \frac{\text{grams of } ^{233}U}{Y} + \frac{\text{grams of Pu}}{Z} \right]$$

2. The calculated CSI must be rounded up to the first decimal place;

3. The values of X, Y, and Z used in the CSI equation must be taken from Tables 71-1 or 71-2, as appropriate;

4. If Table 71-2 is used to obtain the value of X, then the values for the terms in the equation for uranium-233 and plutonium must be assumed to be zero; and

5. Table 71-1 values for X, Y, and Z must be used to determine the CSI if:

A. Uranium-233 is present in the package;

B. The mass of plutonium exceeds one percent (1%) of the mass of uranium-235;

C. The uranium is of unknown uranium-235 enrichment or greater than 24 weight percent enrichment; or

~~RH-3305.e. (Cont'd)~~

D. Substances having a moderating effectiveness (i.e., an average hydrogen density greater than H_2O) (e.g., certain hydrocarbon oils or plastics) are present in any form, except as polyethylene used for packing or wrapping.

Table 71-1. — Mass Limits for General License Packages Containing Mixed Quantities of Fissile Material or Uranium-235 of Unknown Enrichment per RH-3305.e.

Fissile material	Fissile material mass mixed with moderating substances having an average hydrogen density less than or equal to H_2O (grams)	Fissile material mass mixed with moderating substances having an average hydrogen density greater than H_2O[a] (grams)
^{235}U (X)	60	38
^{233}U (Y)	43	27
^{239}Pu or ^{241}Pu (Z)	37	24

[a] When mixtures of moderating substances are present, the lower mass limits shall be used if more than fifteen percent (15%) of the moderating substance has an average hydrogen density greater than H_2O.

~~RH-3305. (Cont'd)~~

Table 71-2. — Mass Limits for General License Packages Containing Uranium-235 of Known Enrichment per RH-3305.e.

Uranium enrichment in weight percent of ^{235}U not exceeding	Fissile material mass of ^{235}U (X) (grams)
24	60
20	63
15	67
11	72
10	76
9.5	78
9	81
8.5	82
8	85
7.5	88
7	90
6.5	93
6	97
5.5	102
5	108
4.5	114
4	120
3.5	132
3	150
2.5	180
2	246
1.5	408
1.35	480
1	1,020
0.92	1,800

RH-3306. **General license:- Plutonium-Beryllium Special Form Material**.

a. A general license is issued to any licensee of the Department to transport fissile material in the form of plutonium-beryllium (Pu-Be) special form sealed sources, or to deliver Pu-Be sealed sources to a carrier for transport, if the material is shipped in accordance with this section.- This material need not be contained in a package which meets the standards of Part E of this Section and 10 CFR Part 71, Subparts E and F; however, the material must be contained in a Type A package. -The Type A package must also meet the DOT requirements of 49 CFR 173.417(a).

b. The general license applies only to a licensee who has a quality assurance program approved by the Department as satisfying the provisions of Part G of this Section.

c. The general license applies only when a package's contents:

1. Contain no more than a Type A quantity of radioactive material; and

2. Contain less than 1000 g of plutonium, provided that: plutonium-239, plutonium-241, or any combination of these radionuclides, constitutes less than 240 g of the total quantity of plutonium in the package.

d. The general license applies only to packages labeled with a CSI which:

1. Has been determined in accordance with paragraph (e) of this section;

2. Has a value less than or equal to 100; and

3. For a shipment of multiple packages containing Pu-Be sealed sources, the sum of the CSIs must be less than or equal to 50 (for shipment on a nonexclusive use conveyance) and less than or equal to 100 (for shipment on an exclusive use conveyance).

e. 1. The value for the CSI must be greater than or equal to the number calculated by the following equation:

$$CSI = 10 \left[\frac{\text{grams of } {}^{239}\text{Pu} + \text{grams of } {}^{241}\text{Pu}}{24} \right]$$; and

2. The calculated CSI must be rounded up to the first decimal place.

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RH-3307.- RH-3399.– _Reserved.

PART E.
PACKAGE APPROVAL STANDARDS

RH- 3400. **External Radiation Standards for All Packages**.

a. Except as provided in RH-3400.b., each package of radioactive materials offered for transportation must be designed and prepared for shipment so that under conditions normally incident to transportation the radiation level does not exceed 2 mSv/h (200 mrem/h) at any point on the external surface of the package, and the transport index does not exceed 10.

b. A package that exceeds the radiation level limits specified in RH-3400.a. must be transported by exclusive use shipment only, and the radiation levels for such shipment must not exceed the following during transportation:

1. 2 mSv/h (200 mrem/h) on the external surface of the package, unless the following conditions are met, in which case the limit is 10 mSv/h (1000 mrem/h):

   A. The shipment is made in a closed transport vehicle;

   B. The package is secured within the vehicle so that its position remains fixed during transportation; and

   C. There are no loading or unloading operations between the beginning and end of the transportation;

2. 2 mSv/h (200 mrem/h) at any point on the outer surface of the vehicle, including the top and underside of the vehicle; or in the case of a flat-bed style vehicle, at any point on the vertical planes projected from the outer edges of the vehicle, on the upper surface of the load or enclosure, if used, and on the lower external surface of the vehicle; and

3. 0.1 mSv/h (10 mrem/h) at any point 2 meters (80 in) from the outer lateral surfaces of the vehicle (excluding the top and underside of the vehicle); or in the case of a flat-bed style vehicle, at any point 2 meters (6.6 feet) from the vertical planes projected by the outer edges of the vehicle (excluding the top and underside of the vehicle); and

4. 0.02 mSv/h (2 mrem/h) in any normally occupied space, except that this provision does not apply to private carriers, if exposed personnel under their control wear radiation dosimetry devices in conformance with RH-1302.

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~~RH-3400. (Cont'd)~~

c. For shipments made under the provisions of RH-3400.b., the shipper shall provide specific written instructions to the carrier for maintenance of the exclusive use shipment controls. The instructions must be included with the shipping paper information.

d. The written instructions required for exclusive use shipments must be sufficient so that, when followed, they will cause the carrier to avoid actions that will unnecessarily delay delivery or unnecessarily result in increased radiation levels or radiation exposures to transport workers or members of the general public.

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RH-3401.- RH-3499. Reserved.

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PART F.
OPERATING CONTROLS AND PROCEDURES

RH-3500. **Applicability of Operating Controls and Procedures**.

A licensee subject to this Section, who, under a general or specific license, transports licensed material or delivers licensed material to a carrier for transport, shall comply with the requirements of this Part F, with the quality assurance requirements of Part G of this Section, and with the general provisions of Part A of this Section.

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RH-3501. **Assumptions as to Unknown Properties**.

When the isotopic abundance, mass, concentration, degree of irradiation, degree of moderation, or other pertinent property of fissile material in any package is not known, the licensee shall package the fissile material as if the unknown properties have credible values that will cause the maximum neutron multiplication.

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RH-3502. **Preliminary Determinations**.

Before the first use of any packaging for the shipment of licensed material, the licensee shall ascertain that the determinations in paragraphs (a) through (c) of 10 CFR 71.85 have been made.

RH-3503. **Routine Determinations**.

Prior to each shipment of licensed material, the licensee shall ensure that the package with its contents satisfies the applicable requirements of this Section and the license. The licensee shall determine that:

a. The package is proper for the contents to be shipped;

b. The package is in unimpaired physical condition except for superficial defects such as marks or dents;

c. Each closure device of the packaging, including any required gasket, is properly installed, secured, and free of defects;

d. Any system for containing liquid is adequately sealed and has adequate space or other specified provision for expansion of the liquid;

~~RH-3503. (Cont'd)~~

e. Any pressure relief device is operable and set in accordance with written procedures;

f. The package has been loaded and closed in accordance with written procedures;

g. For fissile material, any moderator or neutron absorber, if required, is present and in proper condition;

h. Any structural part of the package that could be used to lift or tie down the package during transport is rendered inoperable for that purpose unless it satisfies design requirements of 10 CFR 71.45.

i. The level of non-fixed (removable) radioactive contamination on the external surfaces of each package offered for shipment is as low as reasonably achievable, and within the limits specified in DOT regulations in 49 CFR 173.443;

j. External radiation levels around the package and around the vehicle, if applicable, will not exceed the limits specified in RH-3400 at any time during transportation; and

k. Accessible package surface temperatures will not exceed the limits specified in 10 CFR 71.43(g) at any time during transportation.

RH-3504. **Air Transport of Plutonium**.

a. Notwithstanding the provisions of any general licenses and notwithstanding any exemptions stated directly in this Section or included indirectly by citation of the U.S. Department of Transportation regulations (49 CFR Chapter 1), as may be applicable, the licensee shall assure that plutonium in any form, whether for import, export, or domestic shipment, is not transported by air, or delivered to a carrier for air transport, unless:

1. The plutonium is contained in a medical device designed for individual human application; or

2. The plutonium is contained in a material in which the specific activity is less than or equal to the activity concentration values for plutonium specified in Table A-2 of Appendix A to this Section, and in which the radioactivity is essentially uniformly distributed; or

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~~RH-3504.a. (Cont'd)~~

3. The plutonium is shipped in a single package containing no more than an A_2 quantity of plutonium in any isotope or form and is shipped in accordance with RH-3005.; or

4. The plutonium is shipped in a package specifically authorized for the shipment of plutonium by air in the Certificate of Compliance for that package issued by the U.S. Nuclear Regulatory Commission.

b. Nothing in RH-3504.a. is to be interpreted as removing or diminishing the requirements of the physical protection of plants where special nuclear materials are used as described in 10 CFR Part 73.24, "Prohibitions."

c. For a shipment of plutonium by air which is subject to RH-3504.a.4., the licensee shall, through special arrangement with the carrier, require compliance with 49 CFR 175.704, U.S. Department of Transportation regulations applicable to the air transport of plutonium.

RH-3505. **Opening Instructions**.

Before delivery of a package to a carrier for transport, the licensee shall ensure that any special instructions needed to safely open the package have been sent to, or otherwise made available to, the consignee for the consignee's use in accordance with RH-1307.f.

RH-3506. **Records**.

a. Each licensee shall maintain, for a period of three (3) years after shipment, a record of each shipment of licensed material not exempt under 10 CFR 71.14, showing where applicable:

1. Identification of the packaging by model number and serial number;

2. Verification that there were no significant defects in the packaging, as shipped;

3. Volume and identification of coolant;

4. Type and quantity of licensed material in each package, and the total quantity of each shipment;

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~~RH-3506.a. (Cont'd)~~

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5. For each item of irradiated fissile material:

   A. Identification by model number and serial number;

   B. Irradiation and decay history to the extent appropriate to demonstrate that its nuclear and thermal characteristics comply with license conditions; and

   C. Any abnormal or unusual condition relevant to radiation safety;

6. Date of the shipment;

7. For fissile packages and for Type B packages, any special controls exercised;

8. Name and address of the transferee;

9. Address to which the shipment was made; and

10. Results of the determinations required by RH-3503. and by the conditions of the package approval.

b. The licensee shall make available to the Department for inspection, upon reasonable notice, all records required by this Section. Records are only valid if stamped, initialed, or signed and dated by authorized personnel, or otherwise authenticated.

c. The licensee shall maintain sufficient written records to furnish evidence of the quality of packaging. The records to be maintained include results of the determinations required by RH-3502.; design, fabrication, and assembly records; results of reviews, inspections, tests, and audits; results of monitoring work performance and materials analyses; and results of maintenance, modification, and repair activities. Inspection, test, and audit records must identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted. These records must be retained for three (3) years after the life of the packaging to which they apply.

RH-3507. **Inspection and Tests**.

a. Each licensee shall afford to the Department, at all reasonable times, opportunity to inspect the licensed material, packaging, premises, and

facilities wherein such licensed material or packaging is used, provided, stored, or shipped.

b. Upon instruction from the Department, each licensee shall perform or cause to have performed and shall permit the Department to perform, such reasonable tests as the Department deems appropriate or necessary for the administration of these Rules.

RH-3508. **Reports**.

a. Each licensee shall submit a written report to the Department of:

1. Any instance in which there is a significant reduction in the effectiveness of any packaging during use;

2. Details of any defects with safety significance in any packaging, after first use; or

3. Any instance in which the conditions of approval in the Certificate of Compliance were not observed in making a shipment.

b. Each licensee shall submit, in accordance with RH-3003., the written report required by paragraph a. of this section within sixty (60) days of the event or discovery of the event. The licensee shall also provide a copy of each report submitted to the Department to the applicable certificate holder. Written reports prepared under other rules may be submitted to fulfill this requirement if the reports contain all the necessary information.

The written report must include the following:

1. A brief abstract describing the major occurrences during the event, including all component or system failures that contributed to the event and significant corrective action taken or planned to prevent recurrence.

2. A clear, specific, narrative description of the event that occurred so that knowledgeable readers conversant with the requirements of Section 4 and 10 CFR Part 71, but not familiar with the design of the packaging, can understand the complete event. The narrative description must include the following specific information as appropriate for the particular event.

~~RH-3508.b.2. (Cont'd)~~

A. Status of components or systems that were inoperable at the start of the event and that contributed to the event;

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B. Dates and approximate times of occurrences;

C. The cause of each component or system failure or personnel error, if known;

D. The failure mode, mechanism, and effect of each failed component, if known;

E. A list of systems or secondary functions that were also affected for failures of components with multiple functions;

F. The method of discovery of each component or system failure or procedural error;

G. For each human performance-related root cause, a discussion of the cause(s) and circumstances;

H. The manufacturer and model number (or other identification) of each component that failed during the event; and

I. For events occurring during use of a packaging, the quantities and chemical and physical form(s) of the package contents.

3. An assessment of the safety consequences and implications of the event. ~~-~~This assessment must include the availability of other systems or components that could have performed the same function as the components and systems that failed during the event.

4. A description of any corrective actions planned as a result of the event, including the means employed to repair any defects, and actions taken to reduce the probability of similar events occurring in the future.

5. Reference to any previous similar events involving the same packaging that are known to the licensee.

~~RH-3508.b. (Cont'd)~~

6. The name and telephone number of a person within the licensee's organization who is knowledgeable about the event and can provide additional information.

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7. The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

c. **Report legibility**.

The reports submitted by licensees under this section must be of sufficient quality to permit reproduction and micrographic processing.

RH-3509. **Advance Notification of Shipment of Irradiated Reactor Fuel and Nuclear Waste**.

a. 1. As specified in paragraphs b., c., and d. of this section, each licensee shall provide advance notification to the governor of a State, or the governor's designee, of the shipment of licensed material, within or across the boundary of the State, before the transport, or delivery to a carrier, for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.

2. As specified in paragraphs b., c., and d. of this section, after June 11, 2013, each licensee shall provide advance notification to the Tribal official of participating Tribes referenced in paragraph c.3.C of this section, or the official's designee, of the shipment of licensed material, within or across the boundary of the Tribe's reservation, before the transport, or delivery to a carrier, for transport, of licensed material outside the confines of the licensee's plant or other place of use or storage.

b. Advance notification is also required under this section for the shipment of licensed material, other than irradiated fuel, meeting the following three conditions:

1. The licensed material is required by this Section to be in Type B packaging for transportation;

2. The licensed material is being transported to or across a State boundary en route to a disposal facility or to a collection point for transport to a disposal facility; and

~~RH-3509. (Cont'd)~~

3. The quantity of licensed material in a single package exceeds the least of the following:

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A. 3000 times the A_1 value of the radionuclides as specified in Table A-1 of Appendix A to Section 4 for special form radioactive material;

B. 3000 times the A_2 value of the radionuclides as specified in Table A-1 of Appendix A to Section 4 for normal form radioactive material; or

C. 1000 TBq (27,000 Ci).

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c. **Procedures for submitting advance notification**.

1. The notification must be made in writing to:

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A. The office of each appropriate governor or governor's designee;

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B. The office of each appropriate Tribal official or Tribal official's designee; and

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C. The Director, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission.

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2. A notification delivered by mail must be postmarked at least seven (7) days before the beginning of the seven (7) day period during which departure of the shipment is estimated to occur.

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3. A notification delivered by any other means than mail must reach the office of the governor or of the governor's designee or the Tribal official or Tribal official's designee at least four (4) days before the beginning of the seven (7) day period during which departure of the shipment is estimated to occur.

A. Reserved.

B. Contact information for each State, including telephone and mailing addresses of governors and governors' designees, and participating Tribes, including telephone and mailing addresses of Tribal officials and Tribal officials' designees, is available on the U.S. Nuclear Regulatory Commission website at https://scp.nrc.gov/special/designee.pdf.

~~RH-3509.c.3. (Cont'd)~~

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C. A list of the names and mailing addresses of the governors' designees and Tribal officials' designees of participating Tribes is available on request from the Director, Division of

Materials Safety, Security, State, and Tribal Programs, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

4. The licensee shall retain a copy of the notification as a record for three (3) years.

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d. **Information to be furnished in advance notification of shipment**.

Each advance notification of shipment of irradiated reactor fuel or nuclear waste must contain the following information:

1. The name, address, and telephone number of the shipper, carrier, and receiver of the irradiated reactor fuel or nuclear waste shipment;

2. A description of the irradiated reactor fuel or nuclear waste shipment, as specified in the regulations of the U.S. Department of Transportation in 49 CFR 172.202 and 172.203(d);

3. The point of origin of the shipment and the seven (7) day period during which departure of the shipment is estimated to occur;

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4. The seven (7) day period during which arrival of the shipment at State boundaries or Tribal reservation boundaries is estimated to occur;

5. The destination of the shipment, and the seven (7) day period during which arrival of the shipment is estimated to occur; and

6. A point of contact, with a telephone number, for current shipment information.

~~RH 3509.d. (Cont'd)~~

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e. **Revision notice**.

A licensee who finds that schedule information previously furnished to a governor or governor's designee or a Tribal official or Tribal official's designee, in accordance with this section, will not be met, shall telephone a responsible individual in the office of the governor of the State or of the governor's designee or the Tribal official or the Tribal official's designee

and inform that individual of the extent of the delay beyond the schedule originally reported. -The licensee shall maintain a record of the name of the individual contacted for three (3) years.

f. **Cancellation notice**.

1. Each licensee who cancels an irradiated reactor fuel or nuclear waste shipment for which advance notification has been sent shall send a cancellation notice to the governor of each State or to the governor's designee previously notified, each Tribal official or to the Tribal official's designee previously notified, and the Director, Office of Nuclear Security and Incident Response, U.S. Nuclear Regulatory Commission.

2. The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being canceled.- The licensee shall retain a copy of the notice as a record for three (3) years.

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RH-3510.- RH-3599. _–Reserved.

PART G.
QUALITY ASSURANCE

RH-3600. **Quality Assurance Requirements**.

a. **Purpose**.

This Part, in conjunction with Subpart H of 10 CFR Part 71, describes quality assurance requirements applying to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety. As used in this Part and Subpart H of 10 CFR Part 71, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements. Each certificate holder and applicant for a package approval, entities governed by the U.S. Nuclear Regulatory Commission, is responsible for satisfying the quality assurance requirements in Subpart H of 10 CFR Part 71 that apply to design, fabrication, testing, and modification of packaging. Each Department licensee is responsible for satisfying the quality assurance requirements that apply to its use of a packaging for the shipment of licensed material subject to this Part.

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b. **Establishment of program**.

Each licensee shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of this Part and satisfying any specific provisions that are applicable to the licensee's activities including procurement of packaging. The licensee shall execute the applicable criteria in a graded approach to an extent that is commensurate with the quality assurance requirement's importance to safety.

c. **Approval of program**.

Before the use of any package for the shipment of licensed material subject to this Part, each licensee shall obtain Department approval of its quality assurance program. Each licensee shall submit to the Department a description of its quality assurance program, including a discussion of

which requirements of this Part are applicable and how they will be satisfied.

~~RH-3600. (Cont'd)~~

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d. **Radiography containers**.

A program for transport container inspection and maintenance limited to radiographic exposure devices, source changers, or packages transporting these devices and meeting the requirements of RH-1801.i.2. or equivalent U.S. Nuclear Regulatory Commission or Agreement State requirement, is deemed to satisfy the requirements of RH-3301.b. and RH-3600.b.

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RH-3601. **Quality Assurance Organization**.

a. The licensee shall be responsible for the establishment and execution of the quality assurance program. The licensee may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of the quality assurance program, but shall retain responsibility for the program. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions.

b. The quality assurance functions are:

1. Assuring that an appropriate quality assurance program is established and effectively executed; and

2. Verifying, by procedures such as checking, auditing, and inspection, that activities affecting the functions that are important to safety have been correctly performed.

c. The persons and organizations performing quality assurance functions must have sufficient authority and organizational freedom to:

1. Identify quality problems;

2. Initiate, recommend, or provide solutions; and

3. Verify implementation of solutions.

d. The persons and organizations performing quality assurance functions shall report to a management level that assures that the required authority and organizational freedom, including sufficient independence from cost and schedule, when opposed to safety considerations, are provided.

~~RH-3601. (Cont'd)~~

e. Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance program may take various forms, provided that the persons and organizations assigned the quality assurance functions have the required authority and organizational freedom.

f. Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program, at any location where activities subject to this section are being performed, must have direct access to the levels of management necessary to perform this function.

RH-3602. **Quality Assurance Program**.

a. The licensee shall establish, at the earliest practicable time consistent with the schedule for accomplishing the activities, a quality assurance program that complies with this Part. The licensee shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which the packaging is used. The licensee shall identify the material and components to be covered by the quality assurance program, the major organizations participating in the program, and the designated functions of these organizations.

b. The licensee through its quality assurance program, shall provide control over activities affecting the quality of the identified materials and components to an extent consistent with their importance to safety, and as necessary to assure conformance to the approved design of each individual package used for the shipment of radioactive material. The licensee shall assure that activities affecting quality are accomplished under suitably controlled conditions.

Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanliness; and assurance that all prerequisites for the given activity have been satisfied. The licensee, certificate holder, and applicant for a Certificate of Compliance (CoC) shall take into account, as applicable, the need for special controls, processes, test equipment, tools, and skills to

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attain the required quality, and the need for verification of quality by inspection and test.

RH-3602. ~~(Cont'd)~~

c. The licensee, certificate holder, and applicant for a CoC shall base the requirements and procedures of their respective quality assurance programs on the following considerations, as applicable, concerning the complexity and proposed use of the package and its components:

1. The impact of malfunction or failure of the item to safety;

2. The design and fabrication complexity or uniqueness of the item;

3. The need for special controls and surveillance over processes and equipment;

4. The degree to which functional compliance can be demonstrated by inspection or test; and

5. The quality history and degree of standardization of the item.

d. The licensee shall provide for indoctrination and training of personnel performing activities affecting quality, as necessary to assure that suitable proficiency is achieved and maintained. The licensee shall review the status and adequacy of the quality assurance program at established intervals. Management of other organizations participating in the quality assurance program shall review regularly the status and adequacy of that part of the quality assurance program they are executing.

e. **Changes to quality assurance program.**

1. Each quality assurance program approval holder shall submit to the Department a description of a proposed change to its Department-approved quality assurance program that will reduce commitments in the program description as approved by the Department. The quality assurance program approval holder shall not implement the change before receiving Department approval.

A. The description of a proposed change to the Department-approved quality assurance program must identify the change, the reason for the change, and the basis for

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concluding that the revised program incorporating the change continues to satisfy the applicable requirements of this Part.

B. Reserved.

~~RH-3602.e. (Cont'd)~~

2. Each quality assurance program approval holder may change a previously approved quality assurance program without prior Department approval, if the change does not reduce the commitments in the quality assurance program previously approved by the Department. Changes to the quality assurance program that do not reduce the commitments shall be submitted to the Department every 24 months. In addition to quality assurance program changes involving administrative improvements and clarifications, spelling corrections, and non-substantive changes to punctuation or editorial items, the following changes are not considered reductions in commitment:

A. The use of a quality assurance standard approved by the Department that is more recent than the quality assurance standard in the licensee's current quality assurance program at the time of the change;

B. The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles, provided that there is no substantive change to either the functions of the position or reporting responsibilities;

C. The use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or alternatively, the use of descriptive text, provided that there is no substantive change to the functional relationships, authorities, or responsibilities;

D. The elimination of quality assurance program information that duplicates language in quality assurance regulatory guides and quality assurance standards to which the quality assurance program approval holder has committed to on record; and

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E. Organizational revisions that ensure that persons and organizations performing quality assurance functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations.

3. Each quality assurance program approval holder shall maintain records of quality assurance program changes.

RH-3603. **Handling, Storage, and Shipping Control**.

The licensee shall establish measures to control, in accordance with instructions, the handling, storage, shipping, cleaning, and preservation of materials and equipment to be used in packaging to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, and specific moisture content and temperature levels must be specified and provided.

RH-3604. **Inspection, Test, and Operating Status**.

a. The licensee shall establish measures to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the packaging. These measures must provide for the identification of items that have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of the inspections and tests.

b. The licensee shall establish measures to identify the operating status of components of the packaging, such as tagging valves and switches, to prevent inadvertent operation.

RH-3605. **Nonconforming Materials, Parts, or Components**.

The licensee shall establish measures to control materials, parts, or components that do not conform to the licensee's requirements to prevent their inadvertent use or installation. These measures must include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items must be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.

RH-3606. **Corrective Action**.

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The licensee shall establish measures to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. In the case of a significant condition adverse to quality, the measures must assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken must be documented and reported to appropriate levels of management.

RH-3607. **Quality Assurance Records**.

The licensee shall maintain sufficient written records to describe the activities affecting quality. These records must include changes to the quality assurance program as required by RH-3602.e.; the instructions, procedures, and drawings required by 10 CFR 71.111 to prescribe quality assurance activities; and closely related specifications such as required qualifications of personnel, procedures, and equipment. The records must include the instructions or procedures that establish a records retention program that is consistent with applicable rules and designates factors such as duration, location, and assigned responsibility. The licensee shall retain these records for three (3) years beyond the date when the licensee last engages in the activity for which the quality assurance program was developed. If any portion of the quality assurance program, written procedures, or instructions is superseded, the licensee shall retain the superseded material for three (3) years after it is superseded.

RH-3608. **Audits**.

The licensee shall carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits must be performed in accordance with written procedures or checklists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audited results must be documented and reviewed by management having responsibility in the area audited. Follow-up action, including re-audit of deficient areas, must be taken where indicated.

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PART H.
ENFORCEMENT

RH-3700. **Violations.**

a. An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any rule or order issued thereunder. Any person who willfully violates any provision of the Act or any rule or order issued thereunder may be guilty of a felony, misdemeanor, or crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law. Arkansas Code Annotated §20-21-204 describes criminal and civil penalties which may be assessed.

b. **Impounding**.

Sources of radiation shall be subject to impounding pursuant to Section 5 of these Rules.

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APPENDIX A TO SECTION 4

DETERMINATION OF A_1 AND A_2

I. Values of A_1 and A_2 for individual radionuclides, which are the bases for many activity limits elsewhere in these Rules, are given in Table A-1. The curie (Ci) values specified are obtained by converting from the Terabecquerel (TBq) value. The Terabecquerel values are the regulatory standard. The curie values are for information only and are not intended to be the regulatory standard. Where values of A_1 and A_2 are unlimited, it is for radiation control purposes only. For nuclear criticality safety, some materials are subject to controls placed on fissile material.

II. a. For individual radionuclides whose identities are known, but which are not listed in Table A-1, the A_1 and A_2 values contained in Table A-3 may be used. Otherwise, the licensee shall obtain prior Department approval of the A_1 and A_2 values for radionuclides not listed in Table A-1, before shipping the material.

b. For individual radionuclides whose identities are known, but which are not listed in Table A-2, the exempt material activity concentration and exempt consignment activity values contained in Table A-3 may be used. Otherwise, the licensee shall obtain prior Department approval of the exempt material activity concentration and exempt consignment activity values for radionuclides not listed in Table A-2, before shipping the material.

c. The licensee shall submit requests for prior approval, described under paragraphs II.a. and II.b. of this Appendix, to the Department, in accordance with RH-3003.

III. In the calculations of A_1 and A_2 for a radionuclide not in Table A-1, a single radioactive decay chain, in which radionuclides are present in their naturally occurring proportions, and in which no daughter radionuclide has a half-life either longer than 10 days, or longer than that of the parent radionuclide, shall be considered as a single radionuclide, and the activity to be taken into account, and the A_1 or A_2 value to be applied, shall be those corresponding to the parent radionuclide of that chain. In the case of radioactive decay chains in which any daughter radionuclide has a half-life either longer than 10 days, or greater than that of the parent radionuclide, the parent and those daughter radionuclides shall be considered as mixtures of different radionuclides.

~~Appendix A to Section 4 (Cont'd)~~

IV. For mixtures of radionuclides whose identities and respective activities are known, the following conditions apply:

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a. For special form radioactive material, the maximum quantity transported in a Type A package is as follows:

$$\sum_i \frac{B(i)}{A_1(i)} \leq 1$$

where B(i) is the activity of radionuclide i in special form, and $A_1(i)$ is the A_1 value for radionuclide i.

b. For normal form radioactive material, the maximum quantity transported in a Type A package is as follows:

$$\sum_i \frac{B(i)}{A_2(i)} \leq 1$$

where B(i) is the activity of radionuclide i in normal form, and $A_2(i)$ is the A_2 value for radionuclide i.

c. If the package contains both special and normal form radioactive material, the activity that may be transported in a Type A package is as follows:

$$\sum_i \frac{B(i)}{A_1(i)} + \sum_j \frac{C(j)}{A_2(j)} \leq 1$$

where B(i) is the activity of radionuclide i as special form radioactive material, $A_1(i)$ is the A_1 value for radionuclide i, C(j) is the activity of radionuclide j as normal form radioactive material, and $A_2(j)$ is the A_2 value for radionuclide j.

d. Alternatively, the A_1 value for mixtures of special form material may be determined as follows:

$$A_1 \text{ for mixture} = \frac{1}{\sum_i \frac{f(i)}{A_1(i)}}$$

where f(i) is the fraction of activity for radionuclide i in the mixture, and $A_1(i)$ is the appropriate A_1 value for radionuclide i.

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e. Alternatively, the A_2 value for mixtures of normal form material may be determined as follows:

$$A_2 \text{ for mixture} = \frac{1}{\sum_i \frac{f(i)}{A_2(i)}}$$

where f(i) is the fraction of activity for radionuclide i in the mixture**,** and $A_2(i)$ is the appropriate A_2 value for radionuclide i.

f. The exempt activity concentration for mixtures of nuclides may be determined as follows:

$$\text{Exempt activity concentration for mixture} = \frac{1}{\sum_i \frac{f(i)}{[A](i)}}$$

where f(i) is the fraction of activity concentration of radionuclide i in the mixture, and [A](i) is the activity concentration for exempt material containing radionuclide i.

g. The activity limit for an exempt consignment for mixtures of radionuclides may be determined as follows:

$$\text{Exempt consignment activity limit for mixture} = \frac{1}{\sum_i \frac{f(i)}{A(i)}}$$

where f(i) is the fraction of activity of radionuclide i in the mixture, and A(i) is the activity limit for exempt consignments for radionuclide i.

V. a. When the identity of each radionuclide is known, but the individual activities of some of the radionuclides are not known, the radionuclides may be grouped and the lowest A_1 or A_2 value, as appropriate, for the radionuclides in each group may be used in applying the formulas in paragraph IV. of this Appendix. Groups may be based on the total alpha activity and the total beta/gamma activity when these are known, using the lowest A_1 or A_2 values for the alpha emitters and beta/gamma emitters, respectively.

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~~Appendix A to Section 4 (Cont'd)~~

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b. When the identity of each radionuclide is known, but the individual activities of some of the radionuclides are not known, the radionuclides may be grouped and the lowest [A] (activity concentration for exempt material) or A (activity limit for exempt consignment) value, as appropriate, for the radionuclides in each group may be used in applying the formulas in paragraph IV. of this Appendix. Groups may be based on the total alpha activity and the total beta/gamma activity when these are known, using the lowest [A] or A values for the alpha emitters and beta/gamma emitters, respectively.

TABLE A-1—A_1 AND A_2 VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A_1 (TBq)	A_1(Ci)[b]	A_2 (TBq)	A_2(Ci)[b]	Specific activity	
						(TBq/g)	(Ci/g)
Ac-225 (a)	Actinium (89)	$8.0X10^{-1}$	$2.2X10^{1}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$2.1X10^{3}$	$5.8X10^{4}$
Ac-227 (a)		$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-5}$	$2.4X10^{-3}$	2.7	$7.2X10^{1}$
Ac-228		$6.0X10^{-1}$	$1.6X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$8.4X10^{4}$	$2.2X10^{6}$
Ag-105	Silver (47)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$1.1X10^{3}$	$3.0X10^{4}$
Ag-108m (a)		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$9.7X10^{-1}$	$2.6X10^{1}$
Ag-110m (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.8X10^{2}$	$4.7X10^{3}$
Ag-111		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$5.8X10^{3}$	$1.6X10^{5}$
Al-26	Aluminum (13)	$1.0X10^{-1}$	2.7	$1.0X10^{-1}$	2.7	$7.0X10^{-4}$	$1.9X10^{-2}$
Am-241	Americium (95)	$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$1.3X10^{-1}$	3.4
Am-242m (a)		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.6X10^{-1}$	$1.0X10^{1}$
Am-243 (a)		5.0	$1.4X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$7.4X10^{-3}$	$2.0X10^{-1}$
Ar-37	Argon (18)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.7X10^{3}$	$9.9X10^{4}$
Ar-39		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{1}$	$5.4X10^{2}$	1.3	$3.4X10^{1}$
Ar-41		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.5X10^{6}$	$4.2X10^{7}$
As-72	Arsenic (33)	$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$6.2X10^{4}$	$1.7X10^{6}$
As-73		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$8.2X10^{2}$	$2.2X10^{4}$
As-74		1.0	$2.7X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$3.7X10^{3}$	$9.9X10^{4}$
As-76		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$5.8X10^{4}$	$1.6X10^{6}$
As-77		$2.0X10^{1}$	$5.4X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$3.9X10^{4}$	$1.0X10^{6}$
At-211 (a)	Astatine (85)	$2.0X10^{1}$	$5.4X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$7.6X10^{4}$	$2.1X10^{6}$
Au-193	Gold (79)	7.0	$1.9X10^{2}$	2.0	$5.4X10^{1}$	$3.4X10^{4}$	$9.2X10^{5}$
Au-194		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.5X10^{4}$	$4.1X10^{5}$
Au-195		$1.0X10^{1}$	$2.7X10^{2}$	6.0	$1.6X10^{2}$	$1.4X10^{2}$	$3.7X10^{3}$
Au-198		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$9.0X10^{3}$	$2.4X10^{5}$
Au-199		$1.0X10^{1}$	$2.7X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$7.7X10^{3}$	$2.1X10^{5}$
Ba-131 (a)	Barium (56)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$3.1X10^{3}$	$8.4X10^{4}$

Table A-1 of Appendix A to Section 4 (Cont'd)

Ba-133		3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	9.4	$2.6X10^{2}$
Ba-133m		$2.0X10^{1}$	$5.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.2X10^{4}$	$6.1X10^{5}$
Ba-140 (a)		$5.0X10^{-1}$	$1.4X10^{1}$	$3.0X10^{-1}$	8.1	$2.7X10^{3}$	$7.3X10^{4}$
Be-7	Beryllium (4)	$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{1}$	$5.4X10^{2}$	$1.3X10^{4}$	$3.5X10^{5}$
Be-10		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-1}$	$1.6X10^{1}$	$8.3X10^{-4}$	$2.2X10^{-2}$
Bi-205	Bismuth (83)	$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$1.5X10^{3}$	$4.2X10^{4}$
Bi-206		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$3.8X10^{3}$	$1.0X10^{5}$
Bi-207		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	1.9	$5.2X10^{1}$
Bi-210		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.6X10^{3}$	$1.2X10^{5}$
Bi-210m (a)		$6.0X10^{-1}$	$1.6X10^{1}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.1X10^{-5}$	$5.7X10^{-4}$
Bi-212 (a)		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$5.4X10^{5}$	$1.5X10^{7}$
Bk-247	Berkelium (97)	8.0	$2.2X10^{2}$	$8.0X10^{-4}$	$2.2X10^{-2}$	$3.8X10^{-2}$	1.0
Bk-249 (a)		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{-1}$	8.1	$6.1X10^{1}$	$1.6X10^{3}$
Br-76	Bromine (35)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$9.4X10^{4}$	$2.5X10^{6}$
Br-77		3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$2.6X10^{4}$	$7.1X10^{5}$
Br-82		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{4}$	$1.1X10^{6}$
C-11	Carbon (6)	1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.1X10^{7}$	$8.4X10^{8}$
C-14		$4.0X10^{1}$	$1.1X10^{3}$	3.0	$8.1X10^{1}$	$1.6X10^{-1}$	4.5
Ca-41	Calcium (20)	Unlimited	Unlimited	Unlimited	Unlimited	$3.1X10^{-3}$	$8.5X10^{-2}$
Ca-45		$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$6.6X10^{2}$	$1.8X10^{4}$
Ca-47 (a)		3.0	$8.1X10^{1}$	$3.0X10^{-1}$	8.1	$2.3X10^{4}$	$6.1X10^{5}$
Cd-109	Cadmium (48)	$3.0X10^{1}$	$8.1X10^{2}$	2.0	$5.4X10^{1}$	$9.6X10^{1}$	$2.6X10^{3}$
Cd-113m		$4.0X10^{1}$	$1.1X10^{3}$	$5.0X10^{-1}$	$1.4X10^{1}$	8.3	$2.2X10^{2}$
Cd-115 (a)		3.0	$8.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.9X10^{4}$	$5.1X10^{5}$
Cd-115m		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$9.4X10^{2}$	$2.5X10^{4}$
Ce-139	Cerium (58)	7.0	$1.9X10^{2}$	2.0	$5.4X10^{1}$	$2.5X10^{2}$	$6.8X10^{3}$
Ce-141		$2.0X10^{1}$	$5.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.1X10^{3}$	$2.8X10^{4}$
Ce-143		$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.5X10^{4}$	$6.6X10^{5}$
Ce-144 (a)		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$1.2X10^{2}$	$3.2X10^{3}$
Cf-248	Californium (98)	$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$5.8X10^{1}$	$1.6X10^{3}$
Cf-249		3.0	$8.1X10^{1}$	$8.0X10^{-4}$	$2.2X10^{-2}$	$1.5X10^{-1}$	4.1

Table A-1 of Appendix A to Section 4 (Cont'd)

Cf-250		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	4.0	$1.1X10^{2}$
Cf-251		7.0	$1.9X10^{2}$	$7.0X10^{-4}$	$1.9X10^{-2}$	$5.9X10^{-2}$	1.6
Cf-252		$1.0X10^{-1}$	2.7	$3.0X10^{-3}$	$8.1X10^{-2}$	$2.0X10^{1}$	$5.4X10^{2}$
Cf-253 (a)		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{-2}$	1.1	$1.1X10^{3}$	$2.9X10^{4}$
Cf-254		$1.0X10^{-3}$	$2.7X10^{-2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.1X10^{2}$	$8.5X10^{3}$
Cl-36	Chlorine (17)	$1.0X10^{1}$	$2.7X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.2X10^{-3}$	$3.3X10^{-2}$
Cl-38		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$4.9X10^{6}$	$1.3X10^{8}$
Cm-240	Curium (96)	$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$7.5X10^{2}$	$2.0X10^{4}$
Cm-241		2.0	$5.4X10^{1}$	1.0	$2.7X10^{1}$	$6.1X10^{2}$	$1.7X10^{4}$
Cm-242		$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{-2}$	$2.7X10^{-1}$	$1.2X10^{2}$	$3.3X10^{3}$
Cm-243		9.0	$2.4X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$1.9X10^{-3}$	$5.2X10^{1}$
Cm-244		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	3.0	$8.1X10^{1}$
Cm-245		9.0	$2.4X10^{2}$	$9.0X10^{-4}$	$2.4X10^{-2}$	$6.4X10^{-3}$	$1.7X10^{-1}$
Cm-246		9.0	$2.4X10^{2}$	$9.0X10^{-4}$	$2.4X10^{-2}$	$1.1X10^{-2}$	$3.1X10^{-1}$
Cm-247 (a)		3.0	$8.1X10^{1}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.4X10^{-6}$	$9.3X10^{-5}$
Cm-248		$2.0X10^{-2}$	$5.4X10^{-1}$	$3.0X10^{-4}$	$8.1X10^{-3}$	$1.6X10^{-4}$	$4.2X10^{-3}$
Co-55	Cobalt (27)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$1.1X10^{5}$	$3.1X10^{6}$
Co-56		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.1X10^{3}$	$3.0X10^{4}$
Co-57		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$3.1X10^{2}$	$8.4X10^{3}$
Co-58		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.2X10^{3}$	$3.2X10^{4}$
Co-58m		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$2.2X10^{5}$	$5.9X10^{6}$
Co-60		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.2X10^{1}$	$1.1X10^{3}$
Cr-51	Chromium (24)	$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{1}$	$8.1X10^{2}$	$3.4X10^{3}$	$9.2X10^{4}$
Cs-129	Cesium (55)	4.0	$1.1X10^{2}$	4.0	$1.1X10^{2}$	$2.8X10^{4}$	$7.6X10^{5}$
Cs-131		$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{1}$	$8.1X10^{2}$	$3.8X10^{3}$	$1.0X10^{5}$
Cs-132		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$5.7X10^{3}$	$1.5X10^{5}$
Cs-134		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$4.8X10^{1}$	$1.3X10^{3}$
Cs-134m		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.0X10^{5}$	$8.0X10^{6}$
Cs-135		$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$4.3X10^{-5}$	$1.2X10^{-3}$
Cs-136		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$2.7X10^{3}$	$7.3X10^{4}$
Cs-137 (a)		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	3.2	$8.7X10^{1}$
Cu-64	Copper (29)	6.0	$1.6X10^{2}$	1.0	$2.7X10^{1}$	$1.4X10^{5}$	$3.9X10^{6}$

Table A-1 of Appendix A to Section 4 (Cont'd)

Cu-67		$1.0X10^{1}$	$2.7X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$2.8X10^{4}$	$7.6X10^{5}$
Dy-159	Dysprosium (66)	$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{1}$	$5.4X10^{2}$	$2.1X10^{2}$	$5.7X10^{3}$
Dy-165		$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.0X10^{5}$	$8.2X10^{6}$
Dy-166 (a)		$9.0X10^{-1}$	$2.4X10^{1}$	$3.0X10^{-1}$	8.1	$8.6X10^{3}$	$2.3X10^{5}$
Er-169	Erbium (68)	$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$3.1X10^{3}$	$8.3X10^{4}$
Er-171		$8.0X10^{-1}$	$2.2X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$9.0X10^{4}$	$2.4X10^{6}$
Eu-147	Europium (63)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$1.4X10^{3}$	$3.7X10^{4}$
Eu-148		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.0X10^{2}$	$1.6X10^{4}$
Eu-149		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{1}$	$5.4X10^{2}$	$3.5X10^{2}$	$9.4X10^{3}$
Eu-150 (short lived)		2.0	$5.4X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$6.1X10^{4}$	$1.6X10^{6}$
Eu-150 (long lived)		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$6.1X10^{4}$	$1.6X10^{6}$
Eu-152		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	6.5	$1.8X10^{2}$
Eu-152m		$8.0X10^{-1}$	$2.2X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$8.2X10^{4}$	$2.2X10^{6}$
Eu-154		$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	9.8	$2.6X10^{2}$
Eu-155		$2.0X10^{1}$	$5.4X10^{2}$	3.0	$8.1X10^{1}$	$1.8X10^{1}$	$4.9X10^{2}$
Eu-156		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$2.0X10^{3}$	$5.5X10^{4}$
F-18	Fluorine (9)	1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.5X10^{6}$	$9.5X10^{7}$
Fe-52 (a)	Iron (26)	$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$2.7X10^{5}$	$7.3X10^{6}$
Fe-55		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$8.8X10^{1}$	$2.4X10^{3}$
Fe-59		$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$1.8X10^{3}$	$5.0X10^{4}$
Fe-60 (a)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-1}$	5.4	$7.4X10^{-4}$	$2.0X10^{-2}$
Ga-67	Gallium (31)	7.0	$1.9X10^{2}$	3.0	$8.1X10^{1}$	$2.2X10^{4}$	$6.0X10^{5}$
Ga-68		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$1.5X10^{6}$	$4.1X10^{7}$
Ga-72		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.1X10^{5}$	$3.1X10^{6}$
Gd-146 (a)	Gadolinium (64)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.9X10^{2}$	$1.9X10^{4}$
Gd-148		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	1.2	$3.2X10^{1}$
Gd-153		$1.0X10^{1}$	$2.7X10^{2}$	9.0	$2.4X10^{2}$	$1.3X10^{2}$	$3.5X10^{3}$
Gd-159		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.9X10^{4}$	$1.1X10^{6}$
Ge-68 (a)	Germanium (32)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$2.6X10^{2}$	$7.1X10^{3}$
Ge-71		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$5.8X10^{3}$	$1.6X10^{5}$
Ge-77		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.3X10^{5}$	$3.6X10^{6}$
Hf-172 (a)	Hafnium (72)	$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.1X10^{1}$	$1.1X10^{3}$

Table A-1 of Appendix A to Section 4 (Cont'd)

Hf-175		3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$3.9X10^{2}$	$1.1X10^{4}$
Hf-181		2.0	$5.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.3X10^{2}$	$1.7X10^{4}$
Hf-182		Unlimited	Unlimited	Unlimited	Unlimited	$8.1X10^{-6}$	$2.2X10^{-4}$
Hg-194 (a)	Mercury (80)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.3X10^{-1}$	3.5
Hg-195m (a)		3.0	$8.1X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$1.5X10^{4}$	$4.0X10^{5}$
Hg-197		$2.0X10^{1}$	$5.4X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$9.2X10^{3}$	$2.5X10^{5}$
Hg-197m		$1.0X10^{1}$	$2.7X10^{2}$	$4.0X10^{-1}$	$1.1X10^{1}$	$2.5X10^{4}$	$6.7X10^{5}$
Hg-203		5.0	$1.4X10^{2}$	1.0	$2.7X10^{1}$	$5.1X10^{2}$	$1.4X10^{4}$
Ho-166	Holmium (67)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$2.6X10^{4}$	$7.0X10^{5}$
Ho-166m		$6.0X10^{-1}$	$1.6X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.6X10^{-2}$	1.8
I-123	Iodine (53)	6.0	$1.6X10^{2}$	3.0	$8.1X10^{1}$	$7.1X10^{4}$	$1.9X10^{6}$
I-124		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$9.3X10^{3}$	$2.5X10^{5}$
I-125		$2.0X10^{1}$	$5.4X10^{2}$	3.0	$8.1X10^{1}$	$6.4X10^{2}$	$1.7X10^{4}$
I-126		2.0	$5.4X10^{1}$	1.0	$2.7X10^{1}$	$2.9X10^{3}$	$8.0X10^{4}$
I-129		Unlimited	Unlimited	Unlimited	Unlimited	$6.5X10^{-6}$	$1.8X10^{-4}$
I-131		3.0	$8.1X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$4.6X10^{3}$	$1.2X10^{5}$
I-132		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.8X10^{5}$	$1.0X10^{7}$
I-133		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.2X10^{4}$	$1.1X10^{6}$
I-134		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$9.9X10^{5}$	$2.7X10^{7}$
I-135 (a)		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.3X10^{5}$	$3.5X10^{6}$
In-111	Indium (49)	3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$1.5X10^{4}$	$4.2X10^{5}$
In-113m		4.0	$1.1X10^{2}$	2.0	$5.4X10^{1}$	$6.2X10^{5}$	$1.7X10^{7}$
In-114m (a)		$1.0X10^{1}$	$2.7X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$8.6X10^{2}$	$2.3X10^{4}$
In-115m		7.0	$1.9X10^{2}$	1.0	$2.7X10^{1}$	$2.2X10^{5}$	$6.1X10^{6}$
Ir-189 (a)	Iridium (77)	$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$1.9X10^{3}$	$5.2X10^{4}$
Ir-190		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$2.3X10^{3}$	$6.2X10^{4}$
Ir-192		[c]1.0	[c]$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.4X10^{2}$	$9.2X10^{3}$
Ir-194		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$3.1X10^{4}$	$8.4X10^{5}$
K-40	Potassium (19)	$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$2.4X10^{-7}$	$6.4X10^{-6}$
K-42		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$2.2X10^{5}$	$6.0X10^{6}$
K-43		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.2X10^{5}$	$3.3X10^{6}$

Table A-1 of Appendix A to Section 4 (Cont'd)

Kr-79	Krypton (36)	4.0	$1.1x10^{2}$	2.0	$5.4x10^{1}$	$4.2x10^{4}$	$1.1x10^{6}$
Kr-81		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$7.8X10^{-4}$	$2.1X10^{-2}$
Kr-85		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$1.5X10^{1}$	$3.9X10^{2}$
Kr-85m		8.0	$2.2X10^{2}$	3.0	$8.1X10^{1}$	$3.0X10^{5}$	$8.2X10^{6}$
Kr-87		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$1.0X10^{6}$	$2.8X10^{7}$
La-137	Lanthanum (57)	$3.0X10^{1}$	$8.1X10^{2}$	6.0	$1.6X10^{2}$	$1.6X10^{-3}$	$4.4X10^{-2}$
La-140		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$2.1X10^{4}$	$5.6X10^{5}$
Lu-172	Lutetium (71)	$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.2X10^{3}$	$1.1X10^{5}$
Lu-173		8.0	$2.2X10^{2}$	8.0	$2.2X10^{2}$	$5.6X10^{1}$	$1.5X10^{3}$
Lu-174		9.0	$2.4X10^{2}$	9.0	$2.4X10^{2}$	$2.3X10^{1}$	$6.2X10^{2}$
Lu-174m		$2.0X10^{1}$	$5.4X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$2.0X10^{2}$	$5.3X10^{3}$
Lu-177		$3.0X10^{1}$	$8.1X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$4.1X10^{3}$	$1.1X10^{5}$
Mg-28 (a)	Magnesium (12)	$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$2.0X10^{5}$	$5.4X10^{6}$
Mn-52	Manganese (25)	$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.6X10^{4}$	$4.4X10^{5}$
Mn-53		Unlimited	Unlimited	Unlimited	Unlimited	$6.8X10^{-5}$	$1.8X10^{-3}$
Mn-54		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$2.9X10^{2}$	$7.7X10^{3}$
Mn-56		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$8.0X10^{5}$	$2.2X10^{7}$
Mo-93	Molybdenum (42)	$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{1}$	$5.4X10^{2}$	$4.1X10^{-2}$	1.1
Mo-99 (a) (h)		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.8X10^{4}$	$4.8X10^{5}$
N-13	Nitrogen (7)	$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$5.4X10^{7}$	$1.5X10^{9}$
Na-22	Sodium (11)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$2.3X10^{2}$	$6.3X10^{3}$
Na-24		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$3.2X10^{5}$	$8.7X10^{6}$
Nb-93m	Niobium (41)	$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	8.8	$2.4X10^{2}$
Nb-94		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$6.9X10^{-3}$	$1.9X10^{-1}$
Nb-95		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.5X10^{3}$	$3.9X10^{4}$
Nb-97		$9.0X10^{-1}$	$2.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$9.9X10^{5}$	$2.7X10^{7}$
Nd-147	Neodymium (60)	6.0	$1.6X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.0X10^{3}$	$8.1X10^{4}$
Nd-149		$6.0X10^{-1}$	$1.6X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$4.5X10^{5}$	$1.2X10^{7}$
Ni-59	Nickel (28)	Unlimited	Unlimited	Unlimited	Unlimited	$3.0X10^{-3}$	$8.0X10^{-2}$
Ni-63		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	2.1	$5.7X10^{1}$
Ni-65		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$7.1X10^{5}$	$1.9X10^{7}$

Table A-1 of Appendix A to Section 4 (Cont'd)

Np-235	Neptunium (93)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$5.2X10^{1}$	$1.4X10^{3}$
Np-236 (short-lived)		$2.0X10^{1}$	$5.4X10^{2}$	2.0	$5.4X10^{1}$	$4.7X10^{-4}$	$1.3X10^{-2}$
Np-236 (long-lived)		$9.0X10^{0}$	$2.4X10^{2}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$4.7X10^{-4}$	$1.3X10^{-2}$
Np-237		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{-3}$	$5.4X10^{-2}$	$2.6X10^{-5}$	$7.1X10^{-4}$
Np-239		7.0	$1.9X10^{2}$	$4.0X10^{-1}$	$1.1X10^{1}$	$8.6X10^{3}$	$2.3X10^{5}$
Os-185	Osmium (76)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$2.8X10^{2}$	$7.5X10^{3}$
Os-191		$1.0X10^{1}$	$2.7X10^{2}$	2.0	$5.4X10^{1}$	$1.6X10^{3}$	$4.4X10^{4}$
Os-191m		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	$4.6X10^{4}$	$1.3X10^{6}$
Os-193		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.0X10^{4}$	$5.3X10^{5}$
Os-194 (a)		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.1X10^{1}$	$3.1X10^{2}$
P-32	Phosphorus (15)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$1.1X10^{4}$	$2.9X10^{5}$
P-33		$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$5.8X10^{3}$	$1.6X10^{5}$
Pa-230 (a)	Protactinium (91)	2.0	$5.4X10^{1}$	$7.0X10^{-2}$	1.9	$1.2X10^{3}$	$3.3X10^{4}$
Pa-231		4.0	$1.1X10^{2}$	$4.0X10^{-4}$	$1.1X10^{-2}$	$1.7X10^{-3}$	$4.7X10^{-2}$
Pa-233		5.0	$1.4X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$7.7X10^{2}$	$2.1X10^{4}$
Pb-201	Lead (82)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$6.2X10^{4}$	$1.7X10^{6}$
Pb-202		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{1}$	$5.4X10^{2}$	$1.2X10^{-4}$	$3.4X10^{-3}$
Pb-203		4.0	$1.1X10^{2}$	3.0	$8.1X10^{1}$	$1.1X10^{4}$	$3.0X10^{5}$
Pb-205		Unlimited	Unlimited	Unlimited	Unlimited	$4.5X10^{-6}$	$1.2X10^{-4}$
Pb-210 (a)		1.0	$2.7X10^{1}$	$5.0X10^{-2}$	1.4	2.8	$7.6X10^{1}$
Pb-212 (a)		$7.0X10^{-1}$	$1.9X10^{1}$	$2.0X10^{-1}$	5.4	$5.1X10^{4}$	$1.4X10^{6}$
Pd-103 (a)	Palladium (46)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$2.8X10^{3}$	$7.5X10^{4}$
Pd-107		Unlimited	Unlimited	Unlimited	Unlimited	$1.9X10^{-5}$	$5.1X10^{-4}$
Pd-109		2.0	$5.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$7.9X10^{4}$	$2.1X10^{6}$
Pm-143	Promethium (61)	3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$1.3X10^{2}$	$3.4X10^{3}$
Pm-144		$7.0X10^{-1}$	$1.9X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$9.2X10^{1}$	$2.5X10^{3}$
Pm-145		$3.0X10^{1}$	$8.1X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	5.2	$1.4X10^{2}$
Pm-147		$4.0X10^{1}$	$1.1X10^{3}$	2.0	$5.4X10^{1}$	$3.4X10^{1}$	$9.3X10^{2}$
Pm-148m (a)		$8.0X10^{-1}$	$2.2X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$7.9X10^{2}$	$2.1X10^{4}$
Pm-149		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.5X10^{4}$	$4.0X10^{5}$
Pm-151		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.7X10^{4}$	$7.3X10^{5}$

Table A-1 of Appendix A to Section 4 (Cont'd)

Po-210	Polonium (84)	$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$1.7X10^{2}$	$4.5X10^{3}$
Pr-142	Praseodymium (59)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.3X10^{4}$	$1.2X10^{6}$
Pr-143		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.5X10^{3}$	$6.7X10^{4}$
Pt-188 (a)	Platinum (78)	1.0	$2.7X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$2.5X10^{3}$	$6.8X10^{4}$
Pt-191		4.0	$1.1X10^{2}$	3.0	$8.1X10^{1}$	$8.7X10^{3}$	$2.4X10^{5}$
Pt-193		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	1.4	$3.7X10^{1}$
Pt-193m		$4.0X10^{1}$	$1.1X10^{3}$	$5.0X10^{-1}$	$1.4X10^{1}$	$5.8X10^{3}$	$1.6X10^{5}$
Pt-195m		$1.0X10^{1}$	$2.7X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.2X10^{3}$	$1.7X10^{5}$
Pt-197		$2.0X10^{1}$	$5.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.2X10^{4}$	$8.7X10^{5}$
Pt-197m		$1.0X10^{1}$	$2.7X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.7X10^{5}$	$1.0X10^{7}$
Pu-236	Plutonium (94)	$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{-3}$	$8.1X10^{-2}$	$2.0X10^{1}$	$5.3X10^{2}$
Pu-237		$2.0X10^{1}$	$5.4X10^{2}$	$2.0X10^{1}$	$5.4X10^{2}$	$4.5X10^{2}$	$1.2X10^{4}$
Pu-238		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$6.3X10^{-1}$	$1.7X10^{1}$
Pu-239		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$2.3X10^{-3}$	$6.2X10^{-2}$
Pu-240		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$8.4X10^{-3}$	$2.3X10^{-1}$
Pu-241 (a)		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-2}$	1.6	3.8	$1.0X10^{2}$
Pu-242		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$1.5X10^{-4}$	$3.9X10^{-3}$
Pu-244 (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$6.7X10^{-7}$	$1.8X10^{-5}$
Ra-223 (a)	Radium (88)	$4.0X10^{-1}$	$1.1X10^{1}$	$7.0X10^{-3}$	$1.9X10^{-1}$	$1.9X10^{3}$	$5.1X10^{4}$
Ra-224 (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$5.9X10^{3}$	$1.6X10^{5}$
Ra-225 (a)		$2.0X10^{-1}$	5.4	$4.0X10^{-3}$	$1.1X10^{-1}$	$1.5X10^{3}$	$3.9X10^{4}$
Ra-226 (a)		$2.0X10^{-1}$	5.4	$3.0X10^{-3}$	$8.1X10^{-2}$	$3.7X10^{-2}$	1.0
Ra-228 (a)		$6.0X10^{-1}$	$1.6X10^{1}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$1.0X10^{1}$	$2.7X10^{2}$
Rb-81	Rubidium (37)	2.0	$5.4X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$3.1X10^{5}$	$8.4X10^{6}$
Rb-83 (a)		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$6.8X10^{2}$	$1.8X10^{4}$
Rb-84		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.8X10^{3}$	$4.7X10^{4}$
Rb-86		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$3.0X10^{3}$	$8.1X10^{4}$
Rb-87		Unlimited	Unlimited	Unlimited	Unlimited	$3.2X10^{-9}$	$8.6X10^{-8}$
Rb(nat)		Unlimited	Unlimited	Unlimited	Unlimited	$6.7X10^{6}$	$1.8X10^{8}$
Re-184	Rhenium (75)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$6.9X10^{2}$	$1.9X10^{4}$

Table A-1 of Appendix A to Section 4 (Cont'd)

Re-184m		3.0	$8.1X10^{1}$	1.0	$2.7X10^{1}$	$1.6X10^{2}$	$4.3X10^{3}$
Re-186		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$6.9X10^{3}$	$1.9X10^{5}$
Re-187		Unlimited	Unlimited	Unlimited	Unlimited	$1.4X10^{-9}$	$3.8X10^{-8}$
Re-188		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.6X10^{4}$	$9.8X10^{5}$
Re-189 (a)		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.5X10^{4}$	$6.8X10^{5}$
Re(nat)		Unlimited	Unlimited	Unlimited	Unlimited	0.0	$2.4X10^{-8}$
Rh-99	Rhodium (45)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$3.0X10^{3}$	$8.2X10^{4}$
Rh-101		4.0	$1.1X10^{2}$	3.0	$8.1X10^{1}$	$4.1X10^{1}$	$1.1X10^{3}$
Rh-102		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$4.5X10^{1}$	$1.2X10^{3}$
Rh-102m		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$2.3X10^{2}$	$6.2X10^{3}$
Rh-103m		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$1.2X10^{6}$	$3.3X10^{7}$
Rh-105		$1.0X10^{1}$	$2.7X10^{2}$	$8.0X10^{-1}$	$2.2X10^{1}$	$3.1X10^{4}$	$8.4X10^{5}$
Rn-222 (a)	Radon (86)	$3.0X10^{-1}$	8.1	$4.0X10^{-3}$	$1.1X10^{-1}$	$5.7X10^{3}$	$1.5X10^{5}$
Ru-97	Ruthenium (44)	5.0	$1.4X10^{2}$	5.0	$1.4X10^{2}$	$1.7X10^{4}$	$4.6X10^{5}$
Ru-103 (a)		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$1.2X10^{3}$	$3.2X10^{4}$
Ru-105		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.5X10^{5}$	$6.7X10^{6}$
Ru-106 (a)		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$1.2X10^{2}$	$3.3X10^{3}$
S-35	Sulphur (16)	$4.0X10^{1}$	$1.1X10^{3}$	3.0	$8.1X10^{1}$	$1.6X10^{3}$	$4.3X10^{4}$
Sb-122	Antimony (51)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.5X10^{4}$	$4.0X10^{5}$
Sb-124		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$6.5X10^{2}$	$1.7X10^{4}$
Sb-125		2.0	$5.4X10^{1}$	1.0	$2.7X10^{1}$	$3.9X10^{1}$	$1.0X10^{3}$
Sb-126		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.1X10^{3}$	$8.4X10^{4}$
Sc-44	Scandium (21)	$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$6.7X10^{5}$	$1.8X10^{7}$
Sc-46		$5.0X10^{-1}$	$1.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$1.3X10^{3}$	$3.4X10^{4}$
Sc-47		$1.0X10^{1}$	$2.7X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$3.1X10^{4}$	$8.3X10^{5}$
Sc-48		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$5.5X10^{4}$	$1.5X10^{6}$
Se-75	Selenium (34)	3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$5.4X10^{2}$	$1.5X10^{4}$
Se-79		$4.0X10^{1}$	$1.1X10^{3}$	2.0	$5.4X10^{1}$	$2.6X10^{-3}$	$7.0X10^{-2}$
Si-31	Silicon (14)	$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.4X10^{6}$	$3.9X10^{7}$
Si-32		$4.0X10^{1}$	$1.1X10^{3}$	$5.0X10^{-1}$	$1.4X10^{1}$	3.9	$1.1X10^{2}$
Sm-145	Samarium (62)	$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$9.8X10^{1}$	$2.6X10^{3}$

Table A-1 of Appendix A to Section 4 (Cont'd)

Sm-147		Unlimited	Unlimited	Unlimited	Unlimited	$8.5X10^{-10}$	$2.3X10^{-8}$
Sm-151		$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{1}$	$2.7X10^{2}$	$9.7X10^{-1}$	$2.6X10^{1}$
Sm-153		9.0	$2.4X10^{2}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.6X10^{4}$	$4.4X10^{5}$
Sn-113 (a)	Tin (50)	4.0	$1.1X10^{2}$	2.0	$5.4X10^{1}$	$3.7X10^{2}$	$1.0X10^{4}$
Sn-117m		7.0	$1.9X10^{2}$	$4.0X10^{-1}$	$1.1X10^{1}$	$3.0X10^{3}$	$8.2X10^{4}$
Sn-119m		$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{1}$	$8.1X10^{2}$	$1.4X10^{2}$	$3.7X10^{3}$
Sn-121m (a)		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-1}$	$2.4X10^{1}$	2.0	$5.4X10^{1}$
Sn-123		$8.0X10^{-1}$	$2.2X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$3.0X10^{2}$	$8.2X10^{3}$
Sn-125		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{3}$	$1.1X10^{5}$
Sn-126 (a)		$6.0X10^{-1}$	$1.6X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.0X10^{-3}$	$2.8X10^{-2}$
Sr-82 (a)	Strontium (38)	$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$2.3X10^{3}$	$6.2X10^{4}$
Sr-85		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$8.8X10^{2}$	$2.4X10^{4}$
Sr-85m		5.0	$1.4X10^{2}$	5.0	$1.4X10^{2}$	$1.2X10^{6}$	$3.3X10^{7}$
Sr-87m		3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$4.8X10^{5}$	$1.3X10^{7}$
Sr-89		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.1X10^{3}$	$2.9X10^{4}$
Sr-90 (a)		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	5.1	$1.4X10^{2}$
Sr-91 (a)		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.3X10^{5}$	$3.6X10^{6}$
Sr-92 (a)		1.0	$2.7X10^{1}$	$3.0X10^{-1}$	8.1	$4.7X10^{5}$	$1.3X10^{7}$
T(H-3)	Tritium (1)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.6X10^{2}$	$9.7X10^{3}$
Ta-178 (long-lived)	Tantalum (73)	1.0	$2.7X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$4.2X10^{6}$	$1.1X10^{8}$
Ta-179		$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{1}$	$8.1X10^{2}$	$4.1X10^{1}$	$1.1X10^{3}$
Ta-182		$9.0X10^{-1}$	$2.4X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$2.3X10^{2}$	$6.2X10^{3}$
Tb-157	Terbium (65)	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$5.6X10^{-1}$	$1.5X10^{1}$
Tb-158		1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$5.6X10^{-1}$	$1.5X10^{1}$
Tb-160		1.0	$2.7X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$4.2X10^{2}$	$1.1X10^{4}$
Tc-95m (a)	Technetium (43)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$8.3X10^{2}$	$2.2X10^{4}$
Tc-96		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.2X10^{4}$	$3.2X10^{5}$
Tc-96m (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.4X10^{6}$	$3.8X10^{7}$
Tc-97		Unlimited	Unlimited	Unlimited	Unlimited	$5.2X10^{-5}$	$1.4X10^{-3}$
Tc-97m		$4.0X10^{1}$	$1.1X10^{3}$	1.0	$2.7X10^{1}$	$5.6X10^{2}$	$1.5X10^{4}$
Tc-98		$8.0X10^{-1}$	$2.2X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$3.2X10^{-5}$	$8.7X10^{-4}$

Table A-1 of Appendix A to Section 4 (Cont'd)

Tc-99		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-1}$	$2.4X10^{1}$	$6.3X10^{-4}$	$1.7X10^{-2}$
Tc-99m		$1.0X10^{1}$	$2.7X10^{2}$	4.0	$1.1X10^{2}$	$1.9X10^{5}$	$5.3X10^{6}$
Te-121	Tellurium (52)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$2.4X10^{3}$	$6.4X10^{4}$
Te-121m		5.0	$1.4X10^{2}$	3.0	$8.1X10^{1}$	$2.6X10^{2}$	$7.0X10^{3}$
Te-123m		8.0	$2.2X10^{2}$	1.0	$2.7X10^{1}$	$3.3X10^{2}$	$8.9X10^{3}$
Te-125m		$2.0X10^{1}$	$5.4X10^{2}$	$9.0X10^{-1}$	$2.4X10^{1}$	$6.7X10^{2}$	$1.8X10^{4}$
Te-127		$2.0X10^{1}$	$5.4X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$9.8X10^{4}$	$2.6X10^{6}$
Te-127m (a)		$2.0X10^{1}$	$5.4X10^{2}$	$5.0X10^{-1}$	$1.4X10^{1}$	$3.5X10^{2}$	$9.4X10^{3}$
Te-129		$7.0X10^{-1}$	$1.9X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$7.7X10^{5}$	$2.1X10^{7}$
Te-129m (a)		$8.0X10^{-1}$	$2.2X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.1X10^{3}$	$3.0X10^{4}$
Te-131m (a)		$7.0X10^{-1}$	$1.9X10^{1}$	$5.0X10^{-1}$	$1.4X10^{1}$	$3.0X10^{4}$	$8.0X10^{5}$
Te-132 (a)		$5.0X10^{-1}$	$1.4X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$1.1X10^{4}$	$3.0X10^{5}$
Th-227	Thorium (90)	$1.0X10^{1}$	$2.7X10^{2}$	$5.0X10^{-3}$	$1.4X10^{-1}$	$1.1X10^{3}$	$3.1X10^{4}$
Th-228 (a)		$5.0X10^{-1}$	$1.4X10^{1}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$3.0X10^{1}$	$8.2X10^{2}$
Th-229		5.0	$1.4X10^{2}$	$5.0X10^{-4}$	$1.4X10^{-2}$	$7.9X10^{-3}$	$2.1X10^{-1}$
Th-230		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$7.6X10^{-4}$	$2.1X10^{-2}$
Th-231		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.0X10^{4}$	$5.3X10^{5}$
Th-232		Unlimited	Unlimited	Unlimited	Unlimited	$4.0X10^{-9}$	$1.1X10^{-7}$
Th-234 (a)		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$8.6X10^{2}$	$2.3X10^{4}$
Th(nat)		Unlimited	Unlimited	Unlimited	Unlimited	$8.1X10^{-9}$	$2.2X10^{-7}$
Ti-44 (a)	Titanium (22)	$5.0X10^{-1}$	$1.4X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	6.4	$1.7X10^{2}$
Tl-200	Thallium (81)	$9.0X10^{-1}$	$2.4X10^{1}$	$9.0X10^{-1}$	$2.4X10^{1}$	$2.2X10^{4}$	$6.0X10^{5}$
Tl-201		$1.0X10^{1}$	$2.7X10^{2}$	4.0	$1.1X10^{2}$	$7.9X10^{3}$	$2.1X10^{5}$
Tl-202		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$2.0X10^{3}$	$5.3X10^{4}$
Tl-204		$1.0X10^{1}$	$2.7X10^{2}$	$7.0X10^{-1}$	$1.9X10^{1}$	$1.7X10^{1}$	$4.6X10^{2}$
Tm-167	Thulium (69)	7.0	$1.9X10^{2}$	$8.0X10^{-1}$	$2.2X10^{1}$	$3.1X10^{3}$	$8.5X10^{4}$
Tm-170		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.2X10^{2}$	$6.0X10^{3}$
Tm-171		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$
U-230 (fast lung absorption) (a)(d)	Uranium (92)	$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{-1}$	2.7	$1.0X10^{3}$	$2.7X10^{4}$

Table A-1 of Appendix A to Section 4 (Cont'd)

U-230 (medium lung absorption) (a)(e)		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{-3}$	$1.1X10^{-1}$	$1.0X10^{3}$	$2.7X10^{4}$
U-230 (slow lung absorption) (a)(f)		$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{-3}$	$8.1X10^{-2}$	$1.0X10^{3}$	$2.7X10^{4}$
U-232 (fast lung absorption) (d)		$4.0X10^{1}$	$1.1X10^{3}$	$1.0X10^{-2}$	$2.7X10^{-1}$	$8.3X10^{-1}$	$2.2X10^{1}$
U-232 (medium lung absorption) (e)		$4.0X10^{1}$	$1.1X10^{3}$	$7.0X10^{-3}$	$1.9X10^{-1}$	$8.3X10^{-1}$	$2.2X10^{1}$
U-232 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{2}$	$1.0X10^{-3}$	$2.7X10^{-2}$	$8.3X10^{-1}$	$2.2X10^{1}$
U-233 (fast lung absorption) (d)		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-2}$	2.4	$3.6X10^{-4}$	$9.7X10^{-3}$
U-233 (medium lung absorption) (e)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$3.6X10^{-4}$	$9.7X10^{-3}$
U-233 (slow lung absorption) (f)		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$3.6X10^{-4}$	$9.7X10^{-3}$
U-234 (fast lung absorption) (d)		$4.0X10^{1}$	$1.1X10^{3}$	$9.0X10^{-2}$	2.4	$2.3X10^{-4}$	$6.2X10^{-3}$
U-234 (medium lung absorption) (e)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.3X10^{-4}$	$6.2X10^{-3}$
U-234 (slow lung absorption) (f)		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$2.3X10^{-4}$	$6.2X10^{-3}$
U-235 (all lung absorption types) (a),(d),(e),(f)		Unlimited	Unlimited	Unlimited	Unlimited	$8.0X10^{-8}$	$2.2X10^{-6}$
U-236 (fast lung absorption) (d)		Unlimited	Unlimited	Unlimited	Unlimited	$2.4X10^{-6}$	$6.5X10^{-5}$
U-236 (medium lung absorption) (e)		$4.0X10^{1}$	$1.1X10^{3}$	$2.0X10^{-2}$	$5.4X10^{-1}$	$2.4X10^{-6}$	$6.5X10^{-5}$
U-236 (slow lung absorption) (f)		$4.0X10^{1}$	$1.1X10^{3}$	$6.0X10^{-3}$	$1.6X10^{-1}$	$2.4X10^{-6}$	$6.5X10^{-5}$
U-238 (all lung absorption types) (d),(e),(f)		Unlimited	Unlimited	Unlimited	Unlimited	$1.2X10^{-8}$	$3.4X10^{-7}$
U (nat)		Unlimited	Unlimited	Unlimited	Unlimited	$2.6X10^{-8}$	$7.1X10^{-7}$

Table A-1 of Appendix A to Section 4 (Cont'd)

U (enriched to 20% or less) (g)		Unlimited	Unlimited	Unlimited	Unlimited	See Table A-4	See Table A-4
U (dep)		Unlimited	Unlimited	Unlimited	Unlimited	See Table A-4	(See Table A-3)
V-48	Vanadium (23)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$6.3X10^{3}$	$1.7X10^{5}$
V-49		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.0X10^{2}$	$8.1X10^{3}$
W-178 (a)	Tungsten (74)	9.0	$2.4X10^{2}$	5.0	$1.4X10^{2}$	$1.3X10^{3}$	$3.4X10^{4}$
W-181		$3.0X10^{1}$	$8.1X10^{2}$	$3.0X10^{1}$	$8.1X10^{2}$	$2.2X10^{2}$	$6.0X10^{3}$
W-185		$4.0X10^{1}$	$1.1X10^{3}$	$8.0X10^{-1}$	$2.2X10^{1}$	$3.5X10^{2}$	$9.4X10^{3}$
W-187		2.0	$5.4X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$2.6X10^{4}$	$7.0X10^{5}$
W-188 (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$3.0X10^{-1}$	8.1	$3.7X10^{2}$	$1.0X10^{4}$
Xe-122 (a)	Xenon (54)	$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$4.8X10^{4}$	$1.3X10^{6}$
Xe-123		2.0	$5.4X10^{1}$	$7.0X10^{-1}$	$1.9X10^{1}$	$4.4X10^{5}$	$1.2X10^{7}$
Xe-127		4.0	$1.1X10^{2}$	2.0	$5.4X10^{1}$	$1.0X10^{3}$	$2.8X10^{4}$
Xe-131m		$4.0X10^{1}$	$1.1X10^{3}$	$4.0X10^{1}$	$1.1X10^{3}$	$3.1X10^{3}$	$8.4X10^{4}$
Xe-133		$2.0X10^{1}$	$5.4X10^{2}$	$1.0X10^{1}$	$2.7X10^{2}$	$6.9X10^{3}$	$1.9X10^{5}$
Xe-135		3.0	$8.1X10^{1}$	2.0	$5.4X10^{1}$	$9.5X10^{4}$	$2.6X10^{6}$
Y-87 (a)	Yttrium (39)	1.0	$2.7X10^{1}$	1.0	$2.7X10^{1}$	$1.7X10^{4}$	$4.5X10^{5}$
Y-88		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$5.2X10^{2}$	$1.4X10^{4}$
Y-90		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$2.0X10^{4}$	$5.4X10^{5}$
Y-91		$6.0X10^{-1}$	$1.6X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$9.1X10^{2}$	$2.5X10^{4}$
Y-91m		2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$1.5X10^{6}$	$4.2X10^{7}$
Y-92		$2.0X10^{-1}$	5.4	$2.0X10^{-1}$	5.4	$3.6X10^{5}$	$9.6X10^{6}$
Y-93		$3.0X10^{-1}$	8.1	$3.0X10^{-1}$	8.1	$1.2X10^{5}$	$3.3X10^{6}$
Yb-169	Ytterbium (70)	4.0	$1.1X10^{2}$	1.0	$2.7X10^{1}$	$8.9X10^{2}$	$2.4X10^{4}$
Yb-175		$3.0X10^{1}$	$8.1X10^{2}$	$9.0X10^{-1}$	$2.4X10^{1}$	$6.6X10^{3}$	$1.8X10^{5}$
Zn-65	Zinc (30)	2.0	$5.4X10^{1}$	2.0	$5.4X10^{1}$	$3.0X10^{2}$	$8.2X10^{3}$
Zn-69		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.8X10^{6}$	$4.9X10^{7}$
Zn-69m (a)		3.0	$8.1X10^{1}$	$6.0X10^{-1}$	$1.6X10^{1}$	$1.2X10^{5}$	$3.3X10^{6}$
Zr-88	Zirconium (40)	3.0	$8.1X10^{1}$	3.0	$8.1X10^{1}$	$6.6X10^{2}$	$1.8X10^{4}$
Zr-93		Unlimited	Unlimited	Unlimited	Unlimited	$9.3X10^{-5}$	$2.5X10^{-3}$

Table A-1 of Appendix A to Section 4 (Cont'd)

Zr-95 (a)		2.0	$5.4X10^{1}$	$8.0X10^{-1}$	$2.2X10^{1}$	$7.9X10^{2}$	$2.1X10^{4}$
Zr-97 (a)		$4.0X10^{-1}$	$1.1X10^{1}$	$4.0X10^{-1}$	$1.1X10^{1}$	$7.1X10^{4}$	$1.9X10^{6}$

[a] A_1 ~~and/or~~or A_2 values include contributions from daughter nuclides with half-lives less than 10 days, as listed in the following:

Mg-28	Al-28
Ca-47	Sc-47
Ti-44	Sc-44
Fe-52	Mn-52m
Fe-60	Co-60m
Zn-69m	Zn-69
Ge-68	Ga-68
Rb-83	Kr-83m
Sr-82	Rb-82
Sr-90	Y-90
Sr-91	Y-91m
Sr-92	Y-92
Y-87	Sr-87m
Zr-95	Nb-95m
Zr-97	Nb-97m, Nb-97
Mo-99	Tc-99m
Tc-95m	Tc-95
Tc-96m	Tc-96
Ru-103	Rh-103m
Ru-106	Rh-106
Pd-103	Rh-103m
Ag-108m	Ag-108
Ag-110m	Ag-110
Cd-115	In-115m
In-114m	In-114
Sn-113	In-113m
Sn-121m	Sn-121
Sn-126	Sb-126m
Te-127m	Te-127
Te-129m	Te-129
Te-131m	Te-131

Table A-1 of Appendix A to Section 4 (Cont'd)

Te-132	I-132
I-135	Xe-135m
Xe-122	I-122
Cs-137	Ba-137m
Ba-131	Cs-131
Ba-140	La-140
Ce-144	Pr-144m, Pr-144
Pm-148m	Pm-148
Gd-146	Eu-146
Dy-166	Ho-166
Hf-172	Lu-172
W-178	Ta-178
W-188	Re-188
Re-189	Os-189m
Os-194	Ir-194
Ir-189	Os-189m
Pt-188	Ir-188
Hg-194	Au-194
Hg-195m	Hg-195
Pb-210	Bi-210
Pb-212	Bi-212, Tl-208, Po-212
Bi-210m	Tl-206
Bi-212	Tl-208, Po-212
At-211	Po-211
Rn-222	Po-218, Pb-214, At-218, Bi-214, Po-214
Ra-223	Rn-219, Po-215, Pb-211, Bi-211, Po-211, Tl-207
Ra-224	Rn-220, Po-216, Pb-212, Bi-212, Tl-208, Po-212
Ra-225	Ac-225, Fr-221, At-217, Bi-213, Tl-209, Po-213, Pb-209
Ra-226	Rn-222, Po-218, Pb-214, At-218, Bi-214, Po-214
Ra-228	Ac-228
Ac-225	Fr-221, At-217, Bi-213, Tl-209, Po-213, Pb-209
Ac-227	Fr-223
Th-228	Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208, Po-212
Th-234	Pa-234m, Pa-234
Pa-230	Ac-226, Th-226, Fr-222, Ra-222, Rn-218, Po-214
U-230	Th-226, Ra-222, Rn-218, Po-214

Table A-1 of Appendix A to Section 4 (Cont'd)

U-235	Th-231
Pu-241	U-237
Pu-244	U-240, Np-240m
Am-242m	Am-242, Np-238
Am-243	Np-239
Cm-247	Pu-243
Bk-249	Am-245
Cf-253	Cm-249

[b] The values of A_1 and A_2 in Curies (Ci) are approximate and for information only; the regulatory standard units are Terabecquerels (TBq).- See Appendix A to Section 4 – Determination of A_1 and A_2, Section I.

[c] The activity of Ir-192 in special form may be determined from a measurement of the rate of decay or a measurement of the radiation level at a prescribed distance from the source.

[d] These values apply only to compounds of uranium that take the chemical form of UF_6, UO_2F_2 and $UO_2(NO_3)_2$ in both normal and accident conditions of transport.

[e] These values apply only to compounds of uranium that take the chemical form of UO_3, UF_4, UCl_4 and hexavalent compounds in both normal and accident conditions of transport.

[f] These values apply to all compounds of uranium other than those specified in notes (d) and (e) of this table.

[g] These values apply to unirradiated uranium only.

[h] A_2 = 0.74 TBq (20 Ci) for Mo-99 for domestic use.

TABLE A-2—EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
Ac-225	Actinium (89)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ac-227		$1.0X10^{-1}$	$2.7X10^{-12}$	$1.0X10^{3}$	$2.7X10^{-8}$
Ac-228		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-105	Silver (47)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-108m (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-110m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ag-111		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Al-26	Aluminum (13)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Am-241	Americium (95)	1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Am-242m (b)		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Am-243 (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Ar-37	Argon (18)	$1.0X10^{6}$	$2.7X10^{-5}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ar-39		$1.0X10^{7}$	$2.7X10^{-4}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ar-41		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
As-72	Arsenic (33)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
As-73		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
As-74		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
As-76		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
As-77		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
At-211	Astatine (85)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Au-193	Gold (79)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Au-194		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Au-195		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Au-198		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Au-199		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$

Table A-2 of Appendix A to Section 4 (Cont'd)

Ba-131	Barium (56)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ba-133		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ba-133m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ba-140 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Be-7	Beryllium (4)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Be-10		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-205	Bismuth (83)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-206		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Bi-207		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-210		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Bi-210m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Bi-212 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Bk-247	Berkelium (97)	1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Bk-249		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Br-76	Bromine (35)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Br-77		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Br-82		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
C-11	Carbon (6)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
C-14		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ca-41	Calcium (20)	$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ca-45		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ca-47		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cd-109	Cadmium (48)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cd-113m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cd-115		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cd-115m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ce-139	Cerium (58)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ce-141		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ce-143		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ce-144 (b)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cf-248	Californium (98)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cf-249		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$

Table A-2 of Appendix A to Section 4 (Cont'd)

Cf-250		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cf-251		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cf-252		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cf-253		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cf-254		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cl-36	Chlorine (17)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cl-38		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cm-240	Curium (96)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cm-241		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cm-242		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cm-243		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cm-244		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cm-245		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cm-246		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Cm-247		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cm-248		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Co-55	Cobalt (27)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Co-56		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Co-57		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Co-58		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Co-58m		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Co-60		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cr-51	Chromium (24)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Cs-129	Cesium (55)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-131		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Cs-132		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-134		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cs-134m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-135		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Cs-136		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Cs-137 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Cu-64	Copper (29)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$

Table A-2 of Appendix A to Section 4 (Cont'd)

Cu-67		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Dy-159	Dysprosium (66)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Dy-165		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Dy-166		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Er-169	Erbium (68)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Er-171		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-147	Europium (63)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-148		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-149		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Eu-150 (short lived)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-150 (long lived)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-152		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-152m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-154		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Eu-155		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Eu-156		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
F-18	Fluorine (9)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Fe-52	Iron (26)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Fe-55		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Fe-59		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Fe-60		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ga-67	Gallium (31)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ga-68		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ga-72		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Gd-146	Gadolinium (64)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Gd-148		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Gd-153		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Gd-159		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ge-68	Germanium (32)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ge-71		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ge-77		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$

Table A-2 of Appendix A to Section 4 (Cont'd)

Hf-172	Hafnium (72)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hf-175		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hf-181		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hf-182		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hg-194	Mercury (80)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hg-195m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hg-197		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Hg-197m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Hg-203		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ho-166	Holmium (67)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ho-166m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-123	Iodine (53)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
I-124		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-125		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-126		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-129		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
I-131		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-132		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
I-133		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
I-134		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
I-135		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
In-111	Indium (49)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
In-113m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
In-114m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
In-115m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ir-189	Iridium (77)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ir-190		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ir-192		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ir-194		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
K-40	Potassium (19)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
K-42		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
K-43		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$

Table A-2 of Appendix A to Section 4 (Cont'd)

Kr-79	Krypton (36)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Kr-81		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Kr-85		$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{4}$	$2.7X10^{-7}$
Kr-85m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{10}$	$2.7X10^{-1}$
Kr-87		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
La-137	Lanthanum (57)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
La-140		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Lu-172	Lutetium (71)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Lu-173		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Lu-174		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Lu-174m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Lu-177		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Mg-28	Magnesium (12)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Mn-52	Manganese (25)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Mn-53		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{9}$	$2.7X10^{-2}$
Mn-54		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Mn-56		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Mo-93	Molybdenum (42)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{8}$	$2.7X10^{-3}$
Mo-99		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
N-13	Nitrogen (7)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
Na-22	Sodium (11)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Na-24		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Nb-93m	Niobium (41)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Nb-94		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Nb-95		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Nb-97		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Nd-147	Neodymium (60)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Nd-149		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ni-59	Nickel (28)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ni-63		$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ni-65		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Np-235	Neptunium (93)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$

Table A-2 of Appendix A to Section 4 (Cont'd)

Np-236 (short-lived)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Np-236 (long-lived)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Np-237 (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Np-239		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Os-185	Osmium (76)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Os-191		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Os-191m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Os-193		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Os-194		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
P-32	Phosphorus (15)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
P-33		$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{8}$	$2.7X10^{-3}$
Pa-230	Protactinium (91)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pa-231		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Pa-233		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pb-201	Lead (82)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pb-202		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pb-203		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pb-205		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pb-210 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pb-212 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Pd-103	Palladium (46)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{8}$	$2.7X10^{-3}$
Pd-107		$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{8}$	$2.7X10^{-3}$
Pd-109		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-143	Promethium (61)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-144		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-145		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pm-147		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pm-148m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-149		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pm-151		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$

Table A-2 of Appendix A to Section 4 (Cont'd)

Po-210	Polonium (84)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pr-142	Praseodymium (59)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Pr-143		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-188	Platinum (78)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-191		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-193		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pt-193m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pt-195m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-197		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pt-197m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Pu-236	Plutonium (94)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pu-237		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Pu-238		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pu-239		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pu-240		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Pu-241		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Pu-242		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Pu-244		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ra-223 (b)	Radium (88)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ra-224 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ra-225		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Ra-226 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Ra-228 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Rb-81	Rubidium (37)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rb-83		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rb-84		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rb-86		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Rb-87		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Rb(nat)		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Re-184	Rhenium (75)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Re-184m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$

Table A-2 of Appendix A to Section 4 (Cont'd)

Re-186		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Re-187		$1.0X10^{6}$	$2.7X10^{-5}$	$1.0X10^{9}$	$2.7X10^{-2}$
Re-188		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Re-189		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Re(nat)		$1.0X10^{6}$	$2.7X10^{-5}$	$1.0X10^{9}$	$2.7X10^{-2}$
Rh-99	Rhodium (45)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rh-101		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Rh-102		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rh-102m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Rh-103m		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
Rh-105		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Rn-222 (b)	Radon (86)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{8}$	$2.7X10^{-3}$
Ru-97	Ruthenium (44)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ru-103		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ru-105		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ru-106 (b)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
S-35	Sulphur (16)	$1.0X10^{5}$	$2.7X10^{-6}$	$1.0X10^{8}$	$2.7X10^{-3}$
Sb-122	Antimony (51)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{4}$	$2.7X10^{-7}$
Sb-124		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sb-125		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sb-126		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sc-44	Scandium (21)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sc-46		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sc-47		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sc-48		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Se-75	Selenium (34)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Se-79		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Si-31	Silicon (14)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Si-32		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sm-145	Samarium (62)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sm-147		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Sm-151		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$

Table A-2 of Appendix A to Section 4 (Cont'd)

Sm-153		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sn-113	Tin (50)	$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sn-117m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sn-119m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sn-121m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sn-123		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sn-125		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sn-126		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sr-82	Strontium (38)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sr-85		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sr-85m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Sr-87m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sr-89		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Sr-90 (b)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{4}$	$2.7X10^{-7}$
Sr-91		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Sr-92		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
T(H-3)	Tritium (1)	$1.0X10^{6}$	$2.7X10^{-5}$	$1.0X10^{9}$	$2.7X10^{-2}$
Ta-178 (long-lived)	Tantalum (73)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Ta-179		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Ta-182		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Tb-157	Terbium (65)	$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Tb-158		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tb-160		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tc-95m	Technetium (43)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tc-96		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tc-96m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Tc-97		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{8}$	$2.7X10^{-3}$
Tc-97m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Tc-98		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tc-99		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
Tc-99m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$

Table A-2 of Appendix A to Section 4 (Cont'd)

Te-121	Tellurium (52)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-121m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-123m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Te-125m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Te-127		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-127m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Te-129		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-129m		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-131m		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Te-132		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Th-227	Thorium (90)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Th-228 (b)		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Th-229 (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Th-230		1.0	$2.7X10^{-11}$	$1.0X10^{4}$	$2.7X10^{-7}$
Th-231		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Th-232		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
Th-234 (b)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Th (nat) (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
Ti-44	Titanium (22)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
Tl-200	Thallium (81)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tl-201		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tl-202		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tl-204		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{4}$	$2.7X10^{-7}$
Tm-167	Thulium (69)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tm-170		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Tm-171		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{8}$	$2.7X10^{-3}$
U-230 (fast lung absorption) (b),(d)	Uranium (92)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-230 (medium lung absorption) (e)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$

Table A-2 of Appendix A to Section 4 (Cont'd)

U-230 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-232 (fast lung absorption) (b),(d)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
U-232 (medium lung absorption) (e)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-232 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-233 (fast lung absorption) (d)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-233 (medium lung absorption) (e)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-233 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-234 (fast lung absorption) (d)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-234 (medium lung absorption) (e)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-234 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
U-235 (all lung absorption types) (b),(d),(e),(f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-236 (fast lung absorption) (d)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-236 (medium lung absorption) (e)		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$

Table A-2 of Appendix A to Section 4 (Cont'd)

U-236 (slow lung absorption) (f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U-238 (all lung absorption types) (b),(d),(e),(f)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{4}$	$2.7X10^{-7}$
U (nat) (b)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
U (enriched to 20% or less) (g)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
U (dep)		1.0	$2.7X10^{-11}$	$1.0X10^{3}$	$2.7X10^{-8}$
V-48	Vanadium (23)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$
V-49		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
W-178	Tungsten (74)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
W-181		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
W-185		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{7}$	$2.7X10^{-4}$
W-187		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
W-188		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Xe-122	Xenon (54)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
Xe-123		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{9}$	$2.7X10^{-2}$
Xe-127		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Xe-131m		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{4}$	$2.7X10^{-7}$
Xe-133		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{4}$	$2.7X10^{-7}$
Xe-135		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{10}$	$2.7X10^{-1}$
Y-87	Yttrium (39)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Y-88		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Y-90		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{5}$	$2.7X10^{-6}$
Y-91		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{6}$	$2.7X10^{-5}$
Y-91m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Y-92		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Y-93		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{5}$	$2.7X10^{-6}$
Yb-169	Ytterbium (70)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{7}$	$2.7X10^{-4}$
Yb-175		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Zn-65	Zinc (30)	$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$

Table A-2 of Appendix A to Section 4 (Cont'd)

Zn-69		$1.0X10^{4}$	$2.7X10^{-7}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zn-69m		$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zr-88	Zirconium (40)	$1.0X10^{2}$	$2.7X10^{-9}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zr-93 (b)		$1.0X10^{3}$	$2.7X10^{-8}$	$1.0X10^{7}$	$2.7X10^{-4}$
Zr-95		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{6}$	$2.7X10^{-5}$
Zr-97 (b)		$1.0X10^{1}$	$2.7X10^{-10}$	$1.0X10^{5}$	$2.7X10^{-6}$

[a] [Reserved]

[b] Parent nuclides and their progeny included in secular equilibrium are listed as follows:

Sr-90	Y-90
Zr-93	Nb-93m
Zr-97	Nb-97
Ru-106	Rh-106
Ag-108m	Ag-108
Cs-137	Ba-137m
Ce-144	Pr-144
Ba-140	La-140
Bi-212	Tl-208 (0.36), Po-212 (0.64)
Pb-210	Bi-210, Po-210
Pb-212	Bi-212, Tl-208 (0.36), Po-212 (0.64)
Rn-222	Po-218, Pb-214, Bi-214, Po-214
Ra-223	Rn-219, Po-215, Pb-211, Bi-211, Tl-207
Ra-224	Rn-220, Po-216, Pb-212, Bi-212, Tl-208(0.36), Po-212 (0.64)
Ra-226	Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
Ra-228	Ac-228
Th-228	Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Th-229	Ra-225, Ac-225, Fr-221, At-217, Bi-213, Po-213, Pb-209
Th-nat	Ra-228, Ac-228, Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Th-234	Pa-234m
U-230	Th-226, Ra-222, Rn-218, Po-214
U-232	Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
U-235	Th-231
U-238	Th-234, Pa-234m

Table A-2 of Appendix A to Section 4 (Cont'd)

U-nat	Th-234, Pa-234m, U-234, Th-230, Ra-226, Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
Np-237	Pa-233
Am-242m	Am-242
Am-243	Np-239

[c] [Reserved]

[d] These values apply only to compounds of uranium that take the chemical form of UF_6, UO_2F_2 and $UO_2(NO_3)_2$ in both normal and accident conditions of transport.

[e] These values apply only to compounds of uranium that take the chemical form of UO_3, UF_4, UCl_4 and hexavalent compounds in both normal and accident conditions of transport.

[f] These values apply to all compounds of uranium other than those specified in notes (d) and (e) of this table.

[g] These values apply to unirradiated uranium only.

TABLE A-3—GENERAL VALUES FOR A_1 AND A_2

Contents	A_1		A_2		Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limits for exempt consignments (Bq)	Activity limits for exempt consignments (Ci)
	(TBq)	(Ci)	(TBq)	(Ci)				
Only beta or gamma emitting nuclides are known to be present	1×10^{-1}	2.7×10^{0}	2×10^{-2}	5.4×10^{-1}	1×10^{1}	2.7×10^{-10}	1×10^{4}	2.7×10^{-7}
Alpha emitting nuclides, but no neutron emitters, are known to be present[a]	2×10^{-1}	5.4×10^{0}	9×10^{-5}	2.4×10^{-3}	1×10^{-1}	2.7×10^{-12}	1×10^{3}	2.7×10^{-8}
Neutron emitting nuclides are known to be present or no relevant data are available	1×10^{-3}	2.7×10^{-2}	9×10^{-5}	2.4×10^{-3}	1×10^{-1}	2.7×10^{-12}	1×10^{3}	2.7×10^{-8}

[a] If beta or gamma emitting nuclides are known to be present, the A_1 value of 0.1 TBq (2.7 Ci) should be used.

TABLE A-4—ACTIVITY-MASS RELATIONSHIPS FOR URANIUM

Uranium Enrichment[1] wt % U-235 present	Specific Activity	
	TBq/g	Ci/g
0.45	1.8×10^{-8}	5.0×10^{-7}
0.72	2.6×10^{-8}	7.1×10^{-7}
1	2.8×10^{-8}	7.6×10^{-7}
1.5	3.7×10^{-8}	1.0×10^{-6}
5	1.0×10^{-7}	2.7×10^{-6}
10	1.8×10^{-7}	4.8×10^{-6}
20	3.7×10^{-7}	1.0×10^{-5}
35	7.4×10^{-7}	2.0×10^{-5}
50	9.3×10^{-7}	2.5×10^{-5}
90	2.2×10^{-6}	5.8×10^{-5}
93	2.6×10^{-6}	7.0×10^{-5}
95	3.4×10^{-6}	9.1×10^{-5}

[1] The figures for uranium include representative values for the activity of the uranium-234 that is concentrated during the enrichment process.

SECTION 5.
RULES OF PRACTICE

PART A.
GENERAL

RH-4000. **Authority**.- Act 8 of Second Extraordinary Session of 1961, as amended.

RH-4001. **Effective Date**.- January 1, 1963.

RH-4002. **Scope**.

This Section contains the requirements applicable to and governing the proceeding of any administrative hearing pertinent to these Rules.

RH-4003. **Communications**.

a. Except where otherwise specified, all communications concerning these Rules may be addressed to the Arkansas Department of Health, Radiation Control Section, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

b. The Director of the Arkansas Department of Health or a duly appointed Hearing Officer shall specify the time and place of all hearings.

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RH-4004. **Interpretations**.

Except as specifically authorized by the Department in writing, no interpretations of the meaning of the rules in this Section by an officer or employee of the Department other than a written interpretation by the Department Director or designee will be recognized as binding upon the Department.

PART B.
ADMINISTRATION

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RH-4005. **Administrative Examination of Applications**.

Applications for the issuance of a license or registration, amendment of a license or registration at the request of the holder, and renewal of a license or registration will be given a docket number or other identifier for administrative examination. The applicant may be required to submit additional information and may be requested to confer informally regarding the application.~~-~~ The Department will give to others such notice of the filing of applications as is required under the applicable provisions of these Rules and such additional notices as it deems appropriate.

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RH-4006. **Action on Application, Hearings**.

a. The Department will, upon request of the applicant or intervener and may upon its own initiative, direct the holding of a formal hearing prior to taking action on the application.~~-~~ If no prior formal hearing has been held and no notice of proposed action has been served as provided in paragraph b of this section, the Department will direct the holding of a formal hearing upon receipt of a request therefore from the applicant or intervener within thirty (30) calendar days after the issuance of a license or registration or other approval or a notice of denial.

b. In such cases as it deems appropriate, the Department may cause to be served upon the applicant a notice of proposed action upon ~~his/her~~ his or her application and shall cause copies thereof to be served upon interveners or others entitled to or requesting notification.~~-~~ The notice shall state the terms of the proposed action.~~-~~ If a formal hearing has not been held prior to the issuance of the notice, the Department will direct the holding of a formal hearing upon the request of the applicant or an intervener received within fifteen (15) calendar days following the service of the notice.

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RH-4007. **Effect of Timely Renewal Applications**.

In the case of an application for renewal, if the licensee or registrant has made application for the renewal of a subsisting license or registration at least thirty (30) calendar days prior to its expiration date, the license or registration shall not be deemed to have expired until such application ~~shall have~~ has been finally determined.

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RH-4008. **Notice of Violation**.

a. Prior to the institution of any proceeding for the modification, suspension, or revocation of a license or registration for alleged violation of any provision of the Act, these Rules, conditions of a license, or a registration, the licensee or registrant shall be served with a written notice calling the facts to ~~his/her~~ his or her attention and requesting a written explanation or statement in reply. Within thirty (30) days of the date of the notice or other specified time, the licensee or registrant shall send ~~his/her~~his or her reply to the Department. If the notice relates to conditions or conduct that may be susceptible to correction or to being brought into full compliance by action of the licensee or registrant, ~~he/she~~he or she shall state in ~~his/her~~ his or her reply the corrective steps that have been taken and the results achieved, the corrective steps that will be taken, and the date when full compliance will be achieved. Corrective actions must address methods to prevent future noncompliance.

b. Where, in the opinion of the Department, the public health, interest or safety requires; or the failure to be in compliance is willful; the notice provided for in this section may be omitted.

RH-4009. **Orders**.

In any case described in RH-4008., the Department may issue to the licensee or registrant a notice to comply with the applicable provisions of the Act or the rules of the Arkansas State Board of Health or any order issued by the Department. The order shall apprise the licensee or registrant that ~~he/she~~ he or she has the right to request a hearing within thirty (30) days by making a written request therefore to the Director. In the event a request for a hearing is received by the Director within the time specified, a notice of hearing shall be issued by the Department in accordance with RH-4028.

RH-4010. **Emergency Orders**.

Whenever the Department finds that an emergency exists requiring immediate action to protect the public health and safety, the Department may, without notice or hearing, issue a rule or order reciting the existence of such emergency and requiring that such action be taken as is necessary to meet the emergency. Notwithstanding any provision of the Act (Act 8 of Second Extraordinary Session of 1961), such rule or order shall be effective immediately. Any person to whom such rule or order is directed shall comply therewith immediately, but on application to the Department shall be afforded a hearing within ten (10) days. On the basis of such hearing, the emergency rule or order shall be continued,

modified or revoked within thirty (30) days after such hearing. Any final order entered in any proceeding under this paragraph may be appealed within twenty (20) days from the date of issuance thereof, to the Circuit Court of Pulaski County.

RH-4011. **Enforcement of Obedience to Orders**.

In case of the failure on the part of any person, firm or corporation to comply with any lawful order of the Director or with process or in case of the refusal of any witness to testify concerning any matter on which ~~he/she~~ he or she may be lawfully interrogated, the Circuit Court or a Judge thereof having jurisdiction may, on application of the Director, compel obedience by proceeding as in contempt cases.

RH-4012. **Impounding Materials**.

The Department shall have the authority in the event of an emergency to impound or order the impounding of sources of ionizing radiation in the possession of any person who is not equipped to observe or fails to observe the provisions of the Act or any rules issued thereunder. As promptly as possible and not later than ten (10) days from the impounding, the Department shall serve upon the licensee or registrant an appropriate order for revocation of ~~his/her~~ his or her license or registration together with a notice which shall give the licensee or registrant the right to request a formal hearing concerning the revocation of ~~his/her~~ his or her license or registration and the restoration of the material of which ~~he/she~~ he or she has been deprived.

RH-4013. **Filing of Papers**.

Unless otherwise specified, papers required to be filed with the Department ~~shall~~ may be filed by way of first-class, certified, or registered mail with the Arkansas Department of Health, Radiation Control Section, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867. ~~Papers required to be filed with the Department shall be deemed filed upon actual receipt with the Department at the place specified, accompanied by proof of service upon the parties required to be served as provided in RH-4016. Unless otherwise specified, the filing, when by mail or telegram, shall, upon actual receipt, be deemed complete as of the date of deposit in the mail or with the telegraph company.~~ Papers may also be filed ~~in person~~ by personal delivery, courier, express mail, or expedited deliver service at the Department's Radiation Control Section offices at 5800 W. 10th Street, Suite 401, ~~at~~ Little Rock, Arkansas, 72204. Filing by personal delivery is considered complete upon depositing the document with the Department. Unless otherwise specified, the filing, when by courier, expedited delivery service, or by first-class, express, certified, or registered mail, shall, upon actual receipt, be deemed

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complete as of the date of deposit in the mail or upon depositing the document with the provider of the service.

RH-4014. **Computation of Time**.

The time within which any Act under these Rules is to be accomplished shall be computed by excluding the first day and including the last, unless the last day is Sunday or is a holiday as defined or fixed by statutes now or hereafter in force in this State, and then it shall also be excluded. If the day succeeding such Sunday or holiday is also a holiday or a Sunday, then such succeeding day shall also be excluded.

RH-4015. **Extension of Time**.

Extensions of time for filing or performing any ~~A~~act required or allowed to be accomplished, and continuances of any proceeding or hearing, may be granted at the discretion of the Department upon application and good cause shown by any party, or upon the initiative of the Department or stipulation of all parties. Where a Hearing Officer has been designated for a hearing, the discretion in granting extensions of time and continuances in matters relating to the hearing shall rest with the Hearing Officer.

RH-4016. **Subpoenas, Service and Papers**.

a. Subpoenas for the attendance of witnesses from any place in the State of Arkansas or the production of books, papers, accounts or documents at a hearing in a pending proceeding will be issued by the Department upon its own motion or upon application in writing incorporating a showing that such subpoena is reasonably required.

~~a~~b. ~~**Service.**~~

1. Service shall be made by ~~delivering in person or by depositing in the United States Mail~~personal delivery, courier, expedited delivery service, or by first-class, express, certified, or registered mail, properly addressed with postage prepaid, one copy to each party, if entitled thereto. When any party or parties have appeared by attorney, service upon the attorney shall be deemed service upon such party or parties.

2. ~~Proof of service shall be by certificate of attorney affidavit or acknowledgement.~~

RH-4017. **Representation**.

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a. Except as provided in paragraph b. of this section, any person appearing before the Department may do so in person or by a representative. ~~-~~Any person transacting business with the Department in a representative capacity may be required to show ~~his/her~~ his or her authority to act in that capacity.

~~RH-4017. (Cont'd)~~

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b. In a formal hearing a person may appear in person or be represented by an Attorney-at-Law.

RH-4018. **Intervention**.

a. Any person whose interests may be affected by a proceeding may file a petition to intervene not later than five (5) days before the commencement of the hearing or within such other time as may be specified in the notice, or as permitted by the Hearing Officer, describing ~~his/her~~ his or her interest, how it may be affected by Department action and the position ~~he/she~~ he or she is taking in the matter.~~-~~ Service of copies of the petition shall be made upon all parties to the proceeding. ~~-~~The Department, licensee, registrant, or applicant, upon notice and motion and other parties by leave, may contest the right of the petitioner to intervene.~~-~~ A petition for leave to intervene which is not timely filed will be dismissed unless the petitioner shows good cause for failure to file it on time.

b. As soon as it is practicable after filing of a petition for intervention and a hearing of argument, if any, the Director or Hearing Officer will issue and serve an order either permitting or denying intervention. ~~-~~If the order is a denial of intervention, it shall contain a statement of the grounds.~~-~~ An order permitting intervention may be conditioned upon such terms as the Director or Hearing Officer may direct.

RH-4019. **Effect of Intervention or Denial Thereof**.

A person permitted to intervene becomes a party to the proceeding.

a. Where a notice of hearing has been issued or a hearing has begun, the admission thereafter of an intervener shall not of itself enlarge or alter the issues without amendment as provided in paragraph c of this section.

b. An order denying intervention will be without prejudice to any proposed limited appearance by the petitioner as one who is not party for the purposes provided in RH-4023.

c. At any time prior to the time fixed for hearing but not later than five (5) days prior, the party concerned may amend the petition for intervention by filing an amendment and serving it upon the parties. At any time thereafter, amendments may be permitted at the discretion of the Hearing Officer upon such terms as ~~he/she~~ he or she shall prescribe.

RH-4020. **Consolidation**.

Upon motion and good cause shown or upon its own initiative, the Department or Hearing Officer may consolidate two or more proceedings.

RH-4021. **Hearings - Formal and Informal**.

a. Formal hearings will be held in cases of adjudication of rights.

b. Informal hearings will normally be held for the purposes of obtaining necessary or useful information.

RH-4022. **Authority to Administer Oaths**.

Any oath or affirmation required by or pursuant to the provisions of these Rules may be administered by any person authorized to administer oaths by the laws of the State of Arkansas.

RH-4023. **Informal Hearings Procedure**.

The procedure to be followed in informal hearings shall be such as will best serve the purpose of the hearing. For example, an informal hearing may consist of the submission of written data, views or arguments with or without oral argument, or may partake of the nature of a conference or may assume some of the aspects of a formal hearing in which the subpoena of witnesses and the production of evidence may be permitted or directed. A formal transcript is not necessarily required.

RH-4024. **Formal Hearings**.

The parties to a formal hearing shall be the Department, the licensee, registrant or applicant as the case may be and any person permitted to intervene pursuant to RH-4018.

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RH-4025. **Limited Appearances by Persons Not Parties**.

With the consent of the Hearing Officer, limited appearances may be entered by persons who are not parties to a hearing without request for or grant of permission to intervene. With the consent of the Hearing Officer and on due notice to the parties, such persons may make oral or written statements of their position on the issues involved in the proceeding but may not otherwise participate in the hearing.

RH-4026. **Designation of Hearing Officer**.

The hearings herein provided for may be conducted by the Director or the Director may designate Hearing Officers who shall have the power and authority to conduct hearings in the name of the Department at any reasonable time and place.

RH-4027. **Function of Hearing Officer**.

The function of the Hearing Officer is to schedule and conduct hearings on behalf and in the name of the Department on all matters referred for hearing by the Director. It is the duty of the Hearing Officer to cause to be prepared and furnished to the Director for decision, a complete written transcript of the record of the hearing which contains all evidence introduced at the hearing and all pleas, motions, objections and ruling of the Hearing Officer.

RH-4028. **Notice of Hearing**.

a. Whenever a hearing is granted, the Department will give timely notice of the hearing to all parties and to other persons, if any, entitled to notice. Such notice will state the time, place and nature of the hearing; the legal authority and jurisdiction under which the hearing is to be held; the matters of fact and law asserted or to be considered; and a request for an answer. The time and place for hearing will be fixed with due regard for the convenience and necessity of the parties or their representatives.

b. The notice of hearing may be a separate notice or when appropriate may be embodied in the order issued pursuant to RH-4009.

RH-4029. **Answer**.

a. Within the time allowed by the notice of hearing for filing and serving an answer, and as required, the answer of a licensee, registrant, or applicant shall fully advise the Department and any other parties as to the nature of the defense or other position of the answering party, the issues ~~he/she~~ he or she proposes to controvert and those ~~he/she~~ he or she does not controvert, and whether or not ~~he/she~~he or she proposes to appear and present evidence. If facts are alleged, the answer shall admit or deny

specifically each allegation of fact; or where knowledge is lacking, the answer may so state and the statement shall operate as a denial. Allegations of fact not denied shall be deemed to be admitted. ~~-~~Matters alleged as affirmative defenses or positions shall be separately stated and identified and, in the absence of a reply, shall be deemed to be controverted. ~~-~~The answer of an intervener shall fully advise the Department and other parties of ~~his/her~~ his or her position and whether or not ~~he/she~~ he or she proposes to appear and present evidence.

b. If a party does not oppose any order or proposed action of the Department embodied in or accompanying the notice of hearing or does not wish to appear and give evidence at the hearing, the answer shall so state.~~-~~ In lieu of appearing, the party may, if ~~he/she~~he or she chooses, submit a notarized statement of reasons why the proposed order or sanction should not be issued or should be different than proposed, and the Department will attribute such weight as it deems deserving to the written reasons.

RH-4030. **Reply**.

In appropriate cases the Department may file and serve a reply to the answer or, if the answer affects other parties to the proceeding, the Director or the Hearing Officer may permit such parties to file and serve a reply.

RH-4031. **Default**.

Failure of a party to file and serve an answer within the time provided in the notice of hearing or as prescribed herein or to appear at a hearing shall be deemed to authorize the Department, at its discretion, as to such party:

a. To find the facts alleged to be true and to enter such finding or order as may be appropriate, without further notice or hearing; or

b. To proceed to take proof, without further notice, on the ~~Allegations or issues set forth in the Specification of I~~issues specified.

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RH-4032. **Admissions**.

~~———~~After answer has been filed, any party may file and serve upon the opposing side a written request for the admission of the genuineness and authenticity of any relevant documents described in or attached to the request or for the admission of the truth of any relevant matters of fact stated in the request. Each matter for which an admission is requested shall be deemed admitted unless within the time designated in the request, but not less than ten (10) days after service thereof or such further time as the Hearing Officer may allow upon

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motion and notice, the party to whom the request is directed serves upon motion and notice, ~~the party to whom the request is directed serves upon the requesting party~~ a sworn statement

~~RH-4032. (Cont'd)~~

either denying the matters upon which the admission is requested or setting up the reasons why ~~he/she~~he or she cannot truthfully admit or deny such matters.

RH-4033. **Pre-hearing Conferences**.

a. In order to provide opportunity for the settlement of a proceeding or any of the issues therein or for agreement upon procedural and other matters, there may be held at any time prior to or during a hearing, upon due notice of the time and place given to all parties, such conferences of the parties as, in the discretion of the Hearing Officer, time, the nature of the proceeding, and the public interest may permit.

~~RH-4033. (Cont'd)~~

b. Action taken at a pre-hearing conference may be recorded for appropriate use at the hearing in the form of a written stipulation among the parties reciting the matters upon which there has been an agreement. The stipulation shall be binding upon the parties thereto.

RH-4034. **Public Hearings**.

All formal hearings shall be public except in cases involving restricted data.

RH-4035. **Evidence in Formal Hearings**.

a. Every party to the hearing shall have the right to present such oral or documentary evidence and rebuttal evidence and conduct such cross-examination as may be required for a full and true disclosure of the facts. The parties shall be encouraged to present evidence in written form.

b. The Hearing Officer shall exclude all irrelevant, immaterial, or unduly repetitious evidence.

c. Objections to the admission or exclusion of evidence shall state the grounds of objections. The transcript shall include the objections, the grounds and the rulings, but not the argument of the grounds, unless ordered by the Hearing Officer.

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d. Any offer of proof made in connection with an objection taken to the ruling of the Hearing Officer, excluding or rejecting proffered oral testimony, shall consist of a statement of substance of the evidence which the party contends would be adduced by such testimony. If the excluded material is documentary or written, a copy of such material shall be marked for identification and shall constitute the offer of proof.

e. An official record of a governmental agency or an entry in such record, when admissible, may be evidenced by an official publication thereof or by a copy attested as a true copy by the officer having legal custody of the record, or by ~~his/her~~ his or her deputy and accompanied by a certificate that such officer has the custody.

RH-4036. **Briefs**.

Briefs may be filed within ten (10) days after the close of the hearing provided, however, that the Director may, upon written application, grant an additional period of time not in excess of sixty (60) days within which briefs may be filed.

RH-4037. **Findings and Order**.

The Director shall, after reviewing the entire record of the hearing, make ~~his/her~~ his or her findings and enter ~~his/her~~his or her order. The findings and order shall be in writing and shall contain a statement of findings and conclusions upon all material issues of fact and law and shall be signed by the Director. The original thereof shall be filed as a part of the record of the case which shall be retained in the custody of the Director unless an appeal is taken therefrom, and one certified copy of the findings and order shall be served on all parties to the proceeding.

RH-4038. **Appeals from Decision of Director**.

Any person who is aggrieved by any ruling, decision, or action of the Director may appeal to the State Board of Health within thirty (30) days after service of said ruling, decision, or action by filing with the President of the State Board of Health a written complaint setting out the ruling, decision, or action complained of, the reason that such person is aggrieved and the relief sought by such person. A copy of such complaint shall also be served by the appealing party upon any other party in interest. No new evidence shall be introduced, and the appeal shall be tried upon the record prepared by the Director or Hearing Officer. Additional briefs and oral arguments may be granted by the State Board of Health. The State Board of Health may affirm the Findings and Order of the Director or may reverse, modify, or remand the case for further proceedings. Copies of the State

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Board of Health Order shall be served upon the parties in interest as provided in RH-4037.

RH-4039. **Waiver of Procedures**.

The parties to any hearing may agree to waive any one or more of the procedural steps which would otherwise precede the reaching of a final decision by the Department.

RH-4040. **Public Records - Exceptions**.

a. Except as provided below, all records shall be deemed public records and shall be open to inspection by the public. The following are not to be considered public records which are available for public inspection:

~~RH-4040. (Cont'd)~~

~~a~~1. ~~Documents relating to personnel matters and medical and other personal information, which, under general government personnel practices, are not normally made public.~~ Personnel and medical files and similar files, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;

~~b. Intra-agency and inter-agency communications, including memoranda, reports, correspondence and staff papers prepared by members of the Department personnel or by any other government agency for use within the Department or within the executive branch of the Government.~~

~~c~~2. Records and reports of investigations.

~~d~~3. Documents classified as restricted data under the Atomic Energy Act of 1954, as amended, or classified under Executive Order of the President of the United States as restricted data.

~~e. Correspondence received in confidence by the Department relating to an alleged or possible violation of any statute, rule, order, license, registration, or permit.~~

~~f. Any other document involving matters of internal Department management.~~

4. Trade secrets and commercial or financial information that is obtained from a person and that is privileged or confidential; and

~~g~~5. Any other matter required by law to be kept confidential or not available ~~to~~ for public inspection.

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~~h~~b. The Department may withhold any document or part thereof from public inspection if disclosure of its contents is not required in the public interest and would adversely affect the interest of a person concerned. -Such withholding from public inspection shall not, however, affect the right of persons properly and directly concerned to inspect the document. -Persons requesting that documents or information therein be withheld from public disclosure shall make prompt application identifying the material and giving the reasons. -Where the applicant is responsible for the preparation

of the document, ~~he/she~~he or she shall, insofar as is possible, segregate in a separate paper the information for which the special treatment is requested. -The Department may honor the request upon a finding that public inspection is not required in the public interest and would adversely affect the interest of the person concerned.- If the request is denied, the applicant will be notified thereof with a statement of the reasons.

RH-4041.- RH-4999.– _Reserved.

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SECTION 6.
LICENSES AND RADIATION SAFETY REQUIREMENTS FOR PARTICLE ACCELERATORS

PART A.
GENERAL

RH-5000. **Authority**. Act 8 of Second Extraordinary Session of 1961, as amended.

RH-5001. **Effective Date**. January 1, 1972.

RH-5002. **Purpose and Scope**.

a. This Section establishes procedures for the licensing and the use of particle accelerators.

b. In addition to the requirements of this Section, all licensees are subject to applicable requirements in Sections 3 and 4. Licensees engaged in industrial radiographic operations are subject to the applicable requirements in Part I of Section 3. Licensees engaged in well-logging operations are subject to the applicable requirements of Part J of Section 3. Licensees who use an accelerator for medical therapy are subject to the applicable requirements in Section 11.

c. **Production of radioactive material**.

1. A licensee who produces radioactive material incidentally as a result of the operation of an accelerator shall comply with the license requirements of RH-402.n.

2. A licensee who produces radioactive material intentionally as a result of the operation of an accelerator shall comply with the specific license requirements of Section 2.

RH-5003. **Fees**.

In accordance with Arkansas Code Annotated §20-21-217, annual fees for licensing shall be paid. Applicants shall be charged for a full calendar year

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regardless of the month the license is issued. ~~-~~Nonpayment of fees shall result in escalated enforcement action ~~and/or~~ or revocation of license.

a. The Accelerator License Fees are as follows:

CATEGORY	FEE
Particle accelerator, non-medical	$200
Particle accelerator, medical, non-hospital unit	$450 per unit ($300 for each additional unit)
Cyclotron/accelerator for the production of radioactive material	$3,750

b. Other fees are as follows:

CATEGORY	FEE
Arkansas State Board of Health Rules for Control of Sources of Ionizing Radiation	$0 for first hard copy $30 for each additional hard copy
Amendment to existing license	$50 per amendment

c. Reciprocity fees are as follows:

CATEGORY	FEE
Particle accelerator, industrial	$200

RH-5004. **Communications**.

Except where otherwise specified, all communications concerning these Rules may be addressed to the Arkansas Department of Health, Radiation Control Section, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

RH-5005. **Interpretations**.

Except as specifically authorized by the Department in writing, no interpretations of the meaning of the rules in this Section by an officer or employee of the Department other than a written interpretation by the Department Director or designee will be recognized as binding upon the Department.

RH-5006. **Completeness and Accuracy of Information.**

a. Information provided to the Department by an applicant for a license or by a licensee or information required by statute or by the Department's rules,

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orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects.

b. Each applicant or licensee shall notify the Department of information identified by the applicant or licensee as having for the regulated activity a significant implication for public health and safety or property. An applicant or licensee violates this paragraph only if the applicant or licensee fails to notify the Department of information that the applicant or licensee has identified as having a significant implication for public health and safety or property. Notification shall be provided to the Department within two (2) business days of identifying the information. This requirement is not applicable to information which is already required to be provided to the Department by other reporting or updating requirements.

RH-5007. **Deliberate Misconduct**.

a. Any licensee, applicant for a license, employee of a licensee or of an applicant for a license; or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any licensee or of an applicant for a license, who knowingly provides to any licensee, applicant, contractor or subcontractor, any components, equipment, materials, or other goods or services that relate to a licensee's or applicant's activities subject to this Section, may not:

1. Engage in deliberate misconduct that causes or would have caused, if not detected, a licensee or applicant to be in violation of any rule or order; or any term, condition, or limitation of any license issued by the Department; or

2. Deliberately submit to the Department, a licensee, an applicant, or a licensee's or applicant's, contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the Department.

b. A person who violates paragraph a.1. or a.2. of this section may be subject to enforcement action in accordance with the procedures in RH-5700.

c. For purposes of paragraph a.1. of this section, deliberate misconduct by a person means an intentional act or omission that the person knows:

1. Would cause a licensee or applicant to be in violation of any rule or order; or any term, condition, or limitation of any license issued by the Department; or

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2. Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a licensee, applicant, contractor, or subcontractor.

RH-5006~~8~~.- RH-5099.– _Reserved.

PART B.
DEFINITIONS

RH-5100. **Definitions**.

Accelerator or Particle Accelerator - Any machine capable of accelerating electrons, protons, deuterons or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 MeV. Therapeutic radiation machines capable of generating energies at or above 500 kV/keV shall be considered particle accelerators.

Accelerator License - Except where otherwise specified, a license issued pursuant to these Rules.

Act - Act 8 of Second Extraordinary Session of 1961, as amended.

Calibration - The determination of the response or reading of an instrument relative to a series of known radiation values over the range of the instrument, or the strength of a source of radiation relative to a standard.

Control panel - The part of the radiation machine where the switches, knobs, push buttons, and other hardware necessary for manually setting the technique factors are located. For purposes of this Section, console is an equivalent term.

Department - Arkansas Department of Health.

Dosimetry system - A system of devices used for the detection, measurement, and display of qualitative and quantitative radiation exposures.

Government agency - Any executive department, commission, independent establishment, corporation, wholly or partly owned by the United States of America, which is an instrumentality of the United States, or any board, bureau, division, service, office, officer, authority, administration, or other establishment in the executive branch of the Government.

High Radiation Area -- An area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 0.1 rem (1 mSv) in 1 hour at 30 centimeters from the radiation source or 30 centimeters from any surface that the radiation penetrates.

Human use - The internal or external administration of radiation or radioactive material to human beings.

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Individual - Any human being.

Industrial radiography - The examination of the structure of materials by non-destructive methods utilizing a particle accelerator.

~~RH-5100. (Cont'd)~~

Interlock - A device preventing the start or continued operation of equipment unless certain predetermined conditions prevail.

Licensee - Any person who is licensed by the Department in accordance with these Rules and the Act.

Operator - A person qualified by training and experience to assume responsibility for the safe operation of a particle accelerator.

Person –

1. Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency of this state, political subdivision of this state, any other state or political subdivision or agency thereof; and

2. Any legal successor, representative, agent, or agency of the foregoing, but not including United States Government agencies.

Personnel monitoring equipment - Devices designed to be worn by a single individual for the assessment of dose equivalent. Examples of personnel monitoring equipment are film badges, thermoluminescent dosimeters (TLDs), pocket ionization chambers, optically stimulated luminescence (OSL) dosimeters and personal ("lapel") air sampling devices.

Qualified Expert - An individual specifically approved by the Department as having the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection matters. Individuals shall be certified in an appropriate field, commensurate with ~~his/her~~ his or her duties, either by the American Board of Radiology, the American Board of Health Physics, the American Board of Medical Physics, or the Canadian College of Physicists in Medicine, or individuals may have equivalent qualifications.
An individual that meets the qualifications in RH-10200.d. for a Qualified Medical Physicist also meets the qualifications of a Qualified Expert.

Radiation - Ionizing radiation, i.e., gamma rays and x-rays, alpha and beta particles, neutrons, high speed electrons, high speed protons, and other particles

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capable of producing ions. Radiation, as used in these Rules, does not include non-ionizing radiation, such as radio waves or microwaves, or visible, infrared, or ultraviolet light.

Radiation Safety Officer - An individual who has the knowledge and responsibility to apply appropriate radiation protection rules and has been assigned such responsibility by the licensee.

~~RH-5100. (Cont'd)~~

Research and Development -

1. Theoretical analysis, exploration, or experimentation; or

2. The extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes.

Research and Development does not include the internal or external administration of radiation or radioactive material to human beings.

Test - The process of verifying compliance with an applicable rule.

Very high radiation area - An area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving an absorbed dose in excess of 500 rads (5 grays) in one (1) hour at one (1) meter from a radiation source or from any surface that the radiation penetrates.

Note: At very high doses received at high dose rates, units of absorbed dose (e.g., rads and grays) are appropriate, rather than units of dose equivalent (e.g., rems and sieverts).

RH-5101. RH-5199. Reserved.

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PART C.
LICENSES

RH-5200. **License Requirement**.

Except for persons exempt as provided in RH-5214. and RH-5600., no person shall receive, possess, use, transfer, own or acquire a particle accelerator except as authorized in a license issued pursuant to this Section.

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RH-5201. **Licensing Procedures**.

a. Application for accelerator licenses shall be filed on forms supplied by:

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Radiation Control Section
Arkansas Department of Health
4815 West Markham Street, Slot 30
Little Rock, Arkansas 72205-3867

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The application shall set forth all applicable information called for by the form.

b. The Department may at any time after the filing of the original application and before the expiration of the license, require further statements in order to enable the Department to determine whether the application will be granted or denied or whether a license should be modified or revoked.

c. Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on his behalf.

d. In the application, the applicant may incorporate, by reference, information contained in previous applications, statements, or reports filed with the Department, provided that such references are clear and specific.

e. Applications and documents submitted to the Department may be made available for public inspection except that the Department may withhold any document or part thereof from public inspection if disclosure of its contents is not required in the public interest and would adversely affect the interest of a person concerned.

~~RH-5201. (Cont'd)~~

f. The Department may verify information contained in applications and secure additional information deemed necessary to make a reasonable determination as to whether to issue a license and whether special conditions should be attached thereto by visiting the facility or location where a particle accelerator would be located and used and by discussing details of proposed use of the particle accelerator with the applicant or his designated representative.

g. Every person possessing a particle accelerator on the effective date of these Rules shall have a period of ninety (90) calendar days in which to make application for a license.

RH-5202. **General Requirements for the Issuance of a License for Particle Accelerators**.

A license application will be approved if the Department determines that:

a. The applicant is qualified by reason of training and experience to use the accelerator in question for the purpose requested in accordance with this Section and Section 3 in such a manner as to minimize danger to public health and safety or property;

b. The applicant's proposed equipment, facilities, and operating and emergency procedures are adequate to protect health and minimize danger to public health and safety or property;

c. The issuance of the license will not be inimical to the health and safety of the public;

d. The applicant demonstrates that particle accelerator operators have substantial training and experience concerning the requested uses of the accelerator;

e. The applicant has appointed a Radiation Safety Officer; and

f. The applicant satisfies any applicable special requirements in RH-5203.

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RH-5203. **Special Requirements for the Issuance of a License for Certain Types of Particle Accelerators**.

a. **Use of particle accelerators in medical therapy**.

In addition to the requirements set forth in RH-5202., a license for use of a particle accelerator in medical therapy will be issued only if:

1. The applicant has appointed a medical committee of at least three members to evaluate all proposals for research, diagnostic, and therapeutic use of a particle accelerator within that facility. Membership of the committee should include physicians expert in internal medicine, hematology, and therapeutic radiology; a person experienced in depth dose calculations and protection against radiation; and a representative of the facility's management;

2. Prospective Authorized User physicians meet training and experience requirements specified in Section 11; and

3. The applicant has developed an adequate training program for particle accelerator operators in accordance with the provisions of RH-5411.

b. **Use of particle accelerators in research and development**.

In addition to the requirements of RH-5202., a license for the use of a particle accelerator in research and development will be issued only if:

1. Whenever deemed necessary by the Department, the applicant has established a Radiation Safety Committee to approve, in advance, proposals for uses of particle accelerators in research and development; and

2. The applicant has developed an adequate training program for particle accelerator operators in accordance with the provisions of RH-5411.

c. **Use of particle accelerators for the production of radioactive material**.

In addition to the requirements of RH-5202., a license for the use of a particle accelerator to produce radioactive material will be issued only if:

1. The applicant has developed an adequate training program for particle accelerator operators in accordance with the provisions of

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RH-5411; and

~~RH-5203. (Cont'd)~~

2. The applicant has applied for a radioactive material specific license in accordance with the requirements of Section 2.

d. **Use of particle accelerators in industrial radiography**.

In addition to the requirements of RH-5202., a license for the use of a particle accelerator in industrial radiography will be issued only if:

1. The applicant has developed an adequate training program for radiographers and radiographer's assistants in accordance with the provisions of RH-5411.

RH-5204. **Issuance of Particle Accelerator Licenses**.

Upon a determination that an application meets the requirements of the Act and these Rules of the Department, the Department will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary to effectuate the purposes of the Act.

RH-5205. **Specific Terms and Conditions of Licenses**.

a. Each license issued pursuant to this Section shall be subject to all the provisions of the Act, now or hereafter in effect, and to all rules and orders of the Department.

b. No license issued under this Section and no right to possess or utilize a particle accelerator granted by any license issued pursuant to this Section shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Department shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing.

c. Each person licensed by the Department pursuant to this Section shall confine use and possession of the particle accelerator licensed to the locations and purposes authorized in the license. Any change in facility or location must be approved by the Department.

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~~RH-5205. (Cont'd)~~

d. The Department may incorporate in any license at the time of issuance, or thereafter by appropriate rule, or order, such additional requirements and conditions with respect to the licensee's use of a particle accelerator as it deems appropriate or necessary in order to:

1. Protect health or to minimize danger to life or property; and

2. Require such reports and the keeping of such records, and to provide for such inspection of activities under the license as may be necessary or appropriate to effectuate the purposes of the Act and these Rules thereunder.

e. **Bankruptcy notification**.

1. Each licensee shall notify the Department, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title II (Bankruptcy) of the United States Code by or against:

A. The licensee;

B. An entity (as that term is defined in 11 U.S.C. 101(15)) controlling the licensee or listing the license or licensee as property of the estate; or

C. An affiliate (as that term is defined in 11 U.S.C. 101 (2)) of the licensee.

2. This notification must indicate:

A. The bankruptcy court in which the petition for bankruptcy ~~court~~ was filed; ~~and~~

B. The case name and number; and

C~~B~~. The date of the filing of the petition.

RH-5206. **Expiration and Termination of Licenses.**

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a. Except as provided in RH-5206.e.3.A. and RH-5207.b., each particle accelerator license shall expire at the end of the day, in the month and year stated therein.

b. Expiration of the license does not relieve the licensee of the requirements of these Rules.

~~RH-5206. (Cont'd)~~

c. Each license revoked by the Department expires with the Department's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by Department Order.

d. When a licensee decides to permanently discontinue activities involving accelerators authorized under the license, the licensee shall immediately notify the Department of such, in writing, and request termination of the license. Actions completed by the licensee and information submitted to the Department shall be as that required in paragraph e of this section.

e. 1. If a licensee does not submit an application for renewal of the license in accordance with RH-5207, the licensee shall, on or before the expiration date specified in the license:

A. Terminate the use of all particle accelerators;

B. Request termination of the license in writing;

C. Submit to the Department a record of the disposition of the accelerators, and if transferred, to whom they were transferred;

D. Properly dispose of incidentally produced radioactive material generated by the operation of an accelerator;

E. Submit to the Department a record of the disposition of incidentally produced radioactive material generated by the operation of an accelerator;

F. Submit to the Department, for its approval, a final status radiation survey plan that addresses all incidentally produced radionuclides specific to the site;

G. Conduct a radiation survey of the premises as delineated in the approved survey plan and submit a report of the results of this survey to confirm the absence of radioactive material or to establish the levels of radioactive contamination, unless the Department approves an alternate

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method for demonstrating that the premises are suitable for release. The survey report shall specify the instrumentation used and certify that each instrument was properly calibrated and tested. The licensee shall, as applicable, report levels or quantities of:

~~RH-5206.e.1.G. (Cont'd)~~

i. Beta radiation at 1 centimeter from surfaces and gamma radiation at 1 centimeter and 1 meter from surfaces (in units, multiples, or submultiples of rem or seiverts per hour or microroentgens per hour);

ii. Removable and fixed radioactivity on surfaces (in units, multiples, or submultiples of curies or becquerels per 100 square centimeters or in disintegrations per minute per 100 square centimeters);

iii. Radioactivity in contaminated liquids such as water or oil (in units, multiples, or submultiples of curies or becquerels per milliliter or per gram); and

iv. Radioactivity in contaminated solids such as soils or concrete (in units, multiples, or submultiples of curies or becquerels per gram).

2. If no incidentally produced radioactive contamination attributable to activities conducted under the license is detected, the licensee shall submit a certification that no detectable radioactive contamination was found. The Department will notify the licensee, in writing, of the termination of the license, once the certification has been approved.

3. A. If detectable levels of incidentally produced radioactive contamination attributable to activities conducted under the license are found, the license continues in effect beyond the expiration date, if necessary, until the Department notifies the licensee, in writing, that the license is terminated.

B. In addition to the information submitted under RH-5206.e.1. C., E., F., and G., the licensee shall submit a plan for decontamination and disposal, if required by the Department.

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f. Each accelerator licensee who possesses incidentally produced radioactive material and whose license is to be terminated pursuant to paragraph d or e of this section shall:

~~RH-5206.e. (Cont'd)~~

1. Limit actions involving radioactive material to those related to decontamination and to other activities related to preparation for release for unrestricted use; and

2. Continue to control entry to restricted areas until they are suitable for release for unrestricted use and until the Department notifies the licensee in writing that the license is terminated.

RH-5207. **Renewal of Licenses**.

a. Application for renewal of an accelerator license shall be filed in accordance with RH-5201.

b. In any case in which a licensee, not less than thirty (30) calendar days prior to expiration of this existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until the application status has been determined by the Department.

RH-5208. **Amendment of License at Request of Licensee**.

Applications for amendment of a license shall be filed in accordance with RH-5201. and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

RH-5209. **Department Action on Applications to Renew or Amend**.

In considering an application by a licensee to renew or amend the license, the Department will apply the criteria set forth in RH-5202. and RH-5203., and in Sections 3, 6, and 11 as applicable.

RH-5210. Deleted.

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RH-5211. **Modification, Suspension, and Revocation of Licenses**.

a. The terms and conditions of all licenses shall be subject to revision or modification. A license may be suspended or revoked by reason of amendments to the Act, or by reason of rules or orders issued by the Department.

b. Any license may be revoked, suspended, or modified, in whole or in part, for any of the following:

1. Any material false statement in the application or any statement of fact required under provisions of the Act or of these Rules;

2. Conditions revealed by such application or statement of fact or any report, record, or inspection or other means that would warrant the Department to refuse to grant a license on an original application;

3. Violation of, or failure to observe any of, the terms and conditions of the Act, or the license, or of any rule or order of the Department; or

4. Existing conditions that constitute a substantial threat to public health or safety or the environment.

c. Except in cases of willful violation or those in which the public health, interest, or safety requires otherwise, no license shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefor, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing, and the licensee shall have been accorded opportunity to demonstrate or achieve compliance with all lawful requirements.

d. Deleted. See RH-5206.

RH-5212. **Licensure of Out-of-State Particle Accelerators for Non-Industrial Use**.

a. An out-of-state particle accelerator licensee, or registrant seeking to bring a particle accelerator into the State for non-industrial use shall apply for an Arkansas particle accelerator license in accordance with Part C of this Section.

b. Annual fees for licensing shall be paid in accordance with RH-5003.

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c. The licensee shall notify the Department in writing at least three (3) working days prior to the accelerator's use in the State.- The notice shall include the following:

1. Type of particle accelerator;

2. Nature, duration, and scope of use; and

3. Exact location(s) where the particle accelerator is to be used.

d. If, for a specific case, the three (3) day period would impose an undue hardship, the licensee may, at the determination of the Department, obtain permission to proceed sooner.

RH-5213. **Report of Changes**.

The licensee shall notify the Department in writing before making any change that would render the information contained in the license application ~~and/or~~ or the license no longer accurate.

RH-5214. **Reciprocal Recognition of Out-of-State Particle Accelerator Licenses for Industrial Use**.

a. Whenever any particle accelerator is brought into the State for any temporary industrial use, the person proposing to bring such a machine into the State shall apply for and receive a notice from the Department granting reciprocal recognition prior to beginning operations. -The request for reciprocity shall include the following:

1. Type of particle accelerator;

2. Nature, duration, and scope of use;

3. Exact location(s) where the particle accelerator is to be used;

4. Copy of the person's current license or equivalent document;

5. Qualifications for each radiographer who will be working in Arkansas if the reciprocity request is for industrial radiography as defined in Part I of Section 3; and

6. Applicable fee as specified in RH-5003.

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b. Upon a determination that the request for reciprocity meets the requirements of the Department, the Department may issue a notice granting reciprocal recognition authorizing the proposed use.

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c. Once reciprocity is granted, the out-of-state licensee shall notify the Department in writing prior to each entry into the State. This notice shall be submitted at least three (3) working days before the particle accelerator is to be used in the State. If, for a specific case, the three (3) day period would impose an undue hardship, the out-of-state licensee may, at the determination of the Department, obtain permission to proceed sooner.

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d. The out-of-state licensee shall:

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1. Comply with all applicable rules of the Department and with all the terms and conditions of the out-of-state license, except any such terms and conditions that may be inconsistent with applicable rules of the Department;

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2. Supply the Department with such other information as the Department may reasonably request; and

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3. Only operate in the State for 180 or less calendar days per year.

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e. Use in excess of 180 days per calendar year requires a license in accordance with Part C of this Section.

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f. If the State from which the particle accelerator is brought does not issue licenses or equivalent documents, a license shall be obtained from the Department in accordance with Part C of this Section.

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g. The Department may withdraw, limit, or qualify its acceptance of any license or equivalent document issued by another State upon determining that the action is necessary to prevent undue hazard to occupational or public health and safety.

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RH-5215.- RH-5299. Reserved.

PART D.
[RESERVED]

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RH-5300.- RH-5301.– _Deleted.- See Part G of this Section.

RH-5302.- RH-5399.– _Reserved.

PART E.
RADIATION SAFETY REQUIREMENTS FOR THE USE OF PARTICLE ACCELERATORS

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RH-5400. **General Provisions.**

This Part establishes radiation safety requirements for the use of particle accelerators. The provisions of this Part are in addition to, and not in substitution for, other applicable provisions of these Rules.

RH-5401. **Limitations.**

a. No licensee shall permit any individual to act as particle accelerator operator until such individual:

1. Has been instructed in the subjects detailed in RH-5410. and has demonstrated an understanding thereof;

2. Has received copies of and instruction in this Section, the applicable requirements of Section 3, pertinent license conditions, and the licensee's operating and emergency procedures, and has demonstrated understanding thereof; and

3. Has demonstrated competence to use the particle accelerator, related equipment, and survey instruments that will be utilized by the individual.

b. In addition to the initial training requirements in paragraph a. of this section, the training program for accelerator operators shall also include refresher training at intervals not to exceed twelve (12) months and training to be conducted when a significant change occurs in duties, rules, or terms of the license.

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c. ~~Operators of~~ Radiographers using particle accelerators for industrial radiography shall have successfully completed the x-ray portion of a radiographer certification exam. A radiographer's assistant may operate an accelerator for industrial radiography only when under the ~~direct~~ supervision of a radiographer. Training and supervision requirements in Part I of Section 3 shall be met.

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d. Training records pursuant to paragraphs a. through c. of this section shall be maintained for five (5) years beyond the last date the individual was authorized to operate an accelerator at that facility.

~~RH-5401. (Cont'd)~~

e. The Radiation Safety Officer shall have the authority to restrict or terminate operations at an accelerator facility if such action is deemed necessary to minimize danger to health and safety, property, or the environment.

f. The accelerator facility shall operate within the terms and conditions of the license issued for the operation of the accelerator.

RH-5402. **Shielding and Safety Design Requirements.**

a. A Qualified Expert shall be consulted in the shielding design of a particle accelerator installation.

b. Each accelerator installation shall be provided with such primary ~~and/or~~ or secondary barriers as are necessary to ensure compliance with RH-1200. and RH-1208. All protective barriers shall be fixed except for entrance doors or movable beam interceptors.

c. For portable or mobile accelerators, such as neutron generators that are used at temporary job sites where permanent shielding is not available, radiation protection shall be provided by temporary shielding or by providing an adequate exclusion area around the accelerator while it is in use.

RH-5403. **Accelerator Controls and Interlock Systems.**

a. Instrumentation, readouts, and controls on the accelerator control console shall be clearly identified and easily discernible.

b. All entrances into a target room or other high or very high radiation area shall have interlocks that meet the requirements of RH-1303. regarding the control of access to high and very high radiation areas. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation or treatment by manual action at the control panel.

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c. When an interlock system has been tripped, it shall only be possible to resume operation of the accelerator by manually resetting controls at the interlock position and lastly at the main control console.

d. Each safety interlock shall be on an electrical circuit that allows the interlock to operate independently of all other safety interlocks.

~~RH-5403. (Cont'd)~~

e. All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the accelerator.

f. A scram button or other emergency power cut-off switch shall be located and easily identifiable in all high and very high radiation areas. The cut-off switch shall include a manual reset so that the accelerator cannot be restarted from the accelerator control console without resetting the cut-off switch.

g. The control panel shall be located outside the treatment or irradiation room.

RH-5404. **Warning Devices.**

a. In medical facilities, each high and very high radiation area and entrances to such locations shall be equipped with a continuously-operating warning light system that operates when, and only when, radiation is being produced.

b. In non-medical facilities, each high and very high radiation area and entrances to such locations shall be equipped with an easily observable flashing or rotating warning light system that operates when, and only when, radiation is being produced.

c. In non-medical facilities, each high and very high radiation area shall have an audible warning device that is activated for 15 seconds prior to creation of the high or very high radiation area. The audible warning shall be clearly discernible in the high or very high radiation area and in any adjacent high radiation areas and radiation areas.

d. High and very high radiation areas shall be conspicuously posted in accordance with RH-1303.

e. The safety interlock system shall have a visible or audible alarm that will indicate when any interlock has been activated.

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RH-5405. **Operating Procedures.**

a. Particle accelerators, when not in operation, shall be secured to prevent unauthorized use.

~~RH-5405. (Cont'd)~~

b. Only a button~~/~~ or switch on the accelerator control console shall be routinely used to turn the accelerator beam on and off.~~-~~ The safety interlock system shall not be used to turn off the accelerator beam except in an emergency or for testing the interlock.

c. All safety and warning devices, including interlocks, shall be checked for proper operability at intervals not to exceed three (3) months and shall be repaired as necessary. ~~-~~Results of these checks and records of repairs shall be maintained for five (5) years at the accelerator facility for inspection by the Department.

d. Electrical circuit diagrams of the accelerator and the associated safety, warning, and interlock systems shall be kept current and maintained for inspection by the Department.~~-~~ These diagrams shall also be available to the operator at each accelerator facility.

e. If, for any reason, it is necessary to intentionally bypass a safety interlock or interlocks, such action shall be:

   1. Authorized in writing by the Radiation Safety Committee or the Radiation Safety Officer;

   2. Recorded in a permanent log and posted as a notice at the accelerator control console and at any affected interlock; and

   3. Terminated as soon as possible.

f. In the event of a malfunction of a safety or warning device, the accelerator shall not be operated unless appropriate interim precautions are instituted to provide equivalent protection.

g. A copy of the current operating and emergency procedures shall be maintained at the accelerator control console.

h. For accelerators used to irradiate materials by means of a transfer or conveyance system, a means shall be provided that either terminates the

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irradiation or prevents entry if an individual attempts to access the irradiation room.

~~RH-5405. (Cont'd)~~

i. Windows, mirrors, closed-circuit television, or an equivalent viewing system shall be provided to permit continuous observation of material being irradiated and any transfer or conveyance of material within an irradiation room. The viewing system shall be so located that the operator can observe the material being irradiated from the control panel. The accelerator shall not be used for irradiation unless at least one viewing system is operational.

j. Records of maintenance ~~and/or~~ or modifications performed on an accelerator shall be maintained, including the names of persons who performed the services. The licensee shall keep these records for inspection by the Department for five (5) years.

k. Preventative maintenance on an accelerator shall be performed in accordance with the licensee's written procedures.

RH-5406. **Personnel Monitoring Requirements.**

a. In accordance with RH-1302., "Conditions Requiring Individual Monitoring of External and Internal Occupational Dose," each licensee shall monitor exposures to radiation at levels sufficient to demonstrate compliance with the occupational dose limits of Section 3, "Standards for Protection Against Radiation."

b. Each licensee shall maintain records of doses received by all individuals for whom personnel monitoring is required under RH-1302. Such records shall be maintained in accordance with the provisions of RH-1500.

RH-5407. **Area Monitoring and Survey Requirements.**

a. Radiation levels in all high and very high radiation areas shall be continuously monitored. The monitoring devices shall be electrically independent of the accelerator control and safety interlock systems. The monitoring devices shall be capable of providing a remote and local readout with visible ~~and/or~~ audible alarms at both the control panel and monitoring stations. The monitoring devices shall be set to activate at a level of at least 100 mrem/hr.

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b. All area monitors shall be checked for proper operation before each day of accelerator use and after each servicing or repair. ~~-~~Records of area monitor operability shall be maintained for five (5) years.~~-~~ Each record shall include the date of the check, notation that the monitor indicates when the beam is "ON" and when it is "OFF," and the initials of the individual who performed the check.

c. There shall be available at each accelerator facility, appropriate portable monitoring equipment that is operable and has been calibrated for the applicable radiations being produced at the facility. ~~-~~As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range of 1 mrem (10 µSv) per hour to 1000 mrem (10 mSv) per hour.

d. 1. Portable monitoring equipment shall be tested for proper operation by way of a reference check performed at the following frequencies:

A. At the time of calibration;

B. Before each use and also after each survey to ensure the equipment was operational during the survey;

C. After each maintenance ~~and/or~~ or battery change; and

D. At least quarterly.

2. If any reference check performed using a pre-defined geometry yields a reading that is not within +/- 20% of the reading measured immediately after calibration, the instrument shall be recalibrated.

3. Records of portable monitoring equipment operability shall be maintained for five (5) years.

e. Portable monitoring equipment shall be calibrated before first use, at intervals specified by the Department, and following any repair that will affect the calibration. ~~-~~Survey instruments shall be calibrated in accordance with RH-5412. ~~-~~Records of portable monitoring equipment calibration shall be maintained for five (5) years.

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~~RH-5407. (Cont'd)~~

f. A radiation protection survey shall be performed when the accelerator is first capable of producing radiation; when changes have been made in shielding, operation, occupancy of adjacent areas, or equipment, including relocation of equipment within an irradiation or treatment room; and at least annually to check for unknown changes and malfunctioning equipment. Radiation protection surveys shall be performed by, or under the direction of, a Qualified Expert physically present at the facility.

g. The Qualified Expert shall report the survey results in writing to the licensee. A copy of the initial survey report shall be maintained by the licensee for inspection by the Department until termination of the license. Other radiation protection survey reports shall be maintained for inspection by the Department for five (5) years. The survey report shall include documentation of all instances where the facility, in the opinion of the Qualified Expert, is in violation of applicable rules. Any deficiencies detected during the survey shall be corrected prior to using the accelerator.

h. The survey report shall include, but not be limited to, the following:

1. The date of the measurements;

2. The reason the survey is required;

3. A description of the accelerator including the manufacturer's name, model number and serial number, beam type, and beam energy;

4. A diagram of the facility that details building structures; areas surrounding an irradiation or treatment room, if applicable, that were surveyed; and the position of the accelerator, control panel, and associated equipment;

5. A description of the instrumentation used to determine radiation measurements, including the date of the most recent calibration and who performed the calibration for each instrument used;

6. The conditions under which radiation measurements were taken;

7. Survey data including:

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A. The measured dose rate at several points in each area expressed in millirems (microsieverts) per hour;

~~RH-5407.h. (Cont'd)~~

B. The projected maximum "in-any-one-hour" dose equivalent in each unrestricted area adjacent to the accelerator;

C. The projected maximum annual total effective dose equivalent (TEDE) in each restricted and unrestricted area adjacent to the accelerator; and

D. A description of workload, use, and occupancy factors employed in determining the projected annual TEDE; and

8. The signature of the ~~individual~~ Qualified Expert responsible for ~~conducting~~ the survey.

i. If the survey required by RH-5407.f. indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by RH-1208.a. and RH-1208.b., the licensee shall ensure the following:

1. The unit is equipped with beam direction interlocks or additional radiation shielding is added to ensure compliance with RH-1208.a. and RH-1208.b.;

2. The survey required by RH-5407.f. is performed again; and

3. The survey report generated is in accordance with RH-5407.h. and includes the results of the initial survey, a description of the modification made in order to comply with this paragraph, and the results of the second survey; or

4. A license amendment is requested and received under RH-1208.d.that authorizes radiation levels in unrestricted areas greater than those permitted by RH-1208.a. and RH-1208.b.

j. Copies of the records required in RH-5407.g. and RH-5407.i. shall be submitted to the Department within thirty (30) calendar days following completion of the action that initiated the record requirement. ~~-~~Annual radiation protection surveys shall not be submitted unless it is discovered that radiation levels in unrestricted ~~and/or~~ or restricted areas exceed the dose limits specified in Section 3.

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k. Surveys for airborne radiation hazards shall be performed in accordance with written procedures approved by the Department to ensure that any particulate radioactivity present will not result in doses in excess of the limits specified in Section 3. Records of surveys for airborne radioactivity shall be maintained for five (5) years.

l. Surveys for ambient radiation levels and removable contamination shall be performed in accordance with written procedures approved by the Department in order to quantify residual activity in target and other pertinent areas. Records of surveys for ambient radiation levels and removable contamination shall be maintained for five (5) years.

m. Surveys for residual activity shall be conducted on all accelerators capable of generating energies above 10 MV (10 MeV) prior to machining, removing, or working on accelerator components which may have become activated due to photo-neutron production. Records of surveys pursuant to this paragraph shall be maintained for five (5) years.

n. Area surveys for residual activity shall be conducted regarding accelerators capable of generating energies above 10 MV (10 MeV) in order to request Department approval for release of the area for unrestricted use. Records of surveys pursuant to this paragraph shall be maintained for five (5) years.

o. Surveys performed in accordance with this section shall be in accordance with written procedures established by a Qualified Expert or the Radiation Safety Officer of the accelerator facility.

p. Radiation measurements shall be performed with a calibrated dosimetry system. The dosimetry system calibration shall be traceable to a national standard. The calibration shall have been performed within the previous twenty-four (24) months and after any servicing that may have affected system calibration. Records of dosimetry system calibrations shall be maintained for five (5) years.

RH-5408. **Ventilation Systems and Waste Disposal.**

a. A licensee shall control occupational dose due to airborne radioactivity so as to meet applicable requirements in "Permissible Doses, Levels, and Concentrations," Part C of Section 3.

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b. A licensee shall not vent, release, or otherwise discharge airborne radioactive material to an unrestricted area, unless the requirements of RH-1208., "Dose Limits for Individual Members of the Public," are met. Every reasonable effort shall be made to maintain releases of radioactive material to unrestricted areas as far below these limits as practicable. Compliance with this paragraph shall be demonstrated in accordance with RH-1209.

c. For radioactive material specific licensees, waste disposal shall be in accordance with Part E of Section 3 and as stated in the specific license. General licensees subject to RH-402.n. shall dispose of incidentally produced radioactive material only by way of Department approved procedures.

RH-5409. **Operating and Emergency Procedures.**

a. The licensee's operating and emergency procedures shall include instructions in at least the following:

1. The use of particle accelerators such that no person is likely to be exposed to radiation doses in excess of the limits established in Section 3, "Standards for Protection Against Radiation";

2. Methods and occasions for conducting radiation surveys;

3. Personnel monitoring and the use of personnel monitoring equipment;

4. Minimizing exposures to persons in the event of an accident;

5. Reporting an actual or suspected exposure;

6. Notifying proper persons in the event of an accident;

7. Safety procedures to be employed whenever an interlock has been either tripped or intentionally bypassed;

8. Testing interlocks, entrance controls, and alarm systems;

9. Preventative maintenance;

10. Methods used to secure the accelerator from unauthorized use;

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~~RH-5409.a. (Cont'd)~~

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11. Methods of testing and training operators in accordance with RH-5401.a.;

12. Posting requirements; and

13. Maintenance of records.

RH-5410. **Minimum Radiation Safety Training Subjects for Instruction of Operators.**

Operators shall have received instruction in and shall have demonstrated an understanding of at least the following subjects in order to meet the requirements of RH-5401.a.1.:

a. **Fundamentals of Radiation Safety.**

1. Characteristics of particulate and electromagnetic radiation.

2. Units of radiation dose and quantity of radioactivity.

3. Biological hazards of exposure to radiation.

4. Measurement of radiation.

5. Methods of controlling radiation dose.

6. Radiation safety procedures, interlock systems and warning systems.

b. **Radiation Detection Instrumentation**.

1. Use of radiation survey instruments.

2. Survey technique.

3. Use of personnel monitoring equipment.

c. **Equipment.**

1. Remote handling equipment.

2. Handling of activated materials.

3. Use of shielding.

~~RH-5410.c. (Cont'd)~~

4. Identification of radiation hazards associated with the use of the equipment.

RH-5411. Deleted. See RH-5401.

RH-5412. **Calibration of Survey Instruments.**

a. The licensee shall ensure that the survey instruments used to show compliance with this Section have been calibrated before first use, at intervals not to exceed twelve (12) months, and following any repair that will affect the calibration.

b. To satisfy the requirements of RH-5412.a., the licensee shall ensure:

1. Calibration of all scales with readings up to 1000 mrem (10 mSv) per hour with an appropriate radiation source that is traceable to the National Institute of Standards and Technology (NIST);

2. Calibration of at least two (2) points located at approximately 1/3 and 2/3 of full scale on each scale of a linear scale instrument; calibration at midrange for each decade and at two points of at least one decade on each scale of a logarithmic scale instrument; calibration at three points between 2 and 1000 mrem (0.02 and 10 mSv) per hour for digital instruments.

c. To satisfy the requirements of RH-5412.b., the licensee shall:

1. Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than ten percent (10%); and

2. Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than twenty percent (20%) if a correction factor or graph is conspicuously attached to the instrument and is used to interpret readings to within ten percent (10%).

d. The licensee shall retain a record of each calibration required in RH-5412.a. for five (5) years. The record shall include:

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1. A description of the calibration procedure; and

~~RH-5412.d. (Cont'd)~~

2. A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

e. The licensee may obtain the services of individuals licensed by the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State to perform calibrations of survey instruments. Records of calibrations that contain information required by RH-5412.d. shall be maintained by the licensee.

f. The licensee shall conspicuously note on the instrument the date of calibration.

RH-5413.- RH-5499. Reserved.

PART F.
[RESERVED]

RH-5500.- RH-5513. Deleted. See Section 11, "Therapeutic Radiation Machines."

RH-5514.- RH-5599. Reserved.

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PART G.
EXEMPTIONS, ADDITIONAL REQUIREMENTS, INSPECTIONS, AND TESTS

RH-5600. **Exemptions.**

a. Particle accelerators in transit or in storage incident to transit are exempt from the requirements of this Section. ~~-~~This exemption does not apply to the providers of particle accelerators for mobile services.

b. Facilities that have placed all particle accelerators in storage, including on-site storage, and have notified the Department in writing, are exempt from the requirements of this Section.~~-~~ This exemption is void if any particle accelerator is energized resulting in the production of radiation.

~~b~~c. Inoperable particle accelerators are exempt from the requirements of this Section. ~~-~~For the purposes of this Section, an inoperable particle accelerator means a particle accelerator that cannot be energized when connected to a power supply without repair or modification.

~~e~~d. ~~Financial institutions~~ A person that takes possession of a particle accelerator~~s~~ as the result of foreclosure, bankruptcy, or other default of payment ~~are~~ is exempt from ~~the requirements in this Section~~ licensing for the purposes of selling, leasing, or transferring. If the particle accelerator is energized, it shall be under the supervision of a person authorized under these Rules and shall be energized only to ~~the extent that they~~ demonstrate that the unit is operable for ~~the sole purpose of selling, leasing, or transferring~~sale, lease, or transfer purposes. The Department shall be notified of possession in relation to this paragraph..

~~d~~e. Any U.S. Department of Energy (DOE) contractor or subcontractor and any U.S. Nuclear of Regulatory Commission (NRC) contractor or subcontractor of the following categories operating within this state is exempt from these Rules to the extent that such contractor or subcontractor under his contract receives, possesses, uses, transfers or acquires sources of radiation:

1. Prime contractors performing work for the DOE at U.S. Government-owned or -controlled sites, including the transportation of sources of radiation to or from such sites and the performance of contract services during temporary interruptions of such transportation;

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2. Prime contractors of the DOE performing research in or development, manufacture, storage, testing or transportation of, atomic weapons or components thereof;

3. Prime contractors of the DOE using or operating nuclear reactors or other nuclear devices in a U.S. Government-owned vehicle or vessel; and

~~RH-5600.d. (Cont'd)~~

4. Any other prime contractor or subcontractor of the DOE or of the NRC when the State and the NRC jointly determine:

A. That the exemption of the prime contractor or subcontractor is authorized by law; and

B. That, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety.

~~e~~f. The Department may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the rules in this Section as it determines are authorized by law and will not result in undue hazard to public health and safety or property, and are otherwise in the public interest.

RH-5601. **Additional Requirements.**

The Department may, by rule or order, impose upon any licensee such requirements in addition to those established in these Rules as it deems appropriate or necessary to minimize danger to public health and safety or property.

RH-5602. **Inspections.**

a. Each licensee shall afford to the Department at all reasonable times opportunity to inspect sources of radiation and the premises and facilities wherein such sources of radiation are used or stored.

b. Each licensee shall make available to the Department for inspection, upon reasonable notice, records kept by the licensee pursuant to these Rules.

RH-5603. **Tests.**

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Upon instruction from the Department, each licensee shall perform or cause to have performed and shall permit the Department to perform, such reasonable tests as the Department deems appropriate or necessary, including, but not limited to, tests of:

a. Sources of radiation;

~~RH-5603. (Cont'd)~~

b. Facilities wherein sources of radiation are used or stored;

c. Radiation detection and monitoring instruments; and

d. Other equipment and devices used in connection with utilization or storage of licensed sources of radiation.

RH-5604.- RH-5699.– _Reserved.

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PART H.
ENFORCEMENT

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RH-5700. **Violations.**

a. An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any rule or order issued thereunder. Any person who willfully violates any provision of the Act or any rule or order issued thereunder may be guilty of a felony, misdemeanor, or crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law. Arkansas Code Annotated §20-21-204 describes criminal and civil penalties which may be assessed.

b. **Impounding**.

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Sources of radiation shall be subject to impounding pursuant to Section 5 of these Rules.

RH-5701.- RH-5799. Reserved.

PART I.
RECORDS

RH-5800. **Receipt, Transfer, and Disposal.**

Each licensee shall maintain records of receipt, transfer, and disposal of accelerators specific to each authorized use location. The records shall include the following information and shall be kept until termination of the license:

a. Date of the receipt, transfer, or disposal;

b. Manufacturer's name;

c. Model and serial number from the control panel;

d. Name and address where accelerator was received from, transferred to, or disposed of; and

e. Name of the individual making the record.

RH-5801. **Record Retention Periods.**

a. Each licensee shall retain each record that is required by this Section or by license condition for the period specified by the appropriate rule or license condition. If a retention period is not otherwise specified by rule or license condition, the record must be retained until the Department terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

b. If there is a conflict between the Department's rules in this Section, license condition, or other written Department approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the rules in this Section for such records shall apply unless the Department, pursuant to RH-5600.e., has granted a specific exemption from the record retention requirements specified in the rules in this Section.

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RH-5802. **Record Maintenance.**

Each record required by this Section must be legible throughout the specified retention period. The record may be the original or a reproduced copy or microform if such reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and

legible copy after storage for the period specified by Department rules.- The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures. -The licensee shall maintain adequate safeguards against tampering with and loss of records.

RH-5803.- RH-5999.– _Reserved.

SECTION 7.
NATURALLY OCCURRING RADIOACTIVE MATERIAL (NORM)

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PART A.
GENERAL

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RH-6000. **Authority**.

Act 8 of the Second Extraordinary Session of 1961 as amended (ACA 1987 Title 20 Chapter 21).

RH-6001. **Effective Date**.

The provisions and requirements of this Section shall take effect on June 1, 1992 and shall apply to all facilities or sites owned or controlled by a person on that date. Products distributed and disposals made prior to that date are not subject to the provisions of this Section.

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RH-6002. **Purpose**.

This Section establishes radiation protection standards for the possession, use, transfer, and disposal of naturally occurring radioactive materials (NORM) not subject to regulation by the U.S. Nuclear Regulatory Commission.

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RH-6003. **Scope**.

These Rules apply to any person who engages in the extraction, mining, beneficiating, processing, use, transfer, or disposal of NORM in such a manner as to alter the chemical properties or physical state of the NORM or its potential exposure pathway to humans.

The Rules in this Section address the introduction of NORM into products in which neither the NORM nor the radiation emitted from the NORM is considered to be beneficial to the products. The manufacture and distribution of products containing NORM in which the NORM ~~and/or~~ or its associated radiation(s) is considered to be a beneficial attribute are licensed under the provisions of Section 2. This Section also addresses waste management and disposal standards.

PART B.
DEFINITIONS

RH-6004. **Definitions**.

Beneficial attribute or beneficial to the product - The radioactivity of the product is necessary to the use of the product.

Beneficiating - The processing of materials for the purpose of altering the chemical or physical properties to improve the quality, purity, or assay grade.

Breathing zone - Used in determining respiratory requirements, the area of the body within one (1) foot of the mouth and nose of a worker.

Confirmatory survey - A survey by the potential general licensee of potentially contaminated land, equipment, or sites in order to establish, with reasonable certainty, the absence or magnitude of NORM contamination.

Designated facility - A specific-licensed facility capable of receiving NORM shipments for the purpose of processing, storage, or disposal of NORM.

Department - Arkansas Department of Health.

Dose commitment - The total radiation dose to a section of the body that will result from retention in the body of radioactive material. For purposes of estimating the dose commitment, it is assumed that from the time of intake the period of exposure to retained material will not exceed 50 years.

General environment - The total terrestrial, atmospheric, and aquatic environments outside sites within which any activity, operation, or process authorized by a general or specific license issued under this Section is performed.

Licensing State - Means any State with regulations equivalent to the Suggested State Regulations for Control of Radiation relating to, and an effective program for, the regulatory control of NORM and which has been granted final designation by the Conference of Radiation Control Program Directors, Inc.

Major processor - A user processing, handling, or manufacturing radioactive material exceeding Type A quantities as unsealed sources or material, or exceeding four (4) times Type B quantities as sealed sources. Type A and B quantities are defined in RH-3100.

Natural radioactivity - Radioactivity of naturally occurring nuclides.

~~RH-6004. (Cont'd)~~

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Naturally occurring radioactive material (NORM) - Any nuclide which is radioactive in its natural physical state (i.e., not man-made), but does not include byproduct, source, or special nuclear material.

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NORM facility identification number - The number assigned by the Department to a specific facility of a NORM general licensee having more than one site possessing radioactive material exceeding the exemption criteria specified in RH-6005.

NORM field supervisor - An individual who answers to the corporate NORM RSO approved by the Department as being qualified to oversee radiation protection of workers after attending at least forty (40) hours of classroom training in NORM-related health physics and six (6) months documented on-the-job training with a Department-approved qualified third party Radiation Safety Officer.

NORM general license number - The number assigned by the Department to the generator or other responsible party possessing radioactive material exceeding the exemption criteria specified in RH-6005.

NORM Radiation Safety Officer (RSO) - An individual approved by the Department as being qualified to oversee radiation protection of workers after attending at least forty (40) hours of classroom training in NORM-related health physics and six (6) months documented on-the-the job training with a Department-approved qualified third party Radiation Safety Officer.

NORM surveyor - An individual who has completed at least sixteen (16) hours of classroom training and three (3) months documented on-the-job training in NORM-related surveying techniques and health physics approved by the State as being qualified to perform NORM confirmatory and release surveys at NORM job sites.

NORM waste management plan - The plan for the management, i.e., handling, interim storage and disposal, of NORM.

NORM worker - An individual who has completed at least eight (8) hours of classroom training in NORM-related health physics concerning the protection of the worker, hazards involved in dealing with NORM, and other subjects outlined in RH-6018.

Notifier - The person or party meeting the definition of a general licensee according to RH-6010. and therefore, subject to the notification requirement stated in RH-6010.a.1.

~~RH-6004. (Cont'd)~~

Product - Something produced, made, manufactured, refined, or beneficiated.

Regulations of the U.S. Department of Transportation - The regulations in 49 CFR Parts 100-189.

Release survey - The survey required to release either equipment or land for unrestricted use. A land release survey must be approved by the Department before land will be released for unrestricted use.

Working Level (WL) - Any combination of short-lived radon decay products in one liter of air that will result in the ultimate emission of alpha particles with a total energy of 130 billion electron volts.

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PART C.
EXEMPTIONS

RH-6005. **Exemptions**.

a. Persons who receive, possess, use, process, transfer, distribute, and dispose of NORM are exempt from the requirements of these Rules if:

The materials contain or are contaminated at concentrations less than 5 picocuries per gram of radium-226 ~~and/or~~or radium-228, 0.05% by weight of uranium or thorium, or 150 picocuries per gram of any other NORM radionuclide, provided that these concentrations are not exceeded at any time.

b. Persons who receive products or materials containing NORM distributed in accordance with a specific license issued by the Department pursuant to RH-6022.c or an equivalent license issued by another Licensing State are exempt from these Rules.

c. The manufacturing, distribution, use, and disposal of the following products/materials are exempt from the requirements of these Rules:

1. Potassium and potassium compounds which have not been isotopically enriched in the radionuclide K-40; and

2. Brazil nuts.

d. The wholesale and retail distribution (including custom blending), possession, and use of the following products/ materials are exempt from the requirements of these Rules:

1. Phosphate and potash fertilizer;

2. Phosphogypsum for agricultural uses if it has not been technologically enhanced; and

3. Materials used for building and highway construction if such materials contain NORM which has not been technologically enhanced.

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e. The possession and use of natural gas and natural gas products and crude oil and crude oil products as fuel are exempt from the requirements of these Rules. The distribution of natural gas and crude oil and the manufacturing and distribution of natural gas and crude oil products are exempt from the specific license requirements of this Section but are subject to the general license requirements in RH-6010.

RH-6006. RH-6009. Reserved.

PART D.
LICENSES AND RADIATION SAFETY REQUIREMENTS

RH-6010. **General License**.

a. 1. A general license is hereby issued to mine, extract, receive, possess, own, use, process, and dispose of NORM not exempted in RH-6005. without regard to quantity. This general license does not authorize the manufacturing or distribution of products containing NORM in concentrations greater than those specified in RH-6005.a. nor the disposal of wastes from other entities. Persons subject to the general license shall notify the Department by filing the Notification of a NORM Facility Form with the Department. The Notification of NORM Facility Form is available from the Department.

NOTE: The Department recommends a general licensee under RH-6010.a.1. conduct or arrange to have conducted a confirmatory survey to determine the extent and magnitude of the NORM contamination at the general licensee's facility.

2. Each general licensee performing on-site maintenance of contaminated facilities, sites, or equipment or the excavation of land shall establish and submit to the Department for approval, written procedures as outlined in RH-6019. to ensure worker protection and survey (or screening) of sites and equipment as outlined in RH-6018.

3. On-site maintenance is authorized only if the maximum radiation level does not exceed two (2) millirem per hour at any accessible point of the work area.

b. Facilities and equipment contaminated with NORM in excess of the levels set forth in Appendix A of this Section, or if the maximum radiation exposure level exceeds 50 microroentgen per hour including background at any accessible point shall not be released for unrestricted use. The decontamination of equipment and facilities shall be performed only by persons specifically licensed by the Department or another Licensing State to conduct such work. Each general licensee shall establish for approval written procedures for the evaluation (or screening) of equipment, components, and facilities prior to release for unrestricted use to ensure that the levels in Appendix A of this Section are not exceeded.

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~~RH-6010. (Cont'd)~~

c. No person shall transfer land for unrestricted use where the concentration of radium-226 or radium-228 in soil averaged over any 100 square meters exceeds the background level by more than:

1. 5 pCi/g, averaged over the first 15 cm of soil below the surface; and

2. 15 pCi/g, averaged over 15 cm thick layers of soil more than 15 cm below the surface.

d. Equipment contaminated with NORM is exempt from the requirements of these Rules if the maximum radiation exposure level does not exceed 50 microroentgen per hour including background at any accessible point, and radioactive contamination levels do not exceed levels set forth in Appendix A of this Section.

e. The decontamination of equipment, facilities and land, as described in RH-6020.b. shall only be performed by persons specifically licensed by the Department or another Licensing State to conduct such work.

f. 1. The transfer of NORM not exempt from these Rules from one general licensee to another general licensee may be authorized by the Department if:

A. The equipment and facilities containing NORM are to be used by the recipient for the same purpose or at the same site;

B. The transfer of control or ownership of land containing NORM includes an annotation of the deed records to indicate the presence and quantity of NORM; or

C. The materials being transferred are ores or raw materials for processing or refinement.

2. Transfers made under RH-6010.f.1. do not relieve the general licensee who makes the transfer from the responsibilities of assessing the extent of NORM contamination or material present, evaluating the hazards of the NORM, informing the general licensee receiving the NORM of these assessments and evaluations, and maintaining records required by these Rules.

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~~RH-6010. (Cont'd)~~

g. **Storage of NORM and NORM waste from remediation**.

1. A general licensee is authorized to store NORM waste generated during remediation in a container for ninety (90) days from the date of generation. After such time, the NORM waste must be transferred to an authorized facility for the purposes of treatment, storage, or disposal unless otherwise exempted in writing by the Department.

2. To store NORM waste in an approved container for up to one (1) year from generation, a general licensee must first submit a written NORM waste management plan to the Department and receive authorization from the Department. The general licensee may store NORM waste in an approved container up to one (1) year [365 days] from generation under the written NORM waste management plan while waiting for Department determination unless otherwise exempted in writing by the Department.

RH-6011. **Protection of Workers During Operations**. Each person subject to the general license in RH-6010. or a specific license shall conduct operations in compliance with the standards for radiation protection set out in Section 2 and 3, except for releases of radioactivity in effluents, which shall be regulated by RH-6012. and disposal, which shall be governed by RH-6013.

RH-6012. **Protection of the General Population from Releases of Radioactivity**. Each person subject to the general license in RH-6010. or a specific license shall conduct operations such that concentrations of radioactive material which are released to the general environment in groundwater, surface water, air, soil, plants, and animals do not result in an annual dose above the limits specified in RH-1208. and RH-1209. Doses due to radon-220, radon-222, and their respective decay products, are excluded from these limits.

RH-6013. **Disposal and Transfer of Waste for Disposal**.

a. Each person subject to the general license in RH-6010. or a specific license shall manage and dispose of wastes containing NORM:

1. In accordance with the applicable requirements of the U.S. Environmental Protection Agency for disposal of such wastes;

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~~RH-6013.a. (Cont'd)~~

2. By transfer of the wastes for disposal to a land disposal facility licensed by the U.S. Nuclear Regulatory Commission, an Agreement State, or a Licensing State; or

3. In accordance with alternate methods authorized by the Department upon application or upon the Department's initiative.

b. Records of disposal, including manifests, shall be maintained pursuant to the provisions of Part E of Section 3.

c. Transfers of waste containing NORM for disposal shall be made to a person specifically authorized to receive such waste.

RH-6014. **Containers**.

a. NORM and NORM waste shall be kept in a container that is in good and safe condition.

b. The licensee shall use a container made of, or lined with, materials that will not react with, or be incompatible with, the NORM waste to be stored so that the ability of the container to contain the waste is not impaired or compromised.

c. A container holding NORM waste shall always be closed and sealed during storage, except when it is necessary to add or remove waste.

d. A container holding NORM waste shall not be opened, handled, or stored in a manner that may rupture the container or cause it to leak.

e. At least quarterly, the licensee shall inspect areas where containers of NORM waste are stored, looking for leaking or deteriorating containers or containment systems. Records of these inspections shall be made.

f. All containers of NORM waste shall be stacked in such a manner that each container identification label can be read from the access aisle or area.

g. Each container of NORM shall be labeled with the following information prior to storage:

1. Name and address of generator.

2. Type of material (i.e., sludge, scale, dirt, scrap metal, et cetera).

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~~RH-6014.g. (Cont'd)~~

3. Date stored.

4. Microroentgen per hour exposure readings on contact and at one (1) meter. (These exposure readings shall be updated if NORM waste is added to the container.)

5. Labeled as Radioactive Material.

h. Records of inspections shall be maintained by the licensee for inspection by the Department for five (5) years.

RH-6015. **Tanks Containing NORM**. The licensee shall develop a schedule and procedure for assessing the condition of each tank containing NORM waste. The schedule and procedure must be adequate to detect cracks, leaks, corrosion and erosion that may lead to cracks, leaks, or wall thinning to less than the required thickness to maintain vessel integrity. Procedures for emptying a tank to allow entry, procedures for personnel protection, and inspection of the interior must be established when necessary to detect corrosion of the tank sides and bottom. The frequency of these inspections will be determined based on the type of NORM material being stored and the tank construction material and the type of erosion/corrosion that may exist.

RH-6016. **Transportation of NORM**. Transportation of NORM contaminated equipment ~~and/or~~ or waste shall be subject to the applicable parts of Section 4 and the requirements listed below.

a. Each shipment of NORM waste and NORM contaminated equipment to a facility specifically licensed for treatment, decontamination, storage, or disposal shall be accompanied by a manifest.

b. The manifest form must consist of, at a minimum, the number of copies that will provide the licensee, each transporter, and the operator of the designated facility with one (1) copy each for their records with at least one (1) copy signed by all parties involved returned to the generator/shipper for their records.

~~RH-6016. (Cont'd)~~

c. **General requirements**.

1. A licensee who transports, or offers for transportation, NORM waste ~~and/or~~ or NORM contaminated equipment to a facility specifically licensed for treatment, decontamination, storage, or disposal must prepare and sign sufficient copies of a manifest before transporting the NORM off-site.

2. A licensee must designate on the manifest one facility which is permitted to handle the NORM described on the manifest.

3. If the transporter is unable to deliver the NORM to the designated facility, the licensee must either designate another facility or instruct the transporter to return the NORM.

4. Licensees must provide a statement concerning the nature of the material and general guidelines for an emergency situation involving this waste to accompany the manifest on shipments and loads.

5. If the NORM is to be transported out-of-state, the licensee will be responsible for receiving the completed signed manifest from the out-of-state treatment, decontamination, storage, or disposal facility.

6. Before initiating the shipment, licensees shall obtain written confirmation of the acceptability of the NORM; NORM contaminated equipment, or NORM waste from the operation of the specifically licensed commercial facility. The confirmation must be maintained with the licensee's manifest records.

7. The licensee receiving the shipment is required to report to the Department and to the licensee initiating the shipment any discrepancies between the NORM actually received by the designated facility and the NORM described on the manifest, or any other irregularities, within fifteen (15) days.

   If the designated facility or receiving licensee is located outside the State of Arkansas, the generating or originating licensee must report the irregularities to the Department.

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~~RH 6016. (Cont'd)~~

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d. **Required information**.

1. The manifest must contain all of the following information prior to leaving the licensee's site:

A. The licensee's (generator's) name, mailing address, and telephone number;

B. The name, address, and telephone number of each transporter;

C. The name, address, telephone number, and NORM specific license number of the designated facility, if applicable;

D. The description of the waste(s) [e.g., scale, soil, sludge, et cetera]; and

E. The total quantity of all NORM by units of weight in tons or pounds, and the type and number of containers as loaded into or onto the transport vehicle. -If the weight is unknown, the volume and estimated weight should be provided.

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2. The following certification must appear on the manifest, and must read, and be signed and dated by the licensee as follows:

"I hereby declare that the contents of this consignment are fully and accurately described above by proper shipping name and are classified, packed, marked and labeled, and are in all respects in proper condition for transport according to applicable international and national government regulations."

e. **Use of the manifest**.

1. The licensee must:

A. Sign and date the manifest certification by hand when the initial transporter accepts the shipment;

B. Obtain a handwritten signature of the initial transporter and date of the acceptance of the manifest; and

C. Retain one copy.

~~RH-6016.e. (Cont'd)~~

2. The licensee must give the transporter the remaining copies of the manifest.

3. The licensee must receive the fully signed copy of the manifest from the designated facility within 45 days from the delivery to the initial transporter. In the event the licensee does not receive the signed manifest, the licensee shall:

A. Notify the Department within seven (7) days;

B. Conduct an investigation into the reasons why the manifest was not received; and

C. Report the results of the investigation to the Department.

f. **Transporters**.

1. A transporter may not accept NORM for transportation unless the NORM is accompanied by sufficient copies of a manifest properly prepared, with each copy signed and dated by the licensee and each previous transporter in accordance with these Rules.

2. Before transporting the NORM, the transporter must sign and date each copy of the manifest acknowledging acceptance of the NORM from the licensee or previous transporter and return a signed copy to the licensee or previous transporter.

3. A transporter who delivers NORM to a designated facility or another transporter must obtain the signature and date of the accepting party and retain one copy of the manifest for their records.

g. The designated facility should fill out their portion of the manifest, retain a copy for their files, and send all remaining copies to the licensee no later than fifteen (15) days after delivery of the NORM waste or contaminated equipment.

RH-6017. **Radiation Survey and Counting Instrumentation**.

a. Survey instrumentation used at NORM sites shall consist of, but not be limited to, a minimum of the following:

~~RH-6017.a. (Cont'd)~~

1. Instrumentation to determine rates pursuant to this Section shall be capable of measuring 1 microroentgen per hour through at least 500 microroentgen per hour; and

2. Instrumentation utilized to determine potential contamination, whether wipe tests or airborne, pursuant to this Section shall be able to measure gross alpha (radium-226) and gross beta (radium-228) quantitatively.

b. Each radiation/contamination survey meter shall be calibrated:

1. At intervals not to exceed one (1) year, any time the instrument is found to respond inconsistently to a known source or shows any indication of physical damage, and after each instrument servicing;

2. At energies and radiation levels appropriate for use; and

3. So that accuracy within plus or minus twenty percent (± 20%) of the true radiation level can be demonstrated on each scale.

RH-6018. **Site Surveys and Training**.

This section describes the requirements for confirmatory site release surveys, and the training required before an individual may use survey instruments to release a NORM site or previously NORM contaminated equipment.

a. **Surveys**.

1. Upon completion of land remediation operations or equipment decontamination, a confirmatory survey shall be performed to verify that NORM regulated in this Section is not present, and therefore, the land or equipment in question is exempt from the requirements of this Section pursuant to RH-6005.

2. Any survey submitted to the Department or kept by the specific licensee for review by the Department must include the qualifications of the individual performing the survey. Individuals performing and documenting surveys shall demonstrate understanding of the subjects outlined in RH-6018.b.

b. The following outline describes the subjects that individuals must demonstrate competence in prior to being approved as a NORM surveyor.

~~RH-6018.b. (Cont'd)~~

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1. Fundamentals of Radiation Safety.

   A. Characteristics of radiation.

   B. Units of radiation dose and quantity of radioactivity.

   C. Levels of radiation from sources of radiation.

   D. Methods of minimizing radiation dose:

      i. Working time.

      ii. Working distance.

      iii. Shielding.

      iv. Respiratory precautions.

      v. Use of anti-contamination clothing.

2. Radiation Detection Instrumentation to be Used.

   A. Use of radiation survey instruments:

      i. Operation

      ii. Calibration

      iii. Limitations

   B. Survey techniques.

   C. Use of personnel-monitoring equipment.

3. The Requirements of Pertinent State Regulations.

RH-6019. **Worker Protection Plans**.

A Worker Protection Plan must be submitted to the Department which includes, but may not be limited to, the following items:

a. **Posting procedures**. How an area will be posted to alert the general public of NORM contamination or NORM storage areas.

~~RH 6019. (Cont'd)~~

b. **Dosimetry procedures/program**.- Including how determination of potential internal dose associated with NORM will be calculated (i.e., bioassay, whole body counting; et cetera).

c. **Contamination control procedures**. -Including:

1. Personnel exit procedures from a NORM contaminated area (i.e., frisking, et cetera).

2. Protective clothing requirements depending on the work to be performed.

3. Instrumentation to be used by the licensee to perform surveys and counting procedures, including manufacturer, model number, type of survey meter or counting instrument, probe type, and ranges of detection as well as calibration certificates.

4. **Surveying and Counting Procedures** - This section should include the proper procedure for personnel and equipment exit surveys, as well as procedures for land surveys, airborne contamination surveys (air sampling), and counting procedures. This section should also include the licensee's action levels and limits, if more conservative than the Department's outlined in Section 3 or Section 7.

5. **Operational Procedures** - This section should encompass any operations that might involve the spread of NORM contamination or the potential for internal dose to the worker and how each operation should be handled.

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6. **Respiratory Protection Program** - For operations that have a potential to produce NORM contaminated dusts (i.e., cutting, grinding, sandblasting, welding, drilling, polishing, or handling dry soil) or when loose contamination is suspected, the following additional items should be addressed in the Worker Protection Plan:

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The use of a respirator appropriate for radioactive particulates shall be worn or engineering controls should be utilized to prevent the potential airborne contaminates.

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7. **ALARA Procedures** - An explanation of how the licensee will attempt to maintain worker's exposure As Low As Reasonably

Achievable with regard to engineering controls and the use of time, distance, and shielding.

~~RH 6019. (Cont'd)~~

d. **Training Program**.~~-~~ Including but not limited to the following requirements:

1. **NORM Worker** – eight (8) Classroom Hours.

A. Fundamentals of Radiation Safety.

i. Characteristics of radiation.

ii. Units of radiation dose and definitions of radioactivity, including different sources of radioactivity (including NORM).

iii. Levels of radiation from different sources of radiation.

iv. Methods of minimizing radiation exposure dose.

(a). Working time

(b). Working distance

(c). Shielding

(d). Respiratory precautions

(e). Use of anti-contamination clothing

v. Use and types of personnel-monitoring equipment.

vi. Personnel exit contamination surveys, including meter operation and surveying techniques.

vii. Personnel general decontamination procedures.

viii. Biological effects of ionizing radiation (including effects on the embryo or fetus).

ix. Risks associated with working with NORM.

x. Requirements of pertinent State regulations concerning worker's rights and responsibilities.

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~~RH-6019.d.1.A. (Cont'd)~~

2. **Radiation Safety Officer** - 40 classroom hours plus six (6) months on-the-job training.

A. Fundamentals of Radiation Safety.

i. Characteristics of radiation.

ii. Units of radiation dose and definitions of radioactivity, including different sources of radioactivity (including NORM).

iii. Levels of radiation from different sources of radiation.

iv. Methods of minimizing radiation exposure dose.

(a). Working time

(b). Working distance

(c). Shielding

(d). Respiratory precautions

(e). Use of anti-contamination clothing

v. Use and types of personnel-monitoring equipment.

vi. Biological effects of ionizing radiation (including the effects on embryo or fetus).

vii. Risks associated with working with NORM.

viii. Requirements of pertinent State regulations concerning worker's rights and responsibilities.

B. Radiation Detection Instrumentation.

i. Use of survey instruments.

(a). Operation

(b). Calibration requirements

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~~RH-6019.d.2.B.i. (Cont'd)~~

(c). Limitations

ii. Survey techniques.

(a). Personnel contamination surveys

(b). Equipment surveys

(c). Land surveys

(d). Documentation and record retention requirements

C. Use of counting instrumentation for wipes and air sample filter papers.

D. Personnel decontamination techniques.

E. Air sampling techniques and equipment.

F. Shipping requirements for NORM and NORM-contaminated equipment.

G. Pertinent State regulations.

H. Six (6) months on-the-job training with a State-qualified third party Radiation Safety Officer or Health Physicist documented.

3. **NORM Field Supervisor** - Forty (40) hours classroom and six (6) months on-the-job training.

A. Fundamentals of Radiation Safety.

i. Characteristics of radiation.

ii. Units of radiation dose and definitions of radioactivity, including different sources of radioactivity (including NORM).

iii. Levels of radiation from different sources of radiation.

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~~RH 6019.d.3.A.iv. (Cont'd)~~

iv. Methods of minimizing radiation exposure dose.

(a). Working time

(b). Working distance

(c). Shielding

(d). Respiratory precautions

(e). Use of anti-contamination clothing

v. Use and types of personnel-monitoring equipment.

vi. Biological effects of ionizing radiation including meter operation and surveying techniques.

vii. Risks associated with working with NORM.

viii. Requirements of pertinent State regulations concerning worker's rights and responsibilities.

B. Radiation Detection Instrumentation.

i. Use of survey instruments.

(a). Operation

(b). Calibration requirements

(c). Limitations

ii. Survey techniques.

(a). Personnel contamination surveys

(b). Equipment surveys

(c). Land surveys

(d). Documentation and record retention requirements

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C. Use of counting instrumentation for wipes and air sample filter papers.

~~RH-6019.d.3. (Cont'd)~~

D. Personnel decontamination techniques.

E. Air sampling techniques and equipment.

F. Shipping requirements for NORM and NORM-contaminated equipment.

G. Pertinent State regulations.

H. Six (6) months on-the-job training with a State-qualified Radiation Safety Officer or Health Physicist documented.

RH-6020. **Specific Licenses**.

a. Unless otherwise exempted under the provisions of RH-6005. or licensed under the provisions of Section 2, the manufacturing and distribution of any material or product containing NORM shall be specifically licensed pursuant to the requirements of this Section or pursuant to equivalent regulations of another Licensing State.

b. Persons conducting the following activities involving equipment or facilities contaminated with NORM in excess of the levels set forth in Appendix A of this Section or land contaminated in excess of the limits set forth in RH-60l0. shall be specifically licensed pursuant to the requirements of this Section:

1. Decontamination of equipment, facilities, and land; or

2. Disposal of the resulting waste.

RH-6021. **Filing Application for Specific Licenses**.

a. Applications for specific licenses shall be filed in a manner and on a form prescribed by the Department.

b. The Department may at any time after the filing of the original application, and before the expiration of the license, require further statements in order to enable the Department to determine whether the

application should be granted or denied or whether a license should be modified or revoked.

c. Each application shall be signed by the applicant or licensee or a person duly authorized to act for and on the licensee's behalf.

~~RH-6021.d. (Cont'd)~~

d. An application for a license may include a request for a license authorizing one or more activities.

e. In an application, the applicant may incorporate by reference information contained in previous applications, statements, or reports filed with the Department provided such references are clear and specific.

f. Applications and documents submitted to the Department may be made available for public inspection except that the Department may withhold any document or part thereof from public inspection if disclosure of its contents is not required in the public interest and would adversely affect the interest of a person concerned.

RH-6022. **Requirements for the Issuance of Specific Licenses**.

a. A license application will be approved if the Department determines that:

1. The applicant is qualified by reason of training and experience to use the NORM in question for the purpose requested in accordance with these rules in such a manner as to minimize danger to public health and safety or property;

2. The applicant's proposed equipment, facilities, and procedures are adequate to minimize the danger to public health and safety or property;

3. The issuance of the license will not be inimical to the health and safety of the public;

4. The applicant satisfies any applicable special requirements in this Section; and

5. The applicant has met the financial surety requirements of RH-6033.

b. An application for a specific license to decontaminate equipment ~~and/or~~ or facilities contaminated with NORM in excess of the levels set forth in

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RH-6005.a., RH-60l0.c., or Appendix A of this Section, as applicable, and to dispose of the resulting waste will be approved if:

1. The applicant satisfies the general requirements specified in RH-6022.a.; and

~~RH-6022.b. (Cont'd)~~

2. The applicant has adequately addressed the following items in the application:

   A. Procedures and equipment for protection of workers:

   B. An evaluation of the radiation levels and concentrations of contamination expected during normal operations;

   C. Operating and emergency procedures, including procedures for waste reduction and quality assurance of items released for unrestricted use; and

   D. Method of disposing of the NORM removed from contaminated equipment, facilities, ~~and/or~~ or land.

c. An application for a specific license to manufacture ~~and/or~~ or initially transfer products or materials containing NORM to persons exempted from these Rules pursuant to RH-6005.b. will be approved if:

1. The applicant satisfies the general requirements specified in RH-6022.a.;

2. The NORM is not contained in any food, beverage, cosmetic, drug, or other commodity designed for ingestion or inhalation by, or application to, human being; and

3. The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, and conditions of handling, storage, use, and disposal of the NORM material or product to demonstrate that the material or product will meet the safety criteria set forth in RH-6023. ~~-~~The information shall include:

   A. A description of the material or product and its intended use or uses;

   B. The type, quantity, and concentration of NORM in each material or product;

C. The chemical and physical form of the NORM in the material or product, and changes in chemical and physical form that may occur during the useful life of the material or product;

~~RH-6022.c. (Cont'd)~~

D. An analysis of the solubility in water and body fluids of the NORM in the material or product;

E. The details of manufacture and design of the material or product relating to containment and shielding of the NORM and other safety features under normal and severe conditions of handling, storage, use, reuse, and disposal of the material or product;

F. The degree of access of human beings to the material or product during normal handling, use, and disposal;

G. The total quantity of NORM expected to be distributed annually in the material or product;

H. The expected useful life of the material or product;

I. The proposed method of labeling or marking each unit of the material or product with identification of the manufacturer ~~and/or~~ or initial transferor of the product and the radionuclide(s) and quantity of NORM in the material or product;

J. The procedures for prototype testing of the material or product to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, reuse, and disposal;

K. The results of the prototype testing of the material or product, including any change in the form of the NORM contained in it, the extent to which the NORM may be released to the environment, any change in radiation levels, and any other changes in safety features;

L. The estimated external radiation doses and dose commitments relevant to the safety criteria in RH-6023. and the basis for such estimates;

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M. A determination that the probabilities with respect to doses referred to in RH-6023. meet the safety criteria;

~~RH-6022.c.3. (Cont'd)~~

N. The quality control procedures to be followed in the production of production lots of the material or product, and the quality control standards the material or product will be required to meet; and

O. Any additional information, including experimental studies and tests, required by the Department to facilitate a determination of the radiation safety of the material or product.

d. Notwithstanding the provisions of RH-6023.b., the Department may deny an application for a specific license if the end uses of the product are frivolous or cannot be reasonably foreseen.

RH-6023. **Safety Criteria**.

An applicant for a license under RH-6022.c. shall demonstrate that the product is designed and will be manufactured so that:

a. In normal use and disposal, it is unlikely that the external radiation dose in anyone year, or the dose commitment resulting from the intake of NORM, excluding the radon and radon decay products, in any one (1) year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or NORM from the material or product, will exceed the doses in Column I of RH-6024.

b. In normal handling and storage of the quantities of the material or product likely to accumulate in one location during marketing, distribution, installation, and servicing of the material or product, it is unlikely that the external radiation dose in anyone year, or the dose commitment resulting from the intake of NORM, excluding radon, in any one (1) year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or NORM from the material or product, will exceed the doses in Column II of RH-6024.

c. In normal use, disposal, handling, and storage, it is unlikely that the radon released from the material or product will result in an increase in the average radon concentration in air of more than 0.4 picocuries per liter.

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d. It is unlikely that a significant reduction will occur in the effectiveness of the containment, shielding, or other safety features of the material or product (from wear and abuse in normal handling and use of the material or product during its useful life).

RH-6024. **Table of Organ Doses**.

Part of Body	Column I* Dose in Rem	Column II* Dose in Rem
Whole body; head and trunk; active blood-forming organs; gonads; or lens of eye	0.005	0.5
Hands and forearms; feet and ankles; localized area of skin averaged over areas no larger than 1 square centimeter	0.075	7.5
Other organs	0.015	1.5

*** Dose limit is the dose above background from the product**

RH-6025. **Issuance of Specific Licenses**.

a. Upon determination that an application meets the requirements of the Act and rules of the Department, the Department will issue a specific license authorizing the proposed activity in such form and containing such conditions and limitations as it deems appropriate or necessary.

b. The Department may incorporate in any license at the time of issuance, or thereafter by amendment, such additional requirements and conditions with respect to the licensee's receipt, possession, use, and transfer of NORM subject to this Section as it deems appropriate or necessary in order to:

1. Minimize danger to public health and safety or property;

2. Require such reports and the keeping of such records, and to provide for such inspections of activities under the license as may be appropriate or necessary; and

3. Prevent loss or theft of NORM subject to this Section.

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RH-6026. **Conditions of Specific Licenses Issued Under RH-6022**.

a. **General terms and conditions**.

1. Each specific license issued pursuant to this Section shall be subject to all the provisions of the Act, now or hereafter in effect, and to all rules and orders of the Department.

2. No specific license issued or granted under this Section and no right to possess or utilize NORM granted by any license issued pursuant to this Section shall be transferred, assigned, or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person unless the Department shall, after securing full information, find that the transfer is in accordance with the provisions of the Act, and shall give its consent in writing.

3. Each person specifically licensed by the Department pursuant to this Section shall confine use and possession of the NORM licensed to the locations and purposes authorized in the specific license.

4. Each person specifically licensed by the Department pursuant to this Section is subject to the general license provisions of RH-6011., RH-60l2., and RH-6013.

5. **Notification of bankruptcy**.

A. Each licensee shall notify the Department, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapters of Title 11 (Bankruptcy) of the United States Code (11 U.S.C.) by or against:

i. A licensee;

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ii. An entity [as that term is defined in 11 U.S.C. 101 (15)] controlling a licensee or listing the license or licensee as property of the estate; or

iii. An affiliate [as that term is defined in 11 U.S.C. 101(2)] of the licensee.

~~RH 6026.a.5. (Cont'd)~~

B. This notification must indicate:

i. The bankruptcy court in which the petition for bankruptcy was filed; and

ii. The date of the filing of the petition.

6. **Notification of commencement of activities**.

Each licensee shall notify the Department, in writing, at least five (5) days prior to commencing decontamination or remediation activities at a customer's site. If, for a specific case, the five (5) day period would pose an undue hardship on the licensee, the licensee may, upon application to the Department, obtain permission to proceed sooner. The notification shall specify the following:

A. Type of operation;

B. Mode of decontamination (if more than one mode is authorized on the license);

C. Address and physical location of the decontamination or remediation activity;

D. Dates when the activities will be conducted; and

E. Name of the person supervising the operations at the site.

7. **Notification of completion of activities**.

Each licensee shall notify the Department, in writing, within thirty (30) days following completion of NORM decontamination or remediation work. The notification shall specify the following:

A. Customer name, mailing address, and telephone number;

B. Quantity of contaminated material generated as a result of the decontamination or remediation process;

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C. Disposition of contaminated material;

D. Type of container used for storage of the contaminated material; and

~~RH-6026.a.7. (Cont'd)~~

E. Location and description of where contaminated material is stored. (If a street address is not available, a map must be provided.)

b. **Quality control, labeling, and reports of transfer**.

Each person licensed under RH-6022.c. shall:

1. Carry out adequate control procedures in the manufacture of the material or product to assure that each production lot meets the quality control standards approved by the Department;

2. Label or mark each unit so that the manufacturer, processor, producer, or initial transferor of the material or product and the NORM in the material or product can be identified; and

3. Maintain records identifying, by name and address, each person to whom NORM is transferred for use under RH-6005.b. or the equivalent regulations of another Licensing State, and stating the kinds, quantities, and uses of NORM transferred. An annual summary report stating the total quantity of each radionuclide transferred under the specific license shall be filed with the Department. Each report shall cover the year ending December 31, and shall be filed within thirty (30) days thereafter. If no transfers of NORM have been made pursuant to RH-6022.c. during the reporting period, the report shall so indicate.

RH-6027. **Expiration and Termination of Licenses**.

a. Except as provided in RH-6027.d.3. and RH-6028.b., each specific license shall expire at the end of the specified day in the month and year stated therein.

b. Each licensee shall notify the Department in writing and request termination of the license when the licensee decides to terminate all activities involving NORM authorized under the license. This notification and request for termination of the license must include the reports and

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information specified in RH-6027.d.l.D. The licensee is subject to the provisions of RH-6027.d. and e. as applicable.

c. No less than thirty (30) days before the expiration date specified in a specific license, the licensee shall either:

~~RH-6027. (Cont'd)~~

1. Submit an application for license renewal under RH-6028.; or

2. Notify the Department in writing, under RH-6027.b. if the licensee decides to discontinue all activities involving NORM.

d. 1. If a licensee does not submit an application for license renewal under RH-6028., the licensee shall on or before the expiration date specified in the license:

A. Terminate use of NORM;

B. Remove NORM contamination to the extent practicable;

C. Properly dispose of NORM; and

D. Submit a report of disposal of NORM and radiation survey(s) to confirm the absence of NORM or to establish the levels of residual NORM contamination. The licensee shall, as appropriate:

i Report levels of radiation in units of microrads per hour of beta and gamma radiation at one centimeter and gamma radiation at one meter from surfaces and report levels of radioactivity in units of disintegrations per minute (or microcuries) per 100 square centimeters removable and fixed on surfaces, microcuries per milliliter in water, and picocuries per gram in contaminated solids such as soils or concrete: and

ii. Specify the instrument(s) used and certify that each instrument is properly calibrated and tested.

2. If no radioactivity attributable to activities conducted under the license is detected, the licensee shall submit a certification that no detectable NORM contamination was found.– If the Department determines that the information submitted under RH-6027.d.l.D. and d.2. and is adequate and surveys confirm the findings. The

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Department will notify the licensee in writing that the license is terminated.

~~RH-6027.d. (Cont'd)~~

3. If detectable levels of residual NORM attributable to activities conducted under the license are found, the license continues in effect beyond the expiration date, if necessary, with respect to possession of residual NORM until the Department notifies the licensee in writing that the license is terminated. During this time, the licensee is subject to the provisions of RH-6027.e.

   In addition to the information submitted under RH-6027.d.l.D., the licensee shall submit a plan, if appropriate, for decontaminating the location(s) and disposing of the residual NORM.

e. Each licensee who possesses residual NORM under RH-6027.d.3., following the expiration date specified in the license, shall:

   1. Be limited to actions involving NORM related to preparing the location(s) for release for unrestricted use; and

   2. Continue to control entry to restricted areas until the location(s) are suitable for release for unrestricted use and the Department notifies the licensee in writing that the license is terminated.

RH-6028. **Renewal of Licenses**.

a. Applications for renewal of specific licenses shall be filed in accordance with RH-6021.

b. In any case in which a licensee, not less than thirty (30) days prior to expiration of an existing license, has filed an application in proper form for renewal or for a new license authorizing the same activities, such existing license shall not expire until final action by the Department.

RH-6029. **Amendment of Licenses at Request of Licensee**.

Applications for amendment of a license shall be filed in accordance with RH-6021. and shall specify the respects in which the licensee desires the license to be amended and the grounds for such amendment.

RH-6030. **Department Action on Applications to Renew and Amend**.

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In considering an application by a licensee to renew or amend the license, the Department will apply the criteria set for in RH-6022.

RH-6031. **Modification and Revocation of Licenses**.

a. The terms and conditions of all licenses shall be subject to amendment, revision, or modification or the license may be suspended or revoked by reason of amendments to the Act, or by reason of rules and orders issued by the Department.

b. Any license may be revoked, suspended, or modified, in whole or in part, for any material false statement in the application or any statement of fact required under provisions of the Act, or because of conditions revealed by such application or statements of fact or any report, record, or inspection or other means which would warrant the Department to refuse to grant a license on an original application, or for violation of, or failure to observe any of the terms and conditions of the Act, or of the license, or of any rule or order of the Department.

c. Except in cases of willfulness or those in which the public health, interest or safety requires otherwise, no license shall be modified, suspended, or revoked unless, prior to the institution of proceedings therefore, facts or conduct which may warrant such action shall have been called to the attention of the licensee in writing and the licensee shall have been accorded an opportunity to demonstrate or achieve compliance with all lawful requirements.

RH-6032. **Vacating Premises**.

Each specific licensee shall, no less than thirty (30) days before vacating or relinquishing possession or control of premises which may have been contaminated with Naturally Occurring Radioactive Material as a result of the activities, notify the Department in writing of intent to vacate. When deemed necessary by the Department, the licensee shall decontaminate the premises in such a manner as the Department may specify.

RH-6033. **Financial Assurance and Recordkeeping for Decommissioning**.

Each specific licensee shall be subject to the financial assurance and recordkeeping for decommissioning under RH-409.h.

RH-6034.- RH-6039. _–Reserved.

PART E.
RECIPROCITY

RH-6040. **Reciprocal Recognition of Licenses**.

Subject to these Rules, any person who holds a specific license from a Licensing State, and issued by the agency having jurisdiction where the licensee maintains an office for directing the licensed activity and at which radiation safety records are normally maintained, is hereby granted a general license to conduct the activities authorized in such licensing document within this State for a period not in excess of 180 days in any calendar year provided that:

a. The licensing document does not limit the activity authorized by such document to specific installations or locations;

b. The out-of-state licensee notifies the Department in writing at least five (5) days prior to engaging in such activity. Such notification shall indicate the location, period, and type of proposed possession and use within the State, and shall be accompanied by a copy of the pertinent licensing document. If, for a specific case, the five (5) day period would impose an undue hardship on the out-of-state licensee, the licensee may, upon application to the Department, obtain permission to proceed sooner;

c. The out-of-state licensee complies with all applicable rules of the Department and with all the terms and conditions of the licensing document, except any such terms and conditions which may be inconsistent with applicable rules of the Department;

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d. The out-of-state licensee supplies such other information as the Department may request; and

e. The out-of-state licensee shall not transfer or dispose of NORM possessed or used under the general license provided in RH-6040.a. except by transfer to a person:

1. Specifically licensed by the Department or by another Licensing State to receive such NORM; or

2. Exempt from the requirements for a license for such NORM under RH-6005.

RH-6041.- RH-6999. –Reserved.

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APPENDIX A TO SECTION 7
ACCEPTABLE SURFACE CONTAMINATION[a] LEVELS FOR NORM

	Average[b,c,f]	**Maximum**[b,d,f]	**Removable**[b,c,e,f]
Alpha	5,000 dpm/100 cm^2	15,000 dpm/100 cm^2	1,000 dpm/100 cm^2
Beta-gamma	5,000 dpm /100 cm^2	15,000 dpm/100 cm^2	1,000 dpm /100 cm^2

[a] Where surface contamination by both alpha and beta-gamma emitting nuclides exists, the limits established for alpha and beta-gamma emitting nuclides should apply independently.

[b] As used in this table, dpm (disintegrations per minute) means the rate of emission by radioactive material as determined by correcting the counts per minute observed by an appropriate detector for background, efficiency, and geometric factors associated with the instrumentation.

[c] Measurements of average contamination level should not be averaged over more than one square meter. For objects of less surface area, the average should be derived for each object.

[d] The maximum contamination level applies to an area of not more than 100 cm^2.

[e] The amount of removable radioactive material per 100 cm^2 of surface area should be determined by wiping that area with dry filter or soft absorbent paper, applying moderate pressure, and assessing the amount of radioactive material on the wipe with an appropriate instrument of known efficiency. When removable contamination on objects of surface area A (where A is less than 100 sq. cm) is determined, the entire surface should be wiped and the contamination level multiplied by 100/A to convert to a "per 100 sq. cm" basis.

[f] The average and maximum radiation levels associated with surface contamination resulting from beta-gamma emitters should not exceed 0.2 mrad/hr (2 µGy/hr) at one (1) cm and 1.0 mR/hr (10 µGy/hr) at 1 cm, respectively, measured through not more than seven (7) milligrams per square centimeter of total absorber.

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SECTION 8.
LICENSES AND RADIATION SAFETY REQUIREMENTS FOR IRRADIATORS

PART A.
GENERAL

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RH-7000. Reserved.

RH-7001. **Purpose and Scope**.

a. This Section contains requirements for the issuance of a license authorizing the use of sealed sources containing radioactive materials in irradiators used to irradiate objects or materials using gamma radiation. This Section also contains radiation safety requirements for operating irradiators. The requirements of this Section are in addition to and not in substitution for other requirements of these Rules. Nothing in this Section relieves the licensee from complying with other applicable Federal, State and local regulations governing the siting, zoning, land use, and building code requirements for industrial facilities.

b. The rules in this Section apply to panoramic irradiators that have either dry or wet storage of the radioactive sealed sources and to underwater irradiators in which both the source and the product being irradiated are under water. Irradiators whose dose rates exceed 5 grays (500 rads) per hour at one (1) meter from the radioactive sealed sources in air or in water, as applicable for the irradiator type, are covered by this Section.

c. The rules in this Section do not apply to self-contained dry-source-storage irradiators (those in which both the source and the area subject to irradiation are contained within a device and are not accessible by personnel), medical radiology or teletherapy, radiography (the irradiation of material for nondestructive testing purposes), gauging, or open-field (agricultural) irradiation.

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RH-7002. **Definitions**.

Act - Act 8 of Second Extraordinary Session of 1961, as amended.

Annually - Either:

1. At intervals not to exceed one (1) year, or

2. Once per year, at about the same time each year (plus or minus one [1] month).

Commencement of construction - Any action defined as "construction" or any other activity at the site of a facility subject to the rules in this Section that has a reasonable nexus to radiological health and safety.

Construction - The installation of foundations, or in-place assembly, erection, fabrication, or testing for any structure, system, or component of a facility or activity subject to the rules in this Section that are related to radiological safety or security. The term "construction" does not include:

1. Changes for temporary use of the land for public recreational purposes;

2. Site exploration, including necessary borings to determine foundation conditions or other preconstruction monitoring to establish background information related to the suitability of the site, the environmental impacts of construction or operation, or the protection of environmental values;

3. Preparation of the site for construction of the facility, including clearing of the site, grading, installation of drainage, erosion and other environmental mitigation measures, and construction of temporary roads and borrow areas;

4. Erection of fences and other access control measures that are not related to the safe use of, or security of, radiological materials subject to this part;

5. Excavation;

6. Erection of support buildings (e.g., construction equipment storage sheds, warehouse and shop facilities, utilities, concrete mixing plants, docking and unloading facilities, and office buildings) for use in connection with the construction of the facility;

7. Building of service facilities (e.g., paved roads, parking lots, railroad spurs, exterior utility and lighting systems, potable water systems, sanitary sewerage treatment facilities, and transmission lines);

8. Procurement or fabrication of components or portions of the proposed facility occurring at other than the final, in-place location at the facility; or

9. Taking any other action that has no reasonable nexus to radiological health and safety.

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Doubly encapsulated sealed source - A sealed source in which the radioactive material is sealed within a capsule and that capsule is sealed within another capsule.

Irradiator - A facility that uses radioactive sealed sources for the irradiation of objects or materials and in which radiation dose rates exceeding 5 grays (550 rads) per hour exist at one (1) meter from the sealed radioactive sources in air or water, as applicable for the irradiator type, but does not include irradiators in which both the sealed source and the area subject to irradiation are contained within a device and are not accessible to personnel.

Irradiator operator - An individual who has successfully completed the training and testing described in RH-7051. and is authorized by the terms of the license to operate the irradiator without a supervisor present.

Panoramic dry-source-storage irradiator - An irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored in shields made of solid materials. -The term includes beam-type dry-source-storage irradiators in which only a narrow beam of radiation is produced for performing irradiations.

Panoramic irradiator - An irradiator in which the irradiations are done in air in areas potentially accessible to personnel.- The term includes beam-type irradiators.

Panoramic wet-source-storage irradiator - An irradiator in which the irradiations are done in air in areas potentially accessible to personnel and in which the sources are stored under water in a storage pool.

Pool irradiator - Any irradiator at which the sources are stored or used in a pool of water including panoramic wet-source-storage irradiators and underwater irradiators.

Product conveyor system - A system for moving the product to be irradiated to, from, and within the area where irradiation takes place.

Radiation room - A shielded room in which irradiations take place.- Underwater irradiators do not have radiation rooms.

Radiation safety officer - An individual with responsibility for the overall radiation safety program at the facility.

~~RH-7002. (Cont'd)~~

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Sealed source - Any radioactive material that is used as a source of radiation and is encased in a capsule designed to prevent leakage or escape of the radioactive material.

Seismic area - Any area where the probability of a horizontal acceleration in rock of more than 0.3 times the acceleration of gravity in 250 years is greater than ten percent (10%), as designated by the U.S. Geological Survey.

Underwater irradiator - An irradiator in which the sources always remain shielded under water and humans do not have access to the sealed sources or the space subject to irradiation without entering the pool.

RH-7003. **Communications**.

Except where otherwise specified, all communications concerning these Rules may be addressed to the Arkansas Department of Health, Radiation Control Section, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

RH-7004.____—Reserved.

RH-7005. **Interpretations**.

Except as specifically authorized by the Department in writing, no interpretations of the meaning of the rules in this Section by an officer or employee of the Department other than a written interpretation by the Department Director or designee will be recognized as binding upon the Department.

RH-7006.- RH-7010. Reserved.

PART B.
LICENSES

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RH-7011. **Application for a Specific License**.

A person, as defined in RH-1100., shall file an application for a specific license authorizing the use of sealed sources in an irradiator in accordance with RH-403. and RH-404.

RH-7012. Reserved.

RH-7013. **Specific Licenses for Irradiators**.

The Department will approve an application for a specific license for the use of licensed material in an irradiator if the applicant meets the requirements contained in this section.

a. The applicant shall satisfy the general requirements specified in RH-404.a.-d. and the requirements contained in this Section.

b. The application must describe the training provided to irradiator operators including:

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1. Classroom training;

2. On-the-job or simulator training;

3. Safety reviews;

4. Means employed by the applicant to test each operator's understanding of the Department's rules and licensing requirements and the irradiator operating and emergency procedures; and

5. Minimum training and experience of personnel who may provide training.

c. The application must include an outline of the written operating and emergency procedures listed in RH-7053. that describes the radiation safety aspects of the procedure.

~~RH-7013. (Cont'd)~~

d. The application must describe the organizational structure for managing the irradiator, specifically the radiation safety officer and those management personnel who have important radiation safety responsibilities or authorities. In particular, the application must specify who, within the management structure, has the authority to stop unsafe operations. The application must also describe the training and experience required for the position of radiation safety officer.

e. The application must include a description of the access control systems required by RH-7023., the radiation monitors required by RH-7029., the method of detecting leaking sources required by RH-7059. including the sensitivity of the method, and a diagram of the facility that shows the locations of all required interlocks and radiation monitors.

f. If the applicant intends to perform leak testing of dry-source-storage sealed sources, the applicant shall establish procedures for leak testing and submit a description of these procedures to the Department. The description must include the:

1. Instruments to be used;

2. Methods of performing the analysis; and

3. Pertinent experience of the individual who analyzes the samples.

g. If licensee personnel are to load or unload sources, the applicant shall describe the qualifications and training of the personnel and the procedures to be used. If the applicant intends to contract for source loading or unloading at its facility, the loading or unloading must be done by an organization specifically authorized by the Department, U.S. Nuclear Regulatory Commission, or an Agreement State to load or unload irradiator sources.

h. The applicant shall describe the inspection and maintenance checks, including the frequency of the checks required by RH-7061.

RH-7014. Reserved.

RH-7015. **Commencement of Construction**.

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The applicant may not begin construction of a new irradiator prior to the submission to the Department of both an application for a license for the irradiator and the fee required. As used in this section, the term "construction" includes the construction of any portion of the permanent irradiator structure on the site but does not include: engineering and design work, purchase of a site, site surveys or soil testing, site preparations, site excavation, construction of warehouse or auxiliary structures, and other similar tasks. Any activities undertaken prior to the issuance of a license are entirely at the risk of the applicant and having no bearing on the issuance of a license with respect to the requirements of the Act, and rules and orders issued under the Act.

RH-7016. Reserved.

RH-7017. **Specific Exemptions**.

a. The Department may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the rules in this Section as it determines are authorized by law and will not result in undue hazard to public health and safety or property, and are otherwise in the public interest.

b. Any application for a license or for amendment of a license authorizing use of a teletherapy-type unit for irradiation of materials or objects may include proposed alternatives for the requirements of this Section. The Department will approve the proposed alternatives if the applicant provides adequate rationale for the proposed alternatives and demonstrates that they are likely to provide an adequate level of safety for workers and the public.

RH-7018. Reserved.

RH-7019. **Request for Written Statements**.

a. After the filing of the original application, the Department may request further information necessary to enable the Department to determine whether the application should be granted or denied.

b. ~~b.~~ Each license is issued with the condition that the licensee will, at any time before expiration of the license, upon the Department's request, submit written statements to enable the Department to determine whether the license should be modified, suspended, or revoked.

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PART C.
DESIGN AND PERFORMANCE REQUIREMENTS FOR IRRADIATORS

RH-7020. Reserved.

RH-7021. **Performance Criteria for Sealed Sources**.

a. **Requirements**.- Sealed sources installed after January 1, 1997:

1. Must have a certificate of registration issued by the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or by an Agreement State pursuant to provisions comparable to 10 CFR 32.210;

2. Must be doubly encapsulated;

3. Must use radioactive material that is as nondispersible as practical and that is as insoluble as practical if the source is used in a wet-source-storage or wet-source-change irradiator;

4. Must be encapsulated in a material resistant to general corrosion and to localized corrosion, such 316L stainless steel or other material with equivalent resistance if the sources are for use in irradiator pools; and

5. In prototype testing of the sealed source, must have been leak tested and found leak-free after each of the tests described in paragraphs b. through g. of this section.

b. **Temperature**.- The test source must be held at -40^{0}C for twenty (20) minutes, 600^{0}C for one (1) hour, and then be subjected to a thermal shock test with a temperature drop from 600^{0}C to 20^{0}C within fifteen (15) seconds.

c. **Pressure**. -The test source must be twice subjected for least five (5) minutes to an external pressure (absolute) of at two (2) million newtons per square meter.

d. **Impact**.- A 2-kilogram steel weight, 2.5 centimeters in diameter, must be dropped from a height of one (1) meter onto the test source.

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e. **Vibration**.- The test source must be subjected three (3) times for ten (10) minutes each to vibrations sweeping from 25 hertz to 500 hertz with a peak amplitude of five (5) times the acceleration of gravity. In addition, each test source must be vibrated for thirty (30) minutes at each resonant frequency found.

f. **Puncture**.- A 50-gram weight and pin, 0.30-centimeter pin diameter, must be dropped from a height of one (1) meter onto the test source.

g. **Bend**. -If the length of the source is more than fifteen (15) times larger than the minimum cross-sectional dimension, the test source must be subjected to a force of 2,000 newtons at its center equidistant from two (2) support cylinders, the distance between which is ten (10) times the minimum cross-sectional dimension of the source.

RH-7022. Reserved.

RH-7023. **Access Control**.

a. Each entrance to a radiation room at a panoramic irradiator must have a door or other physical barrier to prevent inadvertent entry of personnel if the sources are not in the shielded position.- Product conveyor systems may serve as barriers as long as they reliably and consistently function as a barrier.- It must not be possible to move the sources out of their shielded position if the door or barrier is open.- Opening the door or barrier while the sources are exposed must cause the sources to return promptly to their shielded position.- The personnel entrance door or barrier must have a lock that is operated by the same key used to move the sources.- The doors and barriers must not prevent any individual in the radiation room from leaving.

b. In addition, each entrance to a radiation room at a panoramic irradiator must have an independent backup access control to detect personnel entry while the sources are exposed. -Detection of entry while the sources are exposed must cause the sources to return to their fully shielded position and must also activate a visible and audible alarm to make the individual entering the room aware of the hazard. -The alarm must also alert at least one other individual who is onsite of the entry.- That individual shall be trained on how to respond to the alarm and prepared to promptly render or summon assistance.

~~RH-7023. (Cont'd)~~

c. A radiation monitor must be provided to detect the presence of high radiation levels in the radiation room of a panoramic irradiator before personnel entry. The monitor must be integrated with personnel access door locks to prevent room access when radiation levels are high. Attempted personnel entry while the monitor measures high radiation levels, must activate the alarm described in RH-7023.b. The monitor may be located in the entrance (normally referred to as the maze) but not in the direct radiation beam.

d. Before the sources move from their shielded position in a panoramic irradiator, the source control must automatically activate conspicuous visible and audible alarms to alert people in the radiation room that the sources will be moved from their shielded position. The alarms must give individuals enough time to leave the room before the sources leave the shielded position.

e. Each radiation room at a panoramic irradiator must have a clearly visible and readily accessible control that would allow an individual in the room to make the sources return to their fully shielded position.

f. Each radiation room of a panoramic irradiator must contain a control that prevents the sources from moving from the shielded position unless the control has been activated and the door or barrier to the radiation room has been closed within a preset time after activation of the control.

g. Each entrance to the radiation room of a panoramic irradiator and each entrance to the area within the personnel access barrier of an underwater irradiator must be posted as required by RH-1303.b. Radiation postings for panoramic irradiators must comply with the posting requirements of RH-1303.b., except that signs may be removed, covered, or otherwise made inoperative when the sources are fully shielded.

h. If the radiation room of a panoramic irradiator has roof plugs or other movable shielding, it must not be possible to operate the irradiator unless the shielding is in its proper location. This requirement may be met by interlocks that prevent operation if shielding is not placed properly or by an operating procedure requiring inspection of shielding before operating.

~~RH-7023. (Cont'd)~~

i. Underwater irradiators must have a personnel access barrier around the pool which must be locked to prevent access when the irradiator is not attended. Only operators and facility management may have access to

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keys to the personnel access barrier. -There must be an intrusion alarm to detect unauthorized entry when the personnel access barrier is locked. Activation of the intrusion alarm must alert an individual (not necessarily onsite) who is prepared to respond or summon assistance.

RH-7024. Reserved.

RH-7025. **Shielding**.

a. The radiation dose rate in areas that are normally occupied during operation of a panoramic irradiator may not exceed 0.02 millisievert (2 millirems) per hour at any location thirty (30) centimeters or more from the wall of the room when the sources are exposed.- The dose rate must be averaged over an area not to exceed 100 square centimeters having no linear dimension greater than twenty (20) centimeters.- Areas where the radiation dose rate exceeds 0.02 millisievert (2 millirems) per hour must be locked, roped off, or posted.

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b. The radiation dose at thirty (30) centimeters over the edge of the pool of a pool irradiator may not exceed 0.02 millisievert (2 millirems) per hour when the sources are in fully shielded position.

c. The radiation dose rate at one (1) meter from the shield of a dry-source-storage panoramic irradiator when the source is shielded may not exceed 0.02 millisievert (2 millirems) per hour and at five (5) centimeters from the shield must not exceed 0.02 millisievert- (20 millirems) per hour.

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RH-7026. Reserved.

RH-7027. **Fire Protection**.

a. The radiation room at a panoramic irradiator must have heat and smoke detectors.- The detectors must activate an audible alarm.- The alarm must be capable of alerting a person who is prepared to summon assistance promptly.- The sources must automatically become fully shielded if a fire is detected.

~~RH-7027. (Cont'd)~~

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b. The radiation room at a panoramic irradiator must be equipped with a fire extinguishing system capable of extinguishing a fire without the entry of

personnel into the room. The system for the radiation room must have a shut-off valve to control flooding into unrestricted areas.

RH-7028. Reserved.

RH-7029. **Radiation Monitors**.

a. Irradiators with automatic product conveyor systems must have a radiation monitor with an audible alarm located to detect loose radioactive sources that are carried toward the product exit. If the monitor detects a source, an alarm must sound and product conveyors must stop automatically. The alarm must be capable of alerting an individual in the facility who is prepared to summon assistance. Underwater irradiators in which the product moves within an enclosed stationary tube are exempt from the requirements of this paragraph.

b. Underwater irradiators that are not in a shielded radiation room must have a radiation monitor over the pool to detect abnormal radiation levels. The monitor must have an audible alarm and a visible indicator at entrances to the personnel access barrier around the pool. The audible alarm may have a manual shut-off. The alarm must be capable of alerting an individual who is prepared to respond promptly.

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RH-7030. Reserved.

RH-7031. **Control of Source Movement**.

a. The mechanism that moves the sources of a panoramic irradiator must require a key to actuate. Actuation of the mechanism must cause an audible signal to indicate that the sources are leaving the shielded position. Only one key may be in use at any time, and only operators or facility management may possess it. The key must be attached to a portable radiation survey meter by a chain or cable. The lock for source control must be designed so that the key may not be removed if the sources are in an unshielded position. The door to the radiation room must require the same key.

~~RH-7031. (Cont'd)~~

b. The console of a panoramic irradiator must have a source position indicator that indicates when the sources are in the fully shielded position, when they are in transit, and when the sources are exposed.

c. The control console of a panoramic irradiator must have a control that promptly returns the sources to the shielded position.

d. Each control for a panoramic irradiator must be clearly marked as to its function.

RH-7032. Reserved.

RH-7033. **Irradiator Pools**.

a. For licenses initially issued after January 1, 1997, irradiator pools must either:

1. Have a water-tight stainless steel liner or a liner metallurgically compatible with other components in the pool; or

2. Be constructed so that there is a low likelihood of substantial leakage and have a surface designed to facilitate decontamination.

In either case, the licensee shall have a method to safely store the sources during repairs of the pool.

b. For licenses initially issued after January 1, 1997, irradiator pools must have no outlets more than 0.5 meter below the normal low water level that could allow water to drain out of the pool. Pipes that have intakes more than 0.5 meter below the normal low water level and that could act as siphons must have siphons breakers to prevent the siphoning of pool water.

c. A means must be provided to replenish water losses from the pool.

d. A visible indicator must be provided in a clearly visible location to indicate if the pool water level is below the normal low water level or above the normal high water level.

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~~RH-7033. (Cont'd)~~

e. Irradiator pools must be equipped with a purification system designed to be capable of maintaining the water during normal operation at a conductivity of twenty (20) microsiemens per centimeter or less and with a clarity so that the sources can be seen clearly.

f. A physical barrier, such as a railing or cover, must be used around or over irradiator pools during normal operation to prevent personnel from accidentally falling into the pool. The barrier may be removed during maintenance, inspection, and service operations.

g. If long-handled tools or poles are used in irradiator pools, the radiation dose rate on the handling areas of the tools may not exceed 0.02 millisievert (2 millirems) per hour.

RH-7034. Reserved.

RH-7035. **Source Rack Protection**.

If the product to be irradiated moves on a product conveyor system, the source rack and the mechanism that moves the rack must be protected by a barrier or guides to prevent products and product carriers from hitting or touching the rack or mechanism.

RH-7036. Reserved.

RH-7037. **Power Failure**.

a. If electrical power at a panoramic irradiator is lost for longer than 10 (ten) seconds, the sources must automatically return to the shielded position.

b. The lock on the door of the radiation room of a panoramic irradiator may not be deactivated by power failure.

c. During a power failure, the area of any irradiator where sources are located may be entered only when using an operable and calibrated radiation survey meter.

RH-7038. Reserved.

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RH-7039. **Design Requirements**.

Irradiators whose construction begins after January 1, 1997, must meet the design requirements of this section.

a. **Shielding**. For panoramic irradiators, the licensee shall design shielding walls to meet generally accepted building code requirements for reinforced concrete and design the walls, wall penetrations, and entranceways to meet the radiation shielding requirements of RH-7025. If the irradiator will use more than 2 x 10^{17} becquerels (5 million curies) of activity, the licensee shall evaluate the effects of heating of the shielding walls by the irradiator sources.

b. **Foundations**. For panoramic irradiators, the licensee shall design the foundation, with consideration given to soil characteristics, to ensure it is adequate to support the weight of the facility shield walls.

c. **Pool integrity**. For pool irradiators, the licensee shall design the pool to assure that it is leak resistant, that it is strong enough to bear the weight of the pool water and shipping casks, that a dropped cask would not fall on sealed sources, that all outlets or pipes meet the requirements of RH-7033.b., and that metal components are metallurgically compatible with other components in the pool.

d. **Water handling system**. For pool irradiators, the licensee shall verify that the design of the water purification system is adequate to meet the requirements of RH-7033.e. The system must be designed so that water leaking from the system does not drain to unrestricted areas without being monitored.

e. **Radiation monitors**. For all irradiators, the licensee shall evaluate the location and sensitivity of the monitor to detect sources carried by the product conveyor system as required by RH-7029.a. The licensee shall verify that the product conveyor is designed to stop before a source on the product conveyor would cause a radiation overexposure to any person. For pool irradiators, if the licensee uses radiation monitors to detect contamination under RH-7059.b., the licensee shall verify that the design of radiation monitoring systems to detect pool contamination includes sensitive detectors located close to where contamination is likely to concentrate.

~~RH-7039. (Cont'd)~~

f. **Source rack**. For pool irradiators, the licensee shall verify that there are no crevices on the source or between the source and source holder that would promote corrosion on a critical area of the source. For panoramic

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irradiators, the licensee shall determine that source rack drops due to loss of power will not damage the source rack and that source rack drops due to failure of cables (or alternate means of support) will not cause loss of integrity of sealed sources. For panoramic irradiators, the licensee shall review the design of the mechanism that moves the sources to assure that the likelihood of a stuck source is low and that, if the rack sticks, a means exists to free it with minimal risk to personnel.

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g. **Access control**. For panoramic irradiators, the licensee shall verify from the design and logic diagram that the access control system will meet the requirements of RH-7023.

h. **Fire protection**. For panoramic irradiators, the licensee shall verify that the number, location, and spacing of the smoke and heat detectors are appropriate to detect fires and that the detectors are protected from mechanical and radiation damage. The licensee shall verify that the design of the fire extinguishing system provides the necessary discharge patterns, densities, and flow characteristics for complete coverage of the radiation room and that the system is protected from mechanical and radiation damage.

i. **Source return**. For panoramic irradiators, the licensee shall verify that the source rack will automatically return to the fully shielded position if offsite power is lost for more than ten (10) seconds.

j. **Seismic**. For panoramic irradiators to be built in seismic areas, the licensee shall design the reinforced concrete radiation shields to retain their integrity in the event of an earthquake by designing to the seismic requirements of an appropriate source such as American Concrete Institute Standard ACI 318-89, **"Building Code Requirements for Reinforced Concrete,"** Chapter 21, **"Special Provisions for Seismic Design,"** or local building codes, if current.

k. **Wiring**. For panoramic irradiators, the licensee shall verify that electrical wiring and electrical equipment in the radiation room are selected to minimize failures due to prolonged exposure to radiation.

RH-7040. Reserved.

RH-7041. **Construction Monitoring and Acceptance Testing**.

These requirements must be met for irradiators whose construction begins after January 1, 1997. The requirements must be met prior to loading sources.

a. **Shielding**. For panoramic irradiators, the licensee shall monitor the construction of the shielding to verify that its construction meets design specifications and generally accepted building code requirements for reinforced concrete.

b. **Foundations**. For panoramic irradiators, the licensee shall monitor the construction of the foundations to verify that their construction meets design specifications.

c. **Pool integrity**. For pool irradiators, the licensee shall verify that the pool meets design specifications and shall test the integrity of the pool. The licensee shall verify that outlets and pipes meet the requirements of RH-7033.b.

d. **Water handling system**. For pool irradiators, the licensee shall verify that the water purification system, the conductivity meter, and the water level indicators operate properly.

e. **Radiation monitors**. For all irradiators, the licensee shall verify the proper operation of the monitor to detect sources carried on the product conveyor system and the related alarms and interlocks required by RH-7029.a. For pool irradiators, the licensee shall verify the proper operation of the radiation monitors and the related alarm if used to meet RH-7059.b. For underwater irradiators, the licensee shall verify the proper operation of the over-the-pool monitor, alarms, and interlocks required by RH-7029.b.

f. **Source rack**. For panoramic irradiators, the licensee shall test the movement of the source racks for proper operation prior to source loading; testing must include source rack lowering due to simulated loss of power. For all irradiators with product conveyor systems, the licensee shall observe and test the operation of the conveyor system to assure that the requirements in RH-7035. are met for protection of the source rack and the mechanism that moves the rack; testing must include tests of any limit switches and interlocks used to protect the source rack and mechanism that moves the rack from moving product carriers.

g. **Access control**. For panoramic irradiators, the licensee shall test the completed access control system to assure that it functions as designed and that all alarms, controls, and interlocks work properly.

~~RH-7041. (Cont'd)~~

h. **Fire protection**. For panoramic irradiators, the licensee shall test the ability of the heat and smoke detectors to detect a fire, to activate alarms,

and to cause the source rack to automatically become fully shielded. The licensee shall test the operability of the fire extinguishing system.

i. **Source return**. For panoramic irradiators, the licensee shall demonstrate that the source racks can be returned to their fully shielded positions without offsite power.

j. **Computer systems**. For panoramic irradiators that use a computer system to control the access control system, the licensee shall verify that the access control system will operate properly if offsite power is lost and shall verify that the computer has security features that prevent an irradiator operator from commanding the computer to override the access control system when it is required to be operable.

k. **Wiring**. For panoramic irradiators, the licensee shall verify that the electrical wiring and electrical equipment that were installed meet the design specifications.

RH-7042. RH-7050. Reserved.

PART D.
RADIATION SAFETY REQUIREMENTS FOR THE OPERATION OF IRRADIATORS

RH-7051. **Training**.

a. Before an individual is permitted to operate an irradiator without a supervisor present, the individual must be instructed in:

1. The fundamentals of radiation protection applied to irradiators (including the differences between external radiation and radioactive contamination, units of radiation dose, Department dose limits, why large radiation doses must be avoided, how shielding and access controls prevent large doses, how an irradiator is designed to prevent contamination, the proper use of survey meters and personnel dosimeters, other radiation safety features of an irradiator, and the basic function of the irradiator);

2. The requirements of Section 3 that are relevant to the irradiator;

3. The operation of the irradiator;

4. Those operating and emergency procedures listed in RH-7053. that the individual is responsible for performing; and

5. Case histories of accidents or problems involving irradiators.

b. Before an individual is permitted to operate an irradiator without a supervisor present, the individual shall pass a written test on the instruction received consisting primarily of questions based on the licensee's operating and emergency procedures that the individual is responsible for performing and other operations necessary to safely operate the irradiator without supervision.

c. Before an individual is permitted to operate an irradiator without a supervisor present, the individual must have received on-the-job training or simulator training in the use of the irradiator as described in the license application. The individual shall also demonstrate the ability to perform those portions of the operating and emergency procedures that he or she is to perform.

~~RH-7051. (Cont'd)~~

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d. The licensee shall conduct safety reviews for irradiator operators at least annually. The licensee shall give each operator a brief written test on the information. Each safety review must include, to the extent appropriate, each of the following:

1. Changes in operating and emergency procedures since the last review, if any;

2. Changes in rules and license conditions since the last review, if any;

3. Reports on recent accidents, mistakes, or problems that have occurred at irradiators, if any;

4. Relevant results of inspections of operator safety performance;

5. Relevant results of the facility's inspection and maintenance checks; and

6. A drill to practice an emergency or abnormal event procedure.

e. The licensee shall evaluate the safety performance of each irradiator operator at least annually to ensure that rules, license conditions, and operating and emergency procedures are followed. The licensee shall discuss the results of the evaluation with the operator and shall instruct the operator on how to correct any mistakes or deficiencies observed.

f. Individuals who will be permitted unescorted access to the radiation room of the irradiator or the area around the pool of an underwater irradiator, but who have not received the training required for operators and the radiation safety officer, shall be instructed and tested in any precautions they should take to avoid radiation exposure, any procedures or parts of procedures listed in RH-7053. that they are expected to perform or comply with, and their proper response to alarms required in this Section. Tests may be oral.

g. Individuals who must be prepared to respond to alarms required by RH-7023.b., RH-7023.i., RH-7027.a., RH-7029.a., RH-7029.b., and RH-7059.b. shall be trained and tested on how to respond. Each individual shall be retested at least once a year. Tests may be oral.

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RH-7052. Reserved.

RH-7053. **Operating and Emergency Procedures**.

a. The licensee shall have and follow written operating procedures for:

1. Operation of the irradiator, including entering and leaving the radiation room;

2. Use of personnel dosimeters;

3. Surveying the shielding of panoramic irradiators;

4. Monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas;

5. Leak testing of sources;

6. Inspection and maintenance checks required by RH-7061;

7. Loading, unloading, and repositioning sources, if the operations will be performed by the licensee; and

8. Inspection of movable shielding required by RH-7023.h., if applicable.

b. The licensee shall have and follow emergency or abnormal event procedures, appropriate for the irradiator type, for:

1. Sources stuck in the unshielded position;

2. Personnel overexposures;

3. A radiation alarm from the product exit portal monitor or pool monitor;

4. Detection of leaking sources, pool contamination, or alarm caused by contamination of pool water;

5. A low or high water level indicator, an abnormal water loss, or leakage from the source storage pool;

6. A prolonged loss of electrical power;

7. A fire alarm or explosion in the radiation room;

8. An alarm indicating unauthorized entry into the radiation room, area around pool, or another alarm area;

~~RH-7053.b. (Cont'd)~~

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9. Natural phenomena, including an earthquake, a tornado, flooding, or other phenomena as appropriate for the geographical location of the facility; and

10. The jamming of automatic conveyor systems.

c. The licensee may revise operating and emergency procedures without Department approval only if all of the following conditions are met:

1. The revisions do not reduce the safety of the facility;

2. The revisions are consistent with the outline or summary of procedures submitted with the license application;

3. The revisions have been reviewed and approved by the radiation safety officer; and

4. The users or operators are instructed and tested on the revised procedures before they are put into use.

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RH-7054. Reserved.

RH-7055. **Personnel Monitoring**.

a. Irradiator operators shall wear a personnel dosimeter while operating a panoramic irradiator or while in the area around the pool of an underwater irradiator. The personnel dosimeter must be capable of detecting high-energy photons in the normal and accident dose ranges. Each personnel dosimeter must be assigned to and worn by only one (1) individual. Film badges must be replaced at least monthly, and all other personnel dosimeters must be replaced at least quarterly. All personnel dosimeters must be evaluated at least quarterly or promptly after replacement, whichever is more frequent.

b. Other individuals who enter the radiation room of a panoramic irradiator shall wear a dosimeter, which may be a pocket dosimeter. For groups of visitors, only two people who enter the radiation room are required to wear dosimeters. If pocket dosimeters are used to meet the requirements of this paragraph, a check of their response to radiation must be done at least annually. Acceptable dosimeters must read within plus or minus thirty percent (± 30%) of the true radiation dose.

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RH-7056. Reserved.

RH-7057. **Radiation Surveys**.

a. A radiation survey of the area outside the shielding of the radiation room of a panoramic irradiator must be conducted with the sources in the exposed position before the facility starts to operate. A radiation survey of the area above the pool of pool irradiators must be conducted after the sources are loaded but before the facility starts to operate. Additional radiation surveys of the shielding must be performed at intervals not to exceed three (3) years and before resuming operation after addition of new sources or any modification to the radiation room shielding or structure that might increase dose rates.

b. If the radiation levels specified in RH-7025. are exceeded, the facility must be modified to comply with the requirements in RH-7025.

c. Portable radiation survey meters must be calibrated at least annually to an accuracy of plus or minus twenty percent (± 20%) for the gamma energy of the sources in use. The calibration must be done at two points on each scale or, for digital instruments, at one point per decade over the range that will be used. Portable radiation survey meters must be of a type that does not saturate and read zero at high radiation dose rates.

d. Water from the irradiator pool, other potentially contaminated liquids, and sediments from pool vacuuming must be monitored for radioactive contamination before release to unrestricted areas. Radioactive concentrations must not exceed those specified in Table II-Column 2 or Table III of Appendix G entitled "Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage" in Section 3.

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e. Before releasing resins for unrestricted use, they must be monitored before release in an area with a background level less than 0.05 millirem (0.5 microsievert) per hour. The resins may be released only if the survey does not detect radiation levels above background radiation levels. The survey meter used must be capable of detecting radiation levels of 0.05 millirem (0.5 microsievert) per hour.

RH-7058. Reserved.

RH-7059. **Detection of Leaking Sources**.

a. Each dry-source-storage sealed source must be tested for leakage at intervals not to exceed six (6) months using a leak test kit or method approved by the Department, U.S. Nuclear Regulatory Commission, or an Agreement State. In the absence of a certificate from a transferor that a test has been made within the six (6) months before the transfer, the sealed source may not be used until tested. The test must be capable of detecting the presence of 200 becquerels (0.005 microcurie) of radioactive material and must be performed by a person approved by the Department, U.S. Nuclear Regulatory Commission, or an Agreement State to perform the test.

b. For pool irradiators, sources may not be put into the pool unless the licensee tests the sources for leaks or has a certificate from a transferor that a leak test has been done within six (6) months before the transfer. Water from the pool must be checked for contamination each day the irradiator operates. The check may be done either by using a radiation monitor on a pool water circulating system or by analysis of a sample of pool water. If a check for contamination is done by analysis of a sample of pool water, the results of the analysis must be available within 24 hours.

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If the licensee uses a radiation monitor on a pool water circulating system, the detection of above normal radiation levels must activate an alarm. The alarm set-point must be set as low as practical, but high enough to avoid false alarms. The licensee may reset the alarm set point to a higher level if necessary to operate the pool water purification system to clean up contamination in the pool if specifically provided for in written emergency procedures.

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c. If a leaking source is detected, the licensee shall arrange to remove the leaking source from service and have it decontaminated, repaired, or disposed of by a Department, U.S. Nuclear Regulatory Commission, or Agreement State licensee that is authorized to perform these functions. The licensee shall promptly check its personnel, equipment, facilities, and irradiated product for radioactive contamination. No product may be shipped until the product has been checked and found free of contamination. If a product has been shipped that may have been inadvertently contaminated, the licensee shall arrange to locate and survey that product for contamination. If any personnel are found to be contaminated, decontamination must be performed promptly. If contaminated equipment, facilities, or products are found, the licensee shall arrange to have them decontaminated or disposed of by a Department, U.S. Nuclear Regulatory Commission, or Agreement State licensee that is authorized to perform these functions. If a pool is

contaminated, the licensee shall arrange to clean the pool until the contamination levels do not exceed the appropriate concentration in Table II-Column 2 of Appendix G to Section 3. (See RH-601. for reporting requirements.)

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RH-7060. Reserved.

RH-7061. **Inspection and Maintenance**.

a. The licensee shall perform inspection and maintenance checks that include, as a minimum, each of the following at the frequency specified in the license or license application:

1. Operability of each aspect of the access control system required by RH-7023.

2. Functioning of the source position indicator required by RH-7031.b.

3. Operability of the radiation monitor for radioactive contamination in pool water required by RH-7059.b. using a radiation check source, if applicable.

4. Operability of the over-pool radiation monitor at underwater irradiators as required by RH-7029.b.

5. Operability of the product exit monitor required by RH-7029.a.

~~RH-7061.a. (Cont'd)~~

6. Operability of the emergency source return control required by RH-7031.c.

7. Leak-tightness of systems through which pool water circulates (visual inspection).

8. Operability of the heat and smoke detectors and extinguisher system required by RH-7027. (but without turning extinguishers on).

9. Operability of the means of pool water replenishment required by RH-7033.c.

10. Operability of the indicators of high and low pool water levels required by RH-7033.d.

11. Operability of the intrusion alarm required by RH-7023.i., if applicable.

12. Functioning and wear of the system, mechanisms, and cables used to raise and lower sources.

13. Condition of the barrier to prevent products from hitting the sources or source mechanism as required by RH-7035.

14. Amount of water added to the pool to determine if the pool is leaking.

15. Electrical wiring on required safety systems for radiation damage.

16. Pool water conductivity measurements and analysis as required by RH-7063.b.

b. Malfunctions and defects found during inspection and maintenance checks must be repaired without undue delay.

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RH-7062. Reserved.

RH-7063. **Pool Water Purity**.

a. Pool water purification system must be run sufficiently to maintain the conductivity of the pool water below twenty (20) microsiemens per centimeter under norm circumstances. If pool water conductivity rises above twenty (20) microsiemens per centimeter, the licensee shall take prompt actions to lower the pool water conductivity and shall take corrective actions to prevent future recurrences.

b. The licensee shall measure the pool water conductivity frequently enough, but no less than weekly, to assure that the conductivity remains below twenty (20) microsiemens per centimeter. Conductivity meters must be calibrated at least annually.

RH-7064. Reserved.

RH-7065. **Attendance During Operation**.

a. Both an irradiator operator and at least one other individual, who is trained on how to respond and prepared to promptly render or summon assistance if the access control alarm sounds, shall be present onsite:

1. Whenever the irradiator is operated using an automatic product conveyor system; and

2. Whenever the product is moved into or out of the radiation room when the irradiator is operated in a batch mode.

b. At a panoramic irradiator at which static irradiations (no movement of the product) are occurring, a person who has received the training on how to respond to alarms described in RH-7051.g. must be onsite.

c. At an underwater irradiator, an irradiator operator must be present at the facility whenever the product is moved into or out of the pool. Individuals who move the product into or out of the pool of an underwater irradiator need not be qualified as irradiator operators; however, they must have received the training described in RH-7051.f. and RH-7051.g. Static irradiations may be performed without a person present at the facility.

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RH-7066. Reserved.

RH-7067. **Entering and Leaving the Radiation Room**.

a. Upon first entering the radiation room of a panoramic irradiator after an irradiation, the irradiator operator shall use a survey meter to determine that the source has returned to its fully shielded position. The operator shall check the functioning of the survey meter with a radiation check source prior to entry.

b. Before exiting from and locking the door to the radiation room of a panoramic irradiator prior to a planned irradiation, the irradiator operator shall:

1. Visually inspect the entire radiation room to verify that no one else is in it; and

2. Activate a control in the radiation room that permits the sources to be moved from the shielded position only if the door to the radiation room is locked within a preset time after setting the control.

c. During a power failure, the area around the pool of an under-water irradiator may not be entered without using an operable and calibrated radiation survey meter unless the over-the-pool monitor required by RH-7029.b. is operating with backup power.

RH-7068. Reserved.

RH-7069. **Irradiation of Explosive or Flammable Materials**.

a. Irradiation of explosive material is prohibited unless the licensee has received prior written authorization from the Department. Authorization will not be granted unless the licensee can demonstrate that detonation of the explosive would not rupture the sealed sources, injure personnel, damage safety systems, or cause radiation overexposures of personnel.

b. Irradiation of more than small quantities of flammable material (flash point below 140° F) is prohibited in panoramic irradiators unless the licensee has received prior written authorization from the Department. Authorization will not be granted unless the licensee can demonstrate that a fire in the radiation room could be controlled without damage to sealed sources or safety systems and without radiation overexposures of personnel.

RH-7070. - RH-7079. Reserved.

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PART E.
RECORDS AND REPORTS

RH-7080. Reserved.

RH-7081. **Records and Retention Periods**.

The licensee shall maintain the following records at the irradiator for the periods specified.

a. A copy of the license, license conditions, documents incorporated into a license by reference, and amendments thereto until superseded by new documents or until the Department terminates the license for documents not superseded.

b. The report must include a telephone report within twenty-four (24) hours as described in RH-601.c.1. and a written report within thirty (30) days as described in RH-601.c.2.

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c. Records of the annual evaluations of the safety performance or irradiator operators required by RH-7051.e. for three (3) years after the evaluation.

d. A copy of the current operating and emergency procedures required by RH-7053. until superseded or the Department terminates the license. Records of the radiation safety officer's review and approval of changes in procedures as required by RH-7053.c.3. retained for three (3) years from the date of the change.

e. Evaluations of personnel dosimeters required by RH-7055. until the Department terminates the license

f. Records of radiation surveys required by RH-7057. for three (3) years from the date of the survey.

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g. Records of radiation survey meter calibrations required by RH-7057. and pool water conductivity meter calibrations required by RH-7063.b. until three (3) years from the date of calibration.

h. Records of the results of leak tests required by RH-7059.a. and the results of contamination checks required by RH-7059.b. for three (3) years from the date of each test.

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~~RH-7081. (Cont'd)~~

i. Records of inspection and maintenance checks required by RH-7061. for three (3) years.

j. Records of major malfunctions, significant defects, operating difficulties or irregularities, and major operating problems that involve required radiation safety equipment for three (3) years after repairs are completed.

k. Records of the receipt, transfer, and disposal, of all licensed sealed sources as required by Part F and RH-600. of Section 2.

l. Records on the design checks required by RH-7039. and the construction control checks as required by RH-7041. until the license is terminated. The records must be signed and dated. The title or qualification of the person signing must be included.

m. Records related to decommissioning of the irradiator as required by RH-409.h.

RH-7082. Reserved.

RH-7083. **Reports**.

a. In addition to the reporting requirements in other Sections of these Rules, the licensee shall report the following events if not reported under other Sections of the Department rules:

1. Source stuck in an unshielded position.

2. Any fire or explosion in a radiation room.

3. Damage to the source racks.

4. Failure of the cable or drive mechanism used to move the source racks.

5. Inoperability of the access control system.

6. Detection of radiation source by the product exit monitor.

7. Detection of radioactive contamination attributable to licensed radioactive material.

~~RH-7083.a. (Cont'd)~~

8. Structural damage to the pool liner or walls.

9. Abnormal water loss or leakage from the source storage pool.

10. Pool water conductivity exceeding 100 microsiemens per centimeter.

b. The report must include a telephone report within 24 (twenty-four) hours as described in RH-601.c.1. and a written report within thirty (30) days as described in RH-601.c.2.

RH-7084.- RH-7090. ~~———~~Reserved.

PART F.
ENFORCEMENT

RH-7091. **Violations**.

a. An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any rule or order issued thereunder. Any person who willfully violates any provision of the Act or any rule or order issued thereunder may be guilty of a felony, misdemeanor, or crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law. Arkansas Code Annotated §20-21-204 describes criminal and civil penalties which may be assessed.

b. **Impounding**.

Sources of radiation shall be subject to impounding pursuant to Section 5 of these Rules.

RH-7092.- RH-7999. Reserved.

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SECTION 9.
USE OF RADIONUCLIDES IN THE HEALING ARTS

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PART A.
GENERAL

RH-8000. **Purpose and Scope**.

This Section establishes additional requirements and provisions for the specific use of radionuclides in the healing arts. These requirements and provisions provide for the protection of public health and safety. The requirements and provisions of this Section are in addition to, and not in substitution for, others in these Rules. The requirements and provisions of these Rules apply to applicants and licensees subject to this Section unless specifically exempted.

RH-8001. **Implementation**.

a. Deleted.

b. When a requirement in Section 9 differs from the requirement in an existing license condition, the requirement in this Section shall govern.

c. Any existing license condition that is not affected by a requirement in Section 9 remains in effect until there is a license amendment or license renewal.

d. If a license condition exempted a licensee from a provision of Section 9 on October 1, 2006, it will continue to exempt a licensee from the corresponding provision in Section 9.

e. Licensees shall continue to comply with any license condition that requires it to implement procedures required by RH-8633., RH-8643., RH-8644., and RH-8645. until there is a license amendment or renewal that modifies the license condition.

RH-8002. **Maintenance of Records**.

Each record required by Section 9 must be legible throughout the retention period specified by each Department rule. The record may be the original, a reproduced copy, or a microform provided that the copy or microform is authenticated by authorized personnel and the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability of reproducing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications must include all pertinent information such as

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stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

RH-8003. **U.S. Food and Drug Administration, Federal, and State Requirements**.

Nothing in this Section relieves the licensee from complying with applicable U.S. Food and Drug Administration, other Federal, and State requirements governing radioactive drugs or devices.

RH-8004. **Provisions for Research Involving Human Subjects**.

A licensee may conduct research involving human subjects using radioactive material provided:

a. That the research is conducted, funded, supported, or regulated by a Federal Agency, which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its Department license before conducting such research. Both types of licensees shall, at a minimum, obtain prior informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects;

b. The research involving human subjects authorized in RH-8004.a. shall be conducted using radioactive material authorized for medical use in the license; and

c. Nothing in RH-8004. relieves licensees from complying with the other requirements in Section 9.

RH-8005. **License Required**.

a. A person shall only manufacture, produce, prepare, acquire, receive, possess, use, or transfer radioactive material for medical use in accordance with a specific license issued by the Department, the Nuclear Regulatory Commission, or an Agreement State, or as allowed in RH-8005.b. or RH-8005.c.

b. An individual may receive, possess, use, or transfer radioactive material in accordance with the rules in Section 9 under the supervision of an authorized user as provided in RH-8306., unless prohibited by license condition.

c. An individual may prepare unsealed radioactive material for medical use in accordance with the rules in Section 9 under the supervision of an

authorized nuclear pharmacist or authorized user as provided in RH-8306., unless prohibited by license condition.

RH-8006. **Communications**.

Except where otherwise specified, all communications concerning these Rules may be addressed to the Arkansas Department of Health, Radiation Control Section, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

RH-8007. **Interpretations**.

Except as specifically authorized by the Department in writing, no interpretations of the meaning of the rules in this Section by an officer or employee of the Department other than a written interpretation by the Department Director or designee will be recognized as binding upon the Department.

RH-8008.- RH-8009. Reserved.

RH-8010. **Application for License, Amendment, or Renewal**.

a. An application must be signed by the applicant's or licensee's management.

b. An application for a license or renewal of a license for medical use of radioactive material as described in RH-8500., RH-8530., RH-8550., RH-8600., RH-8620., RH-8630., or RH-8670. must be made by:

~~RH-8010. (Cont'd)~~

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1. Filing an original of the "Application for Radioactive Material License" and all appropriate information required by the form;

2. Submitting procedures required by sections RH-8308., RH-8400., RH-8633., RH-8643., RH-8644., and RH-8645., as applicable; and

3. Submitting the applicable fee if the application is for a new license. A renewal license application does not require a fee to be paid.

c. A request for a license amendment must be made by:

1. Submitting an original in letter format;

2. Submitting procedures required by sections RH-8308., RH-8400., RH-8633., RH-8643., RH-8644., and RH-8645., as applicable; and

3. Submitting the applicable fee.

d. In addition to the requirements in paragraphs b. and c. of this section, an application for a license, renewal of a license, or amendment of a license for medical use of radioactive material as described in RH-8670. must also include:

1. Any additional aspects of the medical use of the material that are applicable to radiation safety that are not addressed in, or differ from, Parts A through D, M, and N of this Section;

2. Identification of and commitment to follow the applicable radiation safety program requirements in Parts E through I of this Section that are appropriate for the specific RH-8670. medical use; and

3. Any additional specific information on:

A. Radiation safety precautions and instructions;

B. Training and experience of proposed users;

C. Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

D. Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety.

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e. The applicant or licensee shall also provide any other information requested by the Department in its review of the application.

f. An applicant that satisfies the requirements specified in RH-406.b. may apply for a Type A specific license of broad scope.

RH-8011. **License Amendments**.

A licensee shall apply for and must receive a license amendment:

a. Before it receives, prepares or uses radioactive material for a type of use that is permitted under Section 9, but that is not authorized on the licensee's current license issued pursuant to Section 9;

b. Before it permits anyone to work as an authorized user, authorized nuclear pharmacist, authorized medical physicist, or ophthalmic physicist under the license, except:

1. For an authorized user, an individual who meets the requirements in RH-8319. and RH-8510.a., RH-8540.a., RH-8560.a., RH-8570.a., RH-8580.a., RH-8610.a., RH-8621.a., and RH-8660.a.,

2. For an authorized nuclear pharmacist, an individual who meets the requirements in RH-8317.a. and RH-8319.;

3. For an authorized medical physicist, an individual who meets the requirements in RH-8316.a. and c. and RH-8319.;

4. An individual who is identified as an authorized user, an authorized nuclear pharmacist, authorized medical physicist, or an ophthalmic physicist:

A. On a Nuclear Regulatory Commission or Agreement State license or other equivalent permit or license recognized by the NRC that authorizes the use of radioactive material in medical use or in the practice of nuclear pharmacy;

B. On a permit issued by an NRC or Agreement State specific licensee of broad scope that is authorized to permit the use of radioactive material in medical use or in the practice of nuclear pharmacy;

C. On a permit issued by an NRC master material licensee that is authorized to permit the use of byproduct material in medical use or in the practice of nuclear pharmacy; or

~~RH-8011.b. (Cont'd)~~

D. By a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists.

5. Deleted.

c. Before it changes Radiation Safety Officers, except as provided in RH-8300.c.;

d. Before it receives radioactive material in excess of the amount, or in a different physical or chemical form than is authorized on the license;

e. Before it adds to or changes the areas of use identified in the application or on the license;

f. Before it changes the address(es) of use identified in the application or on the license;

g. Before it changes statements, representations, and procedures which are incorporated into the license;

h. Before it releases licensed facilities for unrestricted use; and

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i. Before it receives a sealed source from a different manufacturer or of a different model number than authorized by its license unless the sealed source is used for manual brachytherapy, is listed in the Sealed Source and Device Registry, and is in a quantity and for an isotope authorized by the license.

RH-8012. **Mobile Medical Service Administrative Requirements**.

a. The Department shall license mobile medical services or clients of such services. The mobile medical service shall be licensed if the service receives, uses or possesses radioactive material. The client of the mobile medical service shall be licensed if the client receives or possesses radioactive material to be used by a mobile medical service.

b. Mobile medical service licensees shall obtain a letter signed by the management of each location where services are rendered that authorizes use of radioactive material at the client's address of use. This letter shall clearly delineate the authority and responsibility of both the client and the mobile medical service. If the client is licensed, the letter shall document procedures for notification, receipt, storage, and documentation of transfer of radioactive material delivered to the client's address for use by the mobile medical service.

~~RH-8012. (Cont'd)~~

c. A mobile medical service shall not have radioactive material delivered directly from the manufacturer or the distributor to the client, unless the client has a license allowing possession of the radioactive material. Radioactive material delivered to the client shall be received and handled in conformance with the client's license.

d. A mobile medical service shall inform the client's management who is on site at each client's address of use at the time that radioactive material is being administered.

e. A licensee providing mobile medical services shall retain the letter required in RH-8012.b. in accordance with RH-8711.

f. A mobile medical service licensee shall, at a minimum, maintain the following documents on each mobile unit:

1. The current operating and emergency procedures;

2. A copy of the license;

3. A copy of applicable sections of the Arkansas State Board of Health Rules for Control of Sources of Ionizing Radiation.

4. Copies of the letter required by RH-8012.b.;

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5. Current calibration records for each survey instrument and diagnostic equipment or dose delivery device in use; and

6. Survey records covering uses associated with the mobile unit during, at a minimum, the preceding thirty (30) calendar days.

g. A mobile medical service licensee shall maintain all records required by Section 3 and Section 9 at a location within the Department's jurisdiction that is:

1. A single address of use:

A. Identified as the records retention location; and

B. Staffed at all reasonable hours by individual(s) authorized to provide the Department with access for purposes of inspection; or

2. When no address of use is identified on the license for records retention, the mobile unit:

A. Identified in the license; and

B. Whose current client's address schedule and location schedule is reported to the Department.

RH-8013. **License Issuance**.

a. The Department shall issue a license for the medical use of radioactive material if:

1. The applicant has filed the Application for Radioactive Material License in accordance with the instructions in RH-8010;

2. The applicant has paid any applicable fee;

3. The applicant meets the requirements of Section 2; and

4. The Department finds the applicant equipped and committed to observe the safety standards established by the Department in these Rules for the protection of the public health and safety.

b. The Department shall issue a license for mobile services if the applicant:

1. Meets the requirements in RH-8013.a.; and

2. Assures that individuals to whom radioactive drugs or radiation from implants containing radioactive material will be administered may be released following treatment in accordance with RH-8420.

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RH-8014.- RH-8019.– _Reserved.

RH-8020. **Notifications**.

a. A licensee shall provide to the Department, no later than thirty (30) days after the date that the licensee permits an individual to work under the provisions of RH-8011.b. as an authorized user, authorized medical physicist, ophthalmic physicist, or authorized nuclear pharmacist:

1. A copy of the board certification and, as appropriate, verification of completion of:

A. Training for the authorized medical physicist under RH-8316.c.;

B. Any additional case experience required in RH-8560.b.1.B.vii. for an authorized user under RH-8550.; or

C. Device specific training in RH-8660.c. for the authorized user under RH-8630.; or

2. A copy of the Nuclear Regulatory Commission or Agreement State license, the permit issued by an NRC master material licensee, the permit issued by an NRC or Agreement State licensee of broad scope, the permit issued by an NRC master material license broad scope permittee, or documentation that only accelerator-produced radioactive materials, discrete sources of radium-226, or both, were used for medical use or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC for each individual whom the licensee permits to work under the provisions of this section.

b. A licensee shall notify the Department by letter no later than thirty (30) days after:

1. An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, an Associate Radiation Safety Officer, an authorized medical physicist, or ophthalmic physicist permanently discontinues performance of duties under the license or has a name change;

2. The licensee's mailing address changes;

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3. The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in RH-409.b.; or

4. The licensee obtains a sealed source for use in manual brachytherapy from a different manufacturer or with a different model number than authorized by its license for which it did not require a license amendment as provided in RH-8011.i. The notification must include the manufacturer and model number of the sealed source, the isotope, and the quantity per sealed source.

RH-8021.-RH-8024. Reserved.

RH-8025. **Exemptions Regarding Type A Specific Licenses of Broad Scope**.

A licensee possessing a Type A specific license of broad scope for medical use, issued under RH-406., is exempt from:

a. The provisions of RH-8010.d. regarding the need to file an amendment to the license for medical uses of radioactive material as described in RH-8670.;

b. The provisions of RH-8011.b.;

c. The provisions of RH-8011.e. regarding additions to or changes in the areas of use at the addresses specified in the application or on the license;

d. The provisions of RH-8020.a.;

e. The provisions of RH-8020.b.1. for an authorized user, an authorized nuclear pharmacist, an authorized medical physicist, or an ophthalmic physicist; and

f. The provisions of RH-8310.a.

RH-8026. **Specific Exemptions**.

The Department may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the rules in this Section as it determines are authorized by law and will not result in undue hazard to public health and safety or property, and are otherwise in the public interest.

RH-8027.-RH-8099. Reserved.

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PART B.
DEFINITIONS

RH- 8100. **Definitions**.

-**Act** – Act 8 of Second Extraordinary Session of 1961, as amended.

Address of use – The building or buildings that are identified on the license and where radioactive material may be received, prepared, used, or stored.

Agreement State – Any state with which the Atomic Energy Commission or the U.S. Nuclear Regulatory Commission has entered into an effective agreement under subsection 274 b. of the Atomic Energy Act of 1954 (68 Stat. 919), including any amendments thereto.- Non-agreement State means any other State.

Area of use – A portion of an address of use that has been set aside for the purpose of receiving, preparing, using, or storing radioactive material.

Associate Radiation Safety Officer means an individual who:

1. Meets the requirements in RH-8315. and RH-8319.; and

2. Is currently identified as an Associate Radiation Safety Officer for the types of use of radioactive material for which the individual has been assigned duties and tasks by the Radiation Safety Officer on:

   A. A specific medical use license issued by the Nuclear Regulatory Commission or an Agreement State; or

   B. A medical use permit issued by a Nuclear Regulatory Commission master material licensee.

Authorized medical physicist means an individual who:

1. Meets the requirements in RH-8316.a. and RH-8319.; or

2. Is identified as an authorized medical physicist or teletherapy physicist on:

   A. A specific medical use license issued by the Nuclear Regulatory Commission or Agreement State;

   B. A medical use permit issued by a Nuclear Regulatory Commission master material licensee;

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C. A permit issued by a Nuclear Regulatory Commission or Agreement State broad scope medical use licensee; or

D. A permit issued by a Nuclear Regulatory Commission master material license broad scope medical use committee.

Authorized nuclear pharmacist means a pharmacist who:

1. Meets the requirements in RH-8317.a. and RH-8319.; or

2. Is identified as an authorized nuclear pharmacist on:

A. A specific license issued by the Nuclear Regulatory Commission or Agreement State that authorizes medical use or the practice of nuclear pharmacy;

B. A permit issued by a Nuclear Regulatory Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy;

C. A permit issued by a Nuclear Regulatory Commission or Agreement State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or

D. A permit issued by a Nuclear Regulatory Commission master material license broad scope medical use permittee that authorizes medical use or the practice of nuclear pharmacy; or

3. Is identified as an authorized nuclear pharmacist by a commercial nuclear pharmacy that has been authorized to identify authorized nuclear pharmacists; or

4. Is designated as an authorized nuclear pharmacist in accordance with RH-405.l.2.D.

Authorized user means a physician, dentist, or podiatrist who:

1. Meets the requirements in RH-8319. and RH-8510.a., RH-8540.a., RH-8560.a., RH-8570.a., RH-8580.a., RH-8610.a., RH-8615.a., RH-8621.a., or RH-8660.a.; or

2. Is identified as an authorized user on:

~~RH-8100. (Cont'd)~~

A. A Nuclear Regulatory Commission or Agreement State license that authorizes the medical use of radioactive material;

B. A permit issued by a Nuclear Regulatory Commission

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master material licensee that is authorized to permit the medical use of radioactive material;

C. A permit issued by a Nuclear Regulatory Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of radioactive material; or

D. A permit issued by a Nuclear Regulatory Commission master material license broad scope permittee that is authorized to permit the medical use of radioactive material.

Brachytherapy – A method of radiation therapy on which plated, embedded, activated, or sealed sources are utilized to deliver a radiation dose at a distance of up to a few centimeters, by surface, intracavitary, intraluminal or interstitial application.

Brachytherapy source – A radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.

Client's address (as used in this Section) – The address of use or a temporary jobsite for the purpose of providing mobile medical service in accordance with RH-8425.

Cyclotron – A particle accelerator in which the charged particles travel in an outward spiral or circular path.~~-~~ A cyclotron accelerates charged particles at energies usually in excess of 10 megaelectron volts and is commonly used for production of short half-life radionuclides for medical use.

Dedicated check source – A radioactive source that is used to assure the consistent response of a radiation detection or measurement device over several months or years.

Dentist – An individual licensed to practice dentistry by the state in which the Department is located.

~~RH-8100. (Cont'd)~~

Diagnostic clinical procedures manual – A collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration, or in the case of sealed sources for diagnosis, the procedure.

High dose-rate remote afterloader – A brachytherapy device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

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Low dose-rate remote afterloader – A brachytherapy device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the point or surface where the dose is prescribed.

Management – The chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities, or those persons' delegate or delegates.

Manual brachytherapy – A type of therapy in which brachytherapy sources are manually applied or inserted.

Medical institution – An organization in which several medical disciplines are practiced.

Medical use – The intentional internal or external administration of radioactive material or the radiation from radioactive material to patients or human research subjects under the supervision of an authorized user.

Medium dose-rate remote afterloader – A brachytherapy device that remotely delivers a dose rate of greater than 2 gray (200 rads) per hour, but less than or equal to 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.

Misadministration – An event that meets the criteria in RH-8800.a. or b.

Mobile medical service – The transportation of radioactive material or its medical use at the client's address.

Ophthalmic physicist means an individual who:

1. Meets the requirements in RH-8608.a.2. and RH-8319; and

2. Is identified as an ophthalmic physicist on a:

   A. Specific medical use license issued by the Nuclear Regulatory Commission or an Agreement State;

   B. Permit issued by a Nuclear Regulatory Commission or Agreement State broad scope medical use licensee;

   C. Medical use permit issued by a Nuclear Regulatory Commission master material licensee; or

   D. Permit issued by a Nuclear Regulatory Commission master material licensee broad scope medical use permittee.

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Output – The exposure rate, dose rate, or a quantity related in a known manner to these rates from a brachytherapy source, or a teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.

Patient intervention – Actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

Pharmacist (as used in this Section) – An individual licensed by the appropriate authority to practice pharmacy in the state in which the Department is located.

Physician – A doctor of medicine or doctor of osteopathy licensed by the Arkansas State Medical Board to prescribe drugs in the practice of medicine.

Podiatrist – An individual licensed by the appropriate authority to practice podiatry in the state in which the Department is located.

Positron Emission Tomography (PET) radionuclide production facility – A facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.

Preceptor – An individual who provides, directs, or verifies the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, a Radiation Safety Officer, or an Associate Radiation Safety Officer.

Prescribed dosage – the specified activity or range of activity of a radioactive drug as documented:

1. In a written directive as specified in RH-8307; or

2. In accordance with the directions of the authorized user for procedures performed pursuant to RH-8500. and RH-8530.

Prescribed dose:

1. For gamma stereotactic radiosurgery, the total dose as documented in the written directive;

2. For teletherapy, the total dose and dose per fraction as documented in the written directive;

3. For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or

4. For remote brachytherapy, the total dose and dose per fraction as documented in the written directive.

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Pulsed dose-rate remote afterloader – A special type of remote afterloading device that uses a single source capable of delivering dose rates in the "high dose-rate" range, but:

1. Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and

2. Is used to simulate the radiobiology of a low dose rate treatment by inserting the source for a given fraction of each hour.

Radiation Safety Officer means an individual who:

1. Meets the requirements in RH-8315.a. or -RH-8315.c.l. and RH-8319.; or

2. Is identified as a Radiation Safety Officer on:

   A. A specific medical use license issued by the Nuclear Regulatory Commission or Agreement State; or

   B. A medical use permit issued by a Nuclear Regulatory Commission master material licensee.

Radioactive drug – Any chemical compound containing radioactive material that may be used on or administered to patients or human research subjects as an aid in the diagnosis, treatment, or prevention of disease or other abnormal condition.

Sealed source (as used in this Section) – Any radioactive material that is encased in a capsule designed to prevent leakage or escape of the radioactive material.

~~RH-8100. (Cont'd)~~

Sealed Source and Device Registry – The national registry that contains all the registration certificates, generated by both the Nuclear Regulatory Commission and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.

Stereotactic radiosurgery – The use of external radiation in conjunction with a stereotactic guidance device to precisely deliver a dose to a treatment site.

Structured educational program – An educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

Teletherapy (as used in this Section) – A method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.

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Temporary jobsite (as used in this Section) – A location where mobile medical services are conducted other than the location(s) of use authorized on the license.

Therapeutic dosage – A dosage of unsealed radioactive material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.

Therapeutic dose – A radiation dose delivered from a sealed source containing radioactive material to a patient or human research subject for palliative or curative treatment.

Treatment site – The anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.

Type of use – Use of radioactive material as specified under RH-8500., RH-8530., RH-8550., RH-8600., RH-8620., RH-8630., or RH-8670.

Unit dosage – A dosage that:

1. Is obtained or prepared in accordance with the rules for uses described in RH-8500., RH-8530., or RH-8550.; and

2. Is to be administered as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

~~RH-8100. (Cont'd)~~

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Written directive – An authorized user's written order for the administration of radioactive material or radiation from radioactive material to a specific patient or human research subject, as specified in RH-8307.

RH-8101.- RH-8299.– _Reserved.

PART C.
GENERAL ADMINISTRATIVE REQUIREMENTS

RH-8300. **Authority and Responsibilities for the Radiation Protection Program**.

a. In addition to the radiation protection program requirements of RH-1004., a licensee's management must approve in writing:

1. Requests for license application, renewal, or amendments before submittal to the Department;

2. Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist or authorized medical physicist; and

3. Radiation protection program changes that do not require a license amendment and are permitted under RH-8301.

b. A licensee's management shall appoint a Radiation Safety Officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. A licensee's management may appoint, in writing, one or more Associate Radiation Safety Officers to support the Radiation Safety Officer. The Radiation Safety Officer, with written agreement of the licensee's management, must assign the specific duties and tasks to each Associate Radiation Safety Officer. These duties and tasks are restricted to the types of use for which the Associate Radiation Safety Officer is listed on a license. The Radiation Safety Officer may delegate duties and tasks to the Associate Radiation Safety Officer but shall not delegate the authority or responsibilities for implementing the radiation protection program.

c. For up to sixty (60) days each year, a licensee may permit an authorized user or an individual qualified to be a radiation safety officer to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in paragraph e. of this section, provided the licensee takes the actions required in paragraphs b., d., e., and h. of this section . A licensee may simultaneously appoint more than one (1) temporary RSO, if needed, to ensure that the licensee has a temporary RSO that satisfies the requirements to be an RSO for each of the different uses of radioactive material permitted by the license.

~~RH-8300. (Cont'd)~~

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d. A licensee shall establish the authority, duties, and responsibilities of the Radiation Safety Officer in writing.

e. A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to:

1. Identify radiation safety problems;

2. Initiate, recommend, or provide corrective actions;

3. Stop unsafe operations; and,

4. Verify implementation of corrective actions.

f. Medical institutions that are authorized for radioactive material use under RH-8500., RH-8530., RH-8550., RH-8600., RH-8620., RH-8630., and RH-8670. shall establish a Radiation Safety Committee to oversee all uses of radioactive material permitted by the license.

g. The Committee shall:

1. Include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer, and may include other members the licensee deems appropriate;

2. Meet as necessary, but at a minimum shall meet at intervals not to exceed six (6) months; and

3. Maintain minutes of each meeting in accordance with RH-8700.

h. A licensee shall retain a record of actions taken pursuant to paragraphs a., b., and d. of this section in accordance with RH-8700.

RH-8301. **Radiation Protection Program Changes**.

a. A licensee may revise its radiation protection program without Department approval if:

1. The revision does not require an amendment under RH-8011.;

2. The revision is in compliance with the rules and the license;

~~RH-8301.a. (Cont'd)~~

3. The revision has been reviewed and approved by the Radiation Safety Officer, licensee management and licensee's Radiation Safety Committee (if applicable); and

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4. The affected individuals are instructed on the revised program before the changes are implemented.

b. A licensee shall retain a record of each change in accordance with RH-8701.

RH-8302.- RH-8304.– _Reserved.

RH-8305. **Duties of Authorized User and Authorized Medical Physicist**.

a. A licensee shall assure that only authorized users for the type of radioactive material used:

1. Prescribe the radiopharmaceutical dosage ~~and/or~~or dose to be administered through the issuance of a written directive or reference to the diagnostic clinical procedures manual; and

2. Direct, as specified in RH-8306. and RH-8307., or in license conditions, the administration of radioactive material for medical use to patients or human research subjects;

3. Prepare and administer, or supervise the preparation and administration of radioactive material for medical use, in accordance with RH-8005.b., RH-8005.c., and RH-8306.;

b. A licensee shall assure that only authorized medical physicists perform, as applicable:

1. Full calibration measurements as described in RH-8640., RH-8641., and RH-8642.;

2. Periodic spot checks as described in RH-8643., RH-8644., and RH-8645.; and

3. Radiation surveys as described in RH-8650.

RH-8306. **Supervision**.

a. A licensee that permits the receipt, possession, use, or transfer of radioactive material by an individual under the supervision of an authorized user as allowed by RH-8005.b. shall:

1. In addition to the requirements in RH-2803., instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, rules of Section 9, and

license conditions with respect to the use of radioactive material; and

2. Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures, written directive procedures, rules of Section 9, and license conditions with respect to the medical use of radioactive material.

b. A licensee that permits the preparation of radioactive material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by RH-8005.c., shall:

1. Instruct the supervised individual in the preparation of radioactive material for medical use, as appropriate to that individual's involvement with radioactive material; and

2. Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of radioactive material for medical use, the written radiation protection procedures, the rules of Section 9, and license conditions.

c. Unless physical presence as described in other sections of Section 9 is required, a licensee who permits supervised activities under RH-8306.a. and RH-8306.b. shall require an authorized user to be immediately available (by telephone within ten (10) minutes) to communicate with the supervised individual, and able to be physically present within one (1) hour of notification; and

d. A licensee that permits supervised activities under RH-8306.a. and RH-8306.b. is responsible for the acts and omissions of the supervised individual.

RH-8307. **Written Directives**.

a. A written directive must be dated and signed by an authorized user prior to administration of I-131 sodium iodide greater than 1.11 megabecquerels (30 μCi), any therapeutic dosage of radioactive material or any therapeutic dose of radiation from radioactive material.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented as soon as possible in writing

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in the patient's record and a written directive is prepared within 48 hours of the oral directive.

b. The written directive must contain the patient or human research subject's name and the following:

1. For any administration of quantities greater than 1.11 megabecquerels (30 µCi) of I-131 sodium iodide, the dosage;

2. For an administration of a therapeutic dosage of radioactive material other than I-131 sodium iodide, the radioactive drug, dosage, and route of administration;

3. For gamma stereotactic radiosurgery, the total dose, treatment site, and values for the target coordinate settings per treatment for each anatomically distinct treatment site;

4. For teletherapy, the total dose, dose per fraction, number of fractions, and treatment site;

5. For high dose-rate remote afterloading brachytherapy, the radionuclide, treatment site, dose per fraction, number of fractions, and total dose;

6. For permanent implant brachytherapy:

A. Prior to implantation:~~-~~ the treatment site, radionuclide, and total source strength; and

B. After implantation but before the patient leaves the post-treatment recovery area:~~-~~ the treatment site, number of sources implanted, total source strength implanted, and the date; or

~~RH 8307. (Cont'd)~~

7. For all other brachytherapy, including low, medium, and pulsed dose-rate remote afterloaders:

A. Prior to implantation: ~~-~~the treatment site, radionuclide, and the dose; and

B. After implantation but prior to completion of the procedure: the radionuclide, treatment site, number of sources, total source strength and exposure time (or, the total dose), and the date.

c. A written revision to an existing written directive may be made provided that the revision is dated and signed by an authorized user prior to the

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administration of the dosage of radioactive drug containing radioactive material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

d. The licensee shall retain the written directive in accordance with RH-8702.

RH-8308. **Procedures for Administrations Requiring a Written Directive**.

a. For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:

1. The patient's or human research subject's identity is verified before each administration; and

2. Each administration is in accordance with the written directive.

b. The procedures required by paragraph a. of this section must, at a minimum, address the following items that are applicable to the licensee's use of radioactive material:

1. Verifying the identity of the patient or human research subject;

~~RH-8308. (Cont'd)~~

2. Verifying that the specific details of the administration are in accordance with the treatment plan, if applicable, and the written directive;

3. Checking both manual and computer-generated dose calculations;

4. Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by RH-8630. or RH-8670.;

5. Determining if a misadministration, as defined in RH-8800., has occurred; and

6. Determining, for permanent implant brachytherapy, within sixty (60) calendar days from the date the implant was performed, the total source strength administered outside of the treatment site

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compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.

c. A licensee shall retain a copy of the procedures required under paragraph a. of this section for the duration of the license.

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RH-8309. Reserved.

RH-8310. **Suppliers for Sealed Sources or Devices for Medical Use**.

For medical use, a licensee shall only use:

a. Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to Section 2 or the equivalent requirements of the Nuclear Regulatory Commission or an Agreement State;

b. Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to Section 2 or the equivalent requirements of the Nuclear Regulatory Commission or an Agreement State; or

c. Sealed sources or devices non-commercially transferred from a Section 9 licensee or a Nuclear Regulatory Commission or Agreement State medical use licensee.

RH-8311.- RH-8314.– _Reserved.

RH-8315. **Training for Radiation Safety Officer**.

Except as provided in RH-8318., the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer or an individual assigned duties and tasks as an Associate Radiation Safety Officer as provided in RH-8300. to be an individual who:

a. Is certified by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraph d. of this section.- The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page.- To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. A. Hold a bachelor's or graduate degree from an accredited

college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science;

B. Have five (5) or more years of professional experience in health physics (graduate training may be substituted for no more than two (2) years of the required experience) including at least three (3) years in applied health physics; and

C. Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or

2. A. Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

B. Have two (2) years of full-time practical training ~~and/or~~or supervised experience in medical physics:

~~RH-8315.a.2. (Cont'd)~~

i. Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Nuclear Regulatory Commission or an Agreement State; or

ii. In clinical nuclear medicine facilities providing diagnostic or therapeutic services under the direction of physicians who meet the requirements for authorized users in RH-8318., RH-8540., or RH-8560.; and

iii. Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or

b. 1. Has completed a structured educational program consisting of both:

A. 200 hours of classroom and laboratory training in the following areas:

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i. Radiation physics and instrumentation;

ii. Radiation protection;

iii. Mathematics pertaining to the use and measurement of radioactivity;

iv. Radiation biology; and

v. Radiation dosimetry; and

~~RH-8315.b.1. (Cont'd)~~

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B. One (1) year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on a Nuclear Regulatory Commission or Agreement State license or permit issued by a Nuclear Regulatory Commission master material licensee that authorizes similar type(s) of use(s) of radioactive material. An Associate Radiation Safety Officer may provide supervision for those areas for which the Associate Radiation Safety Officer is authorized on a Nuclear Regulatory Commission or an Agreement State license or permit issued by a Nuclear Regulatory Commission master material licensee. The full-time radiation safety experience must involve the following:

i. Shipping, receiving, and performing related radiation surveys;

ii. Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides;

iii. Securing and controlling radioactive material;

iv. Using administrative controls to avoid mistakes in the administration of radioactive material;

v. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures;

vi. Using emergency procedures to control radioactive material; and

vii. Disposing of radioactive material; and

2. This individual must obtain a written attestation, signed by a preceptor Radiation Safety Officer or Associate Radiation Safety Officer who has experience with the radiation safety aspects of similar types of use of radioactive material for which the individual is seeking approval as a Radiation Safety Officer or an Associate Radiation Safety Officer. -The written attestation must state that the individual has satisfactorily completed the requirements in paragraphs b.1. and d. of this section and is able to independently fulfill the radiation safety-related duties as a Radiation Safety Officer or as an Associate Radiation Safety Officer for a medical use license; or

c. 1. Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State under RH-8316.a., has experience with the radiation safety aspects of similar types of use of radioactive material for which the licensee seeks the approval of the individual as Radiation Safety Officer or an Associate Radiation Safety Officer, and meets the requirements in paragraph d. of this section; or

2. Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on a Nuclear Regulatory Commission or an Agreement State license, a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by a Nuclear Regulatory Commission or an Agreement State licensee of broad scope, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee, has experience with the radiation safety aspects of similar types of use of radioactive material for which the licensee seeks the approval of the individual as the Radiation Safety Officer or Associate Radiation Safety Officer, and meets the requirements in paragraph d. of this section; or

3. Has experience with the radiation safety aspects of the types of use of radioactive material for which the individual is seeking simultaneous approval both as the Radiation Safety Officer and the authorized user on the same new medical use license or new medical use permit issued by a Nuclear Regulatory Commission master material licensee. -The individual must also meet the requirements in paragraph d. of this section.

d. Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that

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is supervised by a Radiation Safety Officer, an Associate Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.

RH-8316. **Training for Authorized Medical Physicist**.

Except as provided in RH-8318., the licensee shall require the authorized medical physicist to be an individual who:

a. Is certified by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraph c. of this section. The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit webpage. To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;

2. Have two (2) years of full-time practical training ~~and/or~~or supervised experience in medical physics:

A. Under the supervision of a medical physicist who is certified in medical physics by a specialty board whose certification process has been recognized under this section by the Nuclear Regulatory Commission or an Agreement State; or

B. In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to one (1) million electron volts) and brachytherapy services under the direction of physicians who meet the requirements in RH-8318., RH-8610., or RH-8660.; and

3. Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or

~~RH-8316. (Cont'd)~~

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b. 1. Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed one (1) year of full-time training in medical physics and an additional year of full-time work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization.

This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to one (1) million electron volts) and brachytherapy services and must include:

A. Performing sealed source leak tests and inventories;

B. Performing decay corrections;

C. Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

D. Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and

2. Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs b.1. and c. of this section and is able to independently fulfill the radiation safety-related duties as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in RH-8316., RH-8318., or equivalent Nuclear Regulatory Commission or Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.

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c. Has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.

RH-8317. **Training for Authorized Nuclear Pharmacist**.

Except as provided in RH-8318, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

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a. Is certified by a specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State. The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Have graduated from a pharmacy program accredited by the Accreditation Council for Pharmacy Education (ACPE) (previously named the American Council on Pharmaceutical Education) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination;

2. Hold a current, active license to practice pharmacy;

3. Provide evidence of having acquired at least 4000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours of the required training and experience; and

4. Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or

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b. 1. Has completed 700 hours in a structured educational program consisting of both:

A. 200 hours of classroom and laboratory training in the following areas:

i. Radiation physics and instrumentation;

ii. Radiation protection;

iii. Mathematics pertaining to the use and measurement of radioactivity;

iv. Chemistry of radioactive material for medical use; and

v. Radiation biology; and

B. Supervised practical experience in a nuclear pharmacy involving:

i. Shipping, receiving, and performing related radiation surveys;

ii. Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha-or beta-emitting radionuclides;

iii. Calculating, assaying, and safely preparing dosages for patients or human research subjects;

iv. Using administrative controls to avoid misadministrations in the administration of radioactive material; and

v. Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

~~RH-8317.b. (Cont'd)~~

2. Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in paragraph b.1. of this section and is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.

RH-8318. **Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist, and Authorized Nuclear Pharmacist**.

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a. 1. An individual identified on a Nuclear Regulatory Commission or an Agreement State license or a permit issued by a Nuclear Regulatory Commission or an Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope as a Radiation Safety Officer, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist or an authorized nuclear pharmacist on or before January 14, 2019, need not comply with the training requirements of RH-8315., RH-8316., or RH-8317., respectively, except the Radiation Safety Officers and authorized medical physicists identified in this paragraph must meet the training requirements in RH-8315.d. or RH-8316.c., as appropriate, for any material or uses for which they were not authorized prior to this date.

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2. Any individual certified by the American Board of Health Physics in Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of RH-8315. to be identified as a Radiation Safety Officer or as an Associate Radiation Safety Officer on a Nuclear Regulatory Commission or an Agreement State license or Nuclear Regulatory Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.

~~RH-8318.a. (Cont'd)~~

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3. Any individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, x-ray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in RH-8316., for those materials and uses that these individuals performed on or before October 24, 2005.

4. A Radiation Safety Officer, a medical physicist, or a nuclear pharmacist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training

requirements of RH-8315., RH-8316, or RH-8317., respectively, when performing the same uses. A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and time period identified in this paragraph, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for the purposes of these Rules.

b. 1. Physicians, dentist, or podiatrists identified as authorized users for the medical use of radioactive material on a license issued by the Nuclear Regulatory Commission or an Agreement State, a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by a Nuclear Regulatory Commission or Agreement State broad scope licensee, or a permit issued by a Nuclear Regulatory Commission master material license broad scope permittee on or before January 14, 2019, who perform only those medical uses for which they were authorized on or before that date need not comply with the training requirements of RH-8510., RH-8540., RH-8560., RH-8570., RH-8580., RH-8590., RH-8610., RH-8615., RH-8621., and RH-8660. (Parts E through I of this Section).

~~RH-8318.a. (Cont'd)~~

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2. Physicians, dentist, or podiatrists not identified as authorized users for the medical use of radioactive material on a license issued by the Nuclear Regulatory Commission or an Agreement State, a permit issued by a Nuclear Regulatory Commission master material licensee, a permit issued by a Nuclear Regulatory Commission or an Agreement State board scope licensee, or a permit issued in accordance with a Nuclear Regulatory Commission master material broad scope license on or before October 24, 2005, need not comply with the training requirements of RH-8510., RH-8540., RH-8560., RH-8570., RH-8580., RH-8590., RH-8610., RH-8615., RH-8621., and RH-8660. (Parts E through I of this Section) for those materials and uses that these individuals performed on or before October 24, 2005, as follows:

A. For uses authorized under RH-8500. or RH-8530., or oral administration of sodium iodide I–131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or

American Osteopathic Board of Nuclear Medicine in nuclear medicine;

B. For uses authorized under RH-8550., a physician who was certified on or before October 24, 2005, by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;

C. For uses authorized under RH-8600. or RH-8630., a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and

~~RH-8318.a. (Cont'd)~~

D. For uses authorized under RH-8620., a physician who was certified on or before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

3. Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of RH-8510., RH-8540., RH-8560., RH-8570., RH-8580., RH-8590., RH-8610., RH-8615., RH-8621., and RH-8660. (Parts E through I of this Section) when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time period identified in this paragraph, qualifies as an authorized user for those materials and uses performed before these dates, for the purposes of these Rules.

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c. Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on Department licenses for the same uses for which these individuals are authorized.

RH-8319. **Recentness of Training**.

The training and experience specified in Section 9's Part C (General Administrative Requirements), Part E (Unsealed Radioactive Material – Written Directive Not Required), Part F (Unsealed Radioactive Material – Written Directive Required), Part G (Manual Brachytherapy), Part H (Sealed Sources for Diagnosis), and Part I (Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units) must have been obtained within the seven (7) years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

RH-8320.-RH-8399.– _Reserved.

PART D:
GENERAL TECHNICAL REQUIREMENTS

RH-8400. **Quality Control of Diagnostic Equipment**.

Each licensee shall establish written quality control procedures for all diagnostic equipment used for radionuclide studies. As a minimum, quality control procedures and frequencies shall be those recommended by equipment manufacturers or approved by the Department. The licensee shall conduct quality control procedures in accordance with written procedures. Each licensee shall retain records of quality control of diagnostic equipment for three (3) years after the record is made.

RH-8401. **Possession, Use, Checking, and Testing of Instruments Used to Measure the Activity of Unsealed Radioactive Material**.

a. For direct measurements performed in accordance with RH-8403., a licensee shall possess and use instrumentation to measure the activity of unsealed radioactive material prior to administration to each patient or human research subject.

b. A licensee shall:

1. Check each instrument for constancy with a dedicated check source before use each day of use. The check shall be performed on a frequently used setting with a sealed source of not less than 50 microcuries (1.85 MBq) of any photon-emitting radionuclide with a half-life greater than 90 days.

2. Test each instrument for accuracy at the time of installation and at least every 12 months thereafter. The test shall be completed by assaying at least two sealed sources containing different radionuclides, the activity of which has been determined by the National Institute of Standards and Technology (NIST) or by the manufacturer who has compared their source to a source calibrated by the NIST. The sources shall have a minimum activity of 50 microcuries (1.85 MBq) of any photon-emitting radionuclide. At least one of the sources shall have a principal photon energy between 100 keV and 500 keV.

3. Test each instrument for linearity at the time of installation and at least every three months thereafter over the range of its use between the highest and lowest dosage that will be administered.

~~RH-8401.b. (Cont'd)~~

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4. Test each instrument for geometry dependence at the time of installation over the range of volumes and volume configurations for which it will be used.

c. A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds manufacturer's instructions, not to exceed ten percent (10%), if the dosage is greater than 30 microcuries (1.11 MBq) and shall repair or replace the instrument if the accuracy or constancy error exceeds manufacturer's instructions, not to exceed ten percent (10%).

d. Prior to medical use, a licensee shall also perform checks and tests required by RH-8401. following adjustment, repair, or relocation of the instrument.

e. Quality control methods not in accordance with RH-8401. must be authorized by the Department prior to use.

f. A licensee shall retain a record of each instrument check or test required by RH-8401. in accordance with RH-8705.

RH-8402. **Calibration of Survey Instruments**.

a. A licensee shall ensure that the survey instruments used to show compliance with Section 9 and Section 3 have been calibrated before first use, annually, and following any repair that will affect the calibration.

b. To satisfy the requirements of RH-8402.a., the licensee shall:

1. Calibrate all required scale readings up to ten (10) millisieverts (1000 mrem) per hour with a radiation source;

2. Have each radiation survey instrument calibrated:

A. At energies appropriate for use and at intervals not to exceed twelve (12) months or after instrument servicing, except for battery changes;

~~RH-8402.b.2. (Cont'd)~~

B. For linear scale instruments, at two (2) points located approximately one-third and two-thirds of full-scale on each scale; for logarithmic scale instruments, at mid-range of each decade, and at two (2) points of at least one (1)

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decade; and for digital instruments, at three (3) points between 0.02 and 10 millisieverts (2 and 1000 mrem) per hour; and

C. For dose rate instruments, so that an accuracy within plus or minus twenty percent (± 20%) of the true radiation dose rate can be demonstrated at each point checked.

3. Conspicuously note on the instrument the date of calibration.

c. The licensee shall not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is greater than twenty percent (20%).

d. A licensee shall check each survey instrument for consistent response with a dedicated check source before each use. The licensee is not required to keep records of these checks.

e. The licensee shall retain a record of each survey instrument calibration in accordance with RH-8706.

RH-8403. **Determination of Dosages of Radioactive Material for Medical Use**.

a. A licensee shall determine and record the activity of each dosage prior to medical use.

b. For all radionuclides, this determination must be made by direct measurement.

c. Unless otherwise directed by the authorized user, a licensee shall not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than twenty percent (20%).

d. Dosage determination methods other than by direct measurement must be authorized by the Department prior to use.

e. A licensee shall retain a record of the dosage determination required by Section 9 in accordance with RH-8707.

RH-8404. **Authorization for Calibration, Transmission, and Reference Sources**.

a. Any person authorized by RH-8005. for medical use of radioactive material may receive, possess, and use the following radioactive material for check, calibration, transmission, and reference use:

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1. Sealed sources, not exceeding 1.11 gigabecquerels (30 mCi) each, manufactured and distributed by a person licensed under RH-405.n. or equivalent Nuclear Regulatory Commission or Agreement State regulations;

2. Sealed sources, not exceeding 1.11 gigabecquerels (30 mCi each), redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under RH-405.n. or equivalent Nuclear Regulatory Commission or Agreement State regulations, provided the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions;

3. Any radioactive material with a half-life of 120 days or less in individual amounts not to exceed 0.56 gigabecquerels (15 mCi);

4. Any radioactive material with a half-life greater than 120 days in individual amounts not to exceed the smaller of:

   A. 7.4 megabecquerels (200 μCi); or

   B. 1000 times the quantities in Schedule B to Section 2 (RH-901); or

5. Technetium-99m in amounts as needed.

b. Radioactive material in sealed sources authorized by this section shall not be:

1. Used for medical use as defined in RH-8100. except in accordance with the requirements in RH-8620.; or

2. Combined (i.e., bundled or aggregated) to create an activity greater than the maximum activity of any single sealed source authorized under this section.

~~RH-8404. (Cont'd)~~

c. A licensee using calibration, transmission, and reference sources in accordance with the requirements in paragraph a. or b. of this section need not list these sources on a specific medical use license.

RH-8405. **Requirements for Possession of Sealed Sources and Brachytherapy Sources**.

a. A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer or equivalent instructions approved by the Department.

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b. A licensee in possession of a sealed source shall:

1. Test the source for leakage in accordance with Section 3.

2. Test the source for leakage at intervals not to exceed six (6) months or at other intervals approved by the Department, an Agreement State or the Nuclear Regulatory Commission in the Sealed Source and Device Registry.

c. The leak test shall be capable of detecting the presence of 185 becquerels (0.005 μCi) of radioactive material on the test sample. The test sample shall be taken from the sealed source or from the surfaces of the device in which the sealed source is mounted or stored on which contamination might be expected to accumulate. Records of the leak test results shall be kept in units of microcuries and maintained for inspection by the Department.

d. If the leak test reveals the presence of 185 becquerels (0.005 μCi) or more of removable contamination, the licensee shall:

1. Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements of Sections 2 and 3;

2. File a report with the Department within five (5) days of receiving the leak tests results in accordance with RH-8802.

e. A licensee in possession of a sealed source or brachytherapy source, except for gamma stereotactic radiosurgery sources, shall conduct a quarterly physical inventory of all such sources. The licensee shall retain each inventory record in accordance with RH-8708.

RH-8406. **Labels**.

Each syringe and vial that contains a radioactive drug shall be labeled to identify the radioactive drug. Each syringe shield and vial shield shall also be labeled unless the label on the syringe or vial is visible when shielded.

RH-8407. **Vial Shields**.

A licensee shall require each individual preparing or handling a vial that contains a radioactive drug to keep the vial in a vial radiation shield.

RH-8408. **Surveys for Ambient Radiation Dose Rate and Contamination**.

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a. Except as provided in RH-8408.b., a licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radioactive drugs containing radioactive material were prepared for use or administered.

b. A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radioactive drugs or radioactive wastes are stored.

c. A licensee shall conduct the surveys required by RH-8408.a. and RH-8408.b. so as to be able to measure dose rates as low as one (1) microsievert (0.1 mrem) per hour.

d. A licensee shall establish dose rate action levels for the surveys required by RH-8408.a. and RH-8408.b. and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds an action level.

e. A licensee shall survey for removable contamination each week of use all areas where radioactive drugs are prepared for use, administered, and where radioactive materials are stored.

f. A licensee shall conduct the surveys required by RH-8408.e. so as to be able to detect contamination on each wipe sample of 33.3 becquerels (2000 dpm).

g. A licensee shall establish removable contamination action levels for the surveys required by RH-8408.e. and shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds action levels.

~~RH-8408. (Cont'd)~~

h. A licensee does not need to perform the surveys required by RH-8408.a. in area(s) where patients or human research subjects are confined when they cannot be released pursuant to RH-8420.

i. A licensee shall retain a record of each survey in accordance with RH-8709.

RH-8409. **Storage and Control of Volatiles and Gases**.

a. A licensee shall store volatile radioactive materials and radioactive gases in a radiation shield and container.

b. A licensee shall store and use a multi-dose container in a properly functioning fume hood.

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c. A licensee who administers radioactive aerosols or gases shall do so with a system that will keep airborne concentrations within the limits prescribed in Section 3.

d. The system shall either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container.

e. A licensee shall check the operation of collection systems at intervals recommended by the manufacturer or approved by the Department. The records of these checks shall be maintained for three (3) years.

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RH-8410. **Decay-in-Storage**.

a. A licensee may hold radioactive material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:

1. Monitors radioactive material at the container surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey instrument set on its most sensitive scale and with no interposed shielding;

2. Removes or obliterates all radiation labels, except for material that will be handled as biomedical waste after release; and

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~~RH-8410.a. (Cont'd)~~

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3. Separates and monitors each generator column individually with all radiation shielding removed to ensure that its contents have decayed to background radiation level before disposal.

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b. For radioactive material disposed in accordance with RH-8410.a. of this section, the licensee shall retain a record of each disposal in accordance with RH-8712.

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RH-8411.- RH-8419. Reserved.

RH-8420. **Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material**.

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a. A licensee may authorize the release from its control of any individual who has been administered unsealed radioactive material or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 0.5 rem (5 mSv) per year.

~~RH-8420. (Cont'd)~~

b. A licensee shall provide the released individual, or the individual's parent or guardian, with oral and written instructions on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 0.1 rem (1 mSv). ~~-~~If the total effective dose equivalent to a breast-feeding infant or child could exceed 0.1 rem (1 mSv) assuming there were no interruption of breast-feeding, the instructions shall also include:

1. Guidance on the interruption or discontinuation of breast-feeding; and

2. Information on the potential consequences, if any, of failure to follow the guidance.

c. Release of the individual shall be directly approved by an authorized user listed on the license, if the release requires a record under RH-8710.~~-~~ The authorized user must be approved for use of the type of radioactive material for which the individual being released has received.

d. Records of the basis for authorizing the release of an individual shall be retained in accordance with RH-8710.

e. Records of instructions provided to a breast-feeding woman shall be retained in accordance with RH-8710.

RH-8421~~-~~ RH-8424.~~–~~ _Reserved.

RH-8425. **Mobile Medical Service Technical Requirements**.

A licensee providing mobile medical service shall:

a. Transport to each client's address only syringes or vials containing prepared drugs or radioactive materials that are intended for reconstitution of radioactive drug kits;

b. Bring into each client's address all radioactive material to be used and, before leaving, remove all unused radioactive material and associated radioactive waste;

c. Secure or keep under constant surveillance and immediate control all radioactive material when in transit or at a client's address;

~~RH-8425. (Cont'd)~~

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d. Check instruments used to measure the activity of unsealed radioactive material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. -At a minimum, the check for proper function shall include a constancy check;

e. Check survey instruments for consistent response with a dedicated check source before use at each client's address;

f. Prior to leaving a client's address, perform area surveys and survey for removable contamination in all areas of use, to ensure compliance with Section 3;

g. Use radioactive gases only in areas of use and under conditions which have been evaluated and approved by the Department for compliance with airborne release standards; and,

h. Retain a record of each survey required by RH-8425.f. in accordance with RH-8711.

RH-8426.- RH-8499.– _Reserved.

PART E:
UNSEALED RADIOACTIVE MATERIAL –
WRITTEN DIRECTIVE NOT REQUIRED

RH-8500. **Use of Unsealed Radioactive Material for Uptake, Dilution, and Excretion Studies for Which a Written Directive Is Not Required**.

Except for quantities that require a written directive under RH-8307., a licensee may use any unsealed radioactive material prepared for medical use for uptake, dilution, or excretion studies that is:

a. Obtained from:

1. A manufacturer or preparer licensed under RH-405.l. or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

2. A PET radioactive drug producer licensed under RH-403.j.– or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

b. Excluding production of PET radionuclides, prepared by:

1. An authorized nuclear pharmacist;

2. A physician who is an authorized user and who meets the requirements specified in RH-8540., or RH-8560. and RH-8540.c.1.B.vii.; or

3. An individual under the supervision, as specified in RH-8306.; of the authorized nuclear pharmacist in paragraph b.1. of RH-8500. or the physician who is an authorized user in paragraph b.2. of RH-8500.; or

c. Obtained from and prepared by a Department, Nuclear Regulatory Commission or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

d. Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

RH-8501. **Possession of Survey Instrument**.

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A licensee authorized to use radioactive material for uptake, dilution, and excretion studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of one (1) microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour. -The instrument shall be operable and calibrated in accordance with RH-8402.

RH-8502.- RH-8509.– _Reserved.

RH-8510. **Training for Uptake, Dilution, and Excretion Studies**.

Except as provided in RH-8318., the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under RH-8500. to be a physician who:

a. Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State. -The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page.- To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for uptake, dilution, and excretion studies as described in paragraphs c.1.A. through c.1.B.vi. of this section; and

2. Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

b. Is an authorized user under RH-8540., RH-8560. or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

_____c. 1. _____———Has completed 60 hours of training and experience, including a___ _____———minimum of eight (8) hours of classroom and laboratory training _____in basic radionuclide handling techniques applicable to the _____medical ——use of unsealed radioactive material for uptake, dilution, _____and excretion studies. -The training and experience must include:

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~~RH-8510. (Cont'd)~~

A. Classroom and laboratory training in the following areas:

i. Radiation physics and instrumentation;

ii. Radiation protection;

iii. Mathematics pertaining to the use and measurement of radioactivity;

iv. Chemistry of radioactive material for medical use; and

v. Radiation biology; and

B. Work experience, under the supervision of an authorized user who meets the requirements in RH-8318., RH-8510., RH-8540., RH-8560., or equivalent Nuclear Regulatory Commission or Agreement State requirements, involving:

i. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

ii. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

iii. Calculating, measuring, and safely preparing patient or human research subject dosages;

iv. Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;

v. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

vi. Administering dosages of radioactive drugs to patients or human research subjects; and

~~RH-8510.c. (Cont'd)~~

2. Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph c.1. of this section and is able to independently fulfill the radiation safety-

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related duties as an authorized user for the medical uses authorized under RH-8500. The attestation must be obtained from either:

A. A preceptor authorized user who meets the requirements in RH-8318., RH-8510., RH-8540., or RH-8560., or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

B. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RH-8318., RH-8510., RH-8540., or RH-8560., or equivalent Nuclear Regulatory Commission or Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraph c.1. of this section.

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RH-8511.- RH-8529. Reserved.

RH-8530. **Use of Unsealed Radioactive Material for Imaging and Localization Studies for Which a Written Directive Is Not Required**.

Except for quantities that require a written directive under RH-8307., a licensee may use any unsealed radioactive material prepared for medical use for imaging and localization studies that is:

a. Obtained from:

1. A manufacturer or preparer licensed under RH-405.l. or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

~~RH-8530.a. (Cont'd)~~

2. A PET radioactive drug producer licensed under RH-403.j. or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

b. Excluding production of PET radionuclides, prepared by:

1. An authorized nuclear pharmacist;

2. A physician who is an authorized user and who meets the requirements in RH-8540, or RH-8560 and RH-8540.c.1.B.vii., or

3. An individual under the supervision, as specified in RH-8306, of the authorized nuclear pharmacist in paragraph b.1. of RH-8530. or the physician who is an authorized user in paragraph b.2. of RH-8530.;

c. Obtained from and prepared by a Department, NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

d. Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

e. Deleted.

RH-8531. **Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations**.

a. A licensee shall not administer to humans a radiopharmaceutical that contains:

1. More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 µCi of Mo-99 per mCi of Tc-99m); or

2. More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 µCi of Sr-82 per mCi of Rb-82 chloride); or more than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 µCi of Sr-85 per mCi of Rb-82).

~~RH-8531. (Cont'd)~~

b. A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each eluate from a generator to demonstrate compliance with paragraph a. of this section.

c. A licensee that uses a strontium-82/rubidium-82 generator for preparing a rubidium-82 radiopharmaceutical shall, before the first patient use of the

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day, measure the concentration of radionuclides strontium-82 and strontium-85 to demonstrate compliance with paragraph a. of this section.

d. If a licensee is required to measure the molybdenum-99 concentration or strontium-82 and strontium-85 concentrations, the licensee shall retain a record of each measurement in accordance with RH-8713.

e. The licensee shall report any measurement that exceeds the limits in paragraph a. of this section at the time of generator elution, in accordance with RH-8805.

RH-8532. **Possession of Survey Instruments**.

A licensee authorized to use radioactive material for imaging and localization studies shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of one (1) microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of ten (10) microsieverts (1 mrem) per hour to ten (10) millisieverts (1000 mrems) per hour. The instruments shall be operable and calibrated in accordance with RH-8402.

RH-8533.- RH-8539. –Reserved.

RH-8540. **Training for Imaging and Localization Studies**.

Except as provided in RH-8318., the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under RH-8530. to be a physician who:

a. Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State. The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:

~~RH-8540.a. (Cont'd)~~

1. Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed radioactive material for imaging and localization studies as described in paragraphs c.1.A. through c.1.B.vii. of this section; and

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2. Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or

b. Is an authorized user under RH-8560. and meets the requirements in RH-8540.c.1.B.vii., or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

c. ~~1.~~ ~~1.~~ Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material for imaging and localization studies. ~~-~~The training and experience must include, at a minimum:

A. Classroom and laboratory training in the following areas:

i. Radiation physics and instrumentation;

ii. Radiation protection;

iii. Mathematics pertaining to the use and measurement of radioactivity;

iv. Chemistry of radioactive material for medical use;

v. Radiation biology; and

B. Work experience, under the supervision of an authorized user who meets the requirements in RH-8318., RH-8540., or RH-8560. and RH-8540.c.1.B.vii., or equivalent Nuclear Regulatory Commission or Agreement State requirements. An authorized nuclear pharmacist who meets the requirements in RH-8317. or RH-8318. may provide the supervised work experience for paragraph c.1.B.vii. of this section. ~~-~~Work experience must involve:

~~RH-8540.c.1.B. (Cont'd)~~

i. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

ii. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

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iii. Calculating, measuring, and safely preparing patient or human research subject dosages;

iv. Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;

v. Using procedures to safely contain spilled radioactive material and using proper decontamination procedures;

vi. Administering dosages of radioactive drugs to patients or human research subjects; and

vii. Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

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2. Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph c.1. of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under RH-8500. and RH-8530. -The attestation must be obtained from either:

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A. A preceptor authorized user who meets the requirements in RH-8318., RH-8540., or RH-8560. and RH-8540.c.1.B.vii., or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

~~RH-8540.c.2. (Cont'd)~~

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B. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RH-8318., RH-8540., or RH-8560. and RH-8540.c.1.B.vii., or equivalent Nuclear Regulatory Commission or Agreement State requirements, and concurs with the attestation provided by the residency program director.
The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic

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Association and must include training and experience specified in paragraph c.1. of this section.

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RH-8541.- RH-8549.– _Reserved.

PART F:
UNSEALED RADIOACTIVE MATERIAL –
WRITTEN DIRECTIVE REQUIRED

RH-8550. **Use of Unsealed Radioactive Material for Which a Written Directive Is Required**.

A licensee may use any unsealed radioactive material identified in RH-8560.b.1.B.vii. prepared for medical use and for which a written directive is required that is:

a. Obtained from:

1. A manufacturer or preparer licensed under RH-405.l. or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

2. A PET radioactive drug producer licensed under RH-403.j. or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

b. Excluding production of PET radionuclides, prepared by:

1. An authorized nuclear pharmacist;

2. A physician who is an authorized user and who meets the requirements specified in RH-8540. or RH-8560.; or

3. An individual under the supervision, as specified in RH-8306., of the authorized nuclear pharmacist in paragraph b.1. of this section or the physician who is an authorized user in paragraph b.2. of this section; or

c. Obtained from and prepared by a Department, Nuclear Regulatory Commission, or Agreement State licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA; or

d. Prepared by the licensee for use in research in accordance with an Investigational New Drug (IND) protocol accepted by FDA.

RH-8551. **Safety Instruction**.

In addition to the requirements of RH-2803:

a. A licensee shall provide radiation safety instruction to personnel caring for patients or human research subjects that have received therapy with a

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radioactive drug, and cannot be released in accordance with RH-8420. The training must be provided initially and at least annually. -The instruction must be appropriate to the personnel's assigned duties and include the following:

1. Patient or human research subject control;

2. Visitor control to include the following:

   A. Routine visitation to hospitalized individuals in accordance with Section 3;

   B. Contamination control;

   C. Waste control; and

   D. Notification of the RSO, or his or her designee, and the authorized user if the patient or the human research subject dies or has a medical emergency.

b. A licensee shall retain a record of individuals receiving instruction in accordance with RH-8715.

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RH-8552. **Safety Precautions**.

a. For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with RH-8420., a licensee shall:

1. Quarter the patient or the human research subject either in:

   A. A private room with a private sanitary facility; or

   B. A room, with a private sanitary facility, with another individual who also has received similar radiopharmaceutical therapy and who cannot be released in accordance with RH-8420.; and,

~~RH-8552.a. (Cont'd)~~

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2. Visibly post the patient's or the human research subject's room with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room; and

2. Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on

its most sensitive scale and with no interposed shielding, or handle such material and items as radioactive waste.

b. The Radiation Safety Officer, or his or her designee, and an authorized user shall be notified immediately if the patient or human research subject dies or has a medical emergency.

RH-8553. **Possession of Survey Instruments**.

A licensee authorized to use radioactive material for which a written directive is required shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of one (1) microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of ten (10) microsieverts (1 mrem) per hour to ten (10) millisieverts (1000 mrems) per hour. The instruments shall be operable and calibrated in accordance with RH-8402.

RH-8554.- RH-8559.– _Reserved.

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RH-8560. **Training for Use of Unsealed Radioactive Material for Which a Written Directive Is Required**.

Except as provided by RH-8318., the licensee shall require an authorized user of unsealed radioactive material for the uses authorized under RH-8550. to be a physician who:

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a. Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraph b.1.B.vii. of this section.- The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page. -To be recognized, a specialty board shall require all candidates for certification to:

1. Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty.- These residency training programs must include 700 hours of training and experience as described in paragraphs b.1.A. through b.1.B.v. of this section.- Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Council on Postdoctoral Training of the American Osteopathic Association; and

2. Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed radioactive material for which a written directive is required; or

b. 1. Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed radioactive material requiring a written directive. The training and experience must include:

A. Classroom and laboratory training in the following areas:

i. Radiation physics and instrumentation;

ii. Radiation protection;

iii. Mathematics pertaining to the use and measurement of radioactivity;

~~RH-8560.b.1.A. (Cont'd)~~

iv. Chemistry of radioactive material for medical use; and

v. Radiation biology; and

B. Work experience, under the supervision of an authorized user who meets the requirements in RH-8318., RH-8560., or equivalent Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user, who meets the requirements in RH-8560.b., must also have experience in administering dosages in the same dosage category or categories (i.e., RH-8560.b.1.B.vii.) as the individual requesting authorized user status. The work experience must involve:

i. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

ii. Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

iii. Calculating, measuring, and safely preparing patient or human research subject dosages;

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iv. Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;

v. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures;

vi. Reserved.

~~RH-8560.b.1.B. (Cont'd)~~

vii. Administering dosages of radioactive drugs to patients or human research subjects from the three categories in this paragraph. Radioactive drugs containing radionuclides in categories not included in this paragraph are regulated under RH-8670. This work experience must involve a minimum of three (3) cases in each of the following categories for which the individual is requesting authorized user status:

(a). Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131, for which a written directive is required;

(b). Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131;

(c). Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required; and

2. Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph b.1. of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under RH-8550. for which the individual is requesting authorized user status. The attestation must be obtained from either:

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A. A preceptor authorized user who meets the requirements in RH-8318., RH-8560., or equivalent Nuclear Regulatory Commission or Agreement State requirements and has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status; or

~~RH-8560.b.1.B. (Cont'd)~~

B. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RH-8318., RH-8560., or equivalent Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraph b.1. of this section.

RH-8561. RH-8569. Reserved.

RH-8570. **Training for the Oral Administration of Sodium Iodide I-131 in Quantities Less Than or Equal to 1.22 Gigabecquerels (33 millicuries) for Which a Written Directive Is Required**.

Except as provided in RH-8318., the licensee shall require an authorized user for the oral administration of sodium iodide I-131 in quantities less than or equal to 1.22 gigabecquerels (33 millicuries), for which a written directive is required, to be a physician who:

a. Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs c.1. and c.2. of this section and whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State. The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page; or

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b. Is an authorized user under RH-8560. for uses listed in RH-8560.b.1.B.vii.(a). or (b)., RH-8580., or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

~~RH-8570. (Cont'd)~~

c. 1. Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive.- The training must include:

A. Radiation physics and instrumentation;

B. Radiation protection;

C. Mathematics pertaining to the use and measurement of radioactivity;

D. Chemistry of radioactive material for medical use; and

E. Radiation biology; and

2. Has work experience, under the supervision of an authorized user who meets the requirements in RH-8318., RH-8560., RH-8570., RH-8580., or equivalent Nuclear Regulatory Commission or Agreement State requirements.- A supervising authorized user, who meets the requirements in RH-8560.b., must also have experience in administering dosages as specified in RH-8560.b.1.B.vii.(a). or (b).– The work experience must involve:

A. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

B. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

C. Calculating, measuring, and safely preparing patient or human research subject dosages;

D. Using administrative controls to prevent a misadministration involving the use of radioactive material;

E. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

F. Administering dosages to patients or human research subjects, that includes at least three (3) cases involving the

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oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

~~RH-8570.c. (Cont'd)~~

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs c.1. and c.2. of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under RH-8550. The attestation must be obtained from either:

   A. A preceptor authorized user who meets the requirements in RH-8318., RH-8560., RH-8570., RH-8580., or equivalent Nuclear Regulatory Commission or Agreement State requirements, and has experience in administering dosages as specified in RH-8560.b.1.B.vii.(a). or (b).; or

   B. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RH-8318., RH-8560., RH-8570., RH-8580., or equivalent Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages as specified in RH-8560.b.1.B.vii.(a). or (b)., and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs c.1. and c.2. of this section.

RH-8571.- RH-8579.– _Reserved.

RH-8580. **Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Greater Than 1.22 Gigabecquerels (33 millicuries)**.

Except as provided in RH-8318., the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries) to be a physician who:

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~~RH-8580. (Cont'd)~~

a. Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs c.1. and c.2. of this section and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State. The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page; or

b. Is an authorized user under RH-8560. for uses listed in RH-8560.b.1.B.vii.(b). or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

c. 1. Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive. The training must include:

A. Radiation physics and instrumentation;

B. Radiation protection;

C. Mathematics pertaining to the use and measurement of radioactivity;

D. Chemistry of radioactive material for medical use; and

E. Radiation biology; and

2. Has work experience, under the supervision of an authorized user who meets the requirements in RH-8318., RH-8560., RH-8580., or equivalent Nuclear Regulatory Commission or Agreement State requirements. A supervising authorized user, who meets the requirements in RH-8560.b., must also have experience in administering dosages as specified in RH-8560.b.1.B.vii.(b). The work experience must involve:

A. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

B. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

C. Calculating, measuring, and safely preparing patient or human research subject dosages;

D. Using administrative controls to prevent a misadministration involving the use of radioactive material;

E. Using procedures to contain spilled radioactive material safely and using proper decontamination procedures; and

F. Administering dosages to patients or human research subjects, that includes at least three (3) cases involving the oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131; and

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs c.1. and c.2. of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under RH-8550. The attestation must be obtained from either:

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A. A preceptor authorized user who meets the requirements in RH-8318., RH-8560., RH-8580., or equivalent Nuclear Regulatory Commission or Agreement State requirements and has experience in administering dosages as specified in RH-8560.b.1.B.vii.(b).; or

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B. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RH-8318., RH-8560., RH-8580., or equivalent Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages as specified in RH-8560.b.1.B.vii.(b)., and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs c.1. and c.2. of this section.

RH-8581.- RH-8589. Reserved.

RH-8590. **Training for the Parenteral Administration of Unsealed Radioactive Material Requiring a Written Directive**.

a. Except as provided in RH-8318., the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who:

1. Is an authorized user under RH-8560. for uses listed in RH-8560.b.1.B.vii.(c)., or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

2. Is an authorized user under RH-8610., RH-8660., or equivalent Nuclear Regulatory Commission or Agreement State requirements, and who meets the requirements in paragraph b. of this section; or

3. Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State under RH-8610. or RH-8660., and who meets the requirements in paragraph b. of this section.

b. The physician:

1. Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations listed in RH- 8560.b.1.B.vii.(c).- The training must include:

A. Radiation physics and instrumentation;

B. Radiation protection;

C. Mathematics pertaining to the use and measurement of radioactivity;

D. Chemistry of radioactive material for medical use; and

E. Radiation biology; and

~~RH-8590.d. (Cont'd).~~

2. Has work experience, under the supervision of an authorized user who meets the requirements in RH-8318., RH- 8560., RH-8590., or equivalent Nuclear Regulatory Commission or Agreement State requirements, in the parenteral administrations listed in RH-8560.b.1.B.vii.(c).- A supervising authorized user who meets the requirements in RH-8560., RH-8590., or equivalent Nuclear Regulatory Commission or Agreement State requirements, must have experience in administering dosages- in the same category or categories as the individual requesting authorized user status.- The work experience must involve:

A. Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;

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B. Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

C. Calculating, measuring, and safely preparing patient or human research subject dosages;

D. Using administrative controls to prevent a misadministration involving the use of unsealed radioactive material;

E. Using procedures to contain spilled radioactive material safely, and using proper decontamination procedures; and

F. Administering dosages to patients or human research subjects, that include at least three (3) cases of the parenteral administrations as specified in RH-8560.b.1.B.vii.(c).; and

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs b.1. and b.2. of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed radioactive material requiring a written directive. The attestation must be obtained from either:

~~RH-8590.d. (Cont'd)~~

A. A preceptor authorized user who meets the requirements in RH-8318., RH-8560., RH-8590., or equivalent Nuclear Regulatory Commission or Agreement State requirements. A preceptor authorized user who meets the requirements in RH-8560., RH-8590., or equivalent Nuclear Regulatory Commission or Agreement State requirements must have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or

B. ~~B.~~ A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RH-8318., RH-8560., RH-8590., or equivalent Nuclear Regulatory Commission or Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director.

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-The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs b.1. and b.2. of this section.

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RH-8591.- RH-8599.– _Reserved.

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PART G:
MANUAL BRACHYTHERAPY

RH-8600. **Use of Sealed Sources for Manual Brachytherapy**.

A licensee shall use only brachytherapy sources:

a. Approved in the Sealed Source and Device Registry for manual brachytherapy medical use. The manual brachytherapy sources may be used for manual brachytherapy uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

b. In research to deliver therapeutic doses for medical use in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of RH-8310.a. are met.

RH-8601. **Surveys After Source Implant and Removal**.

a. Immediately after implanting sources in a patient or a human research subject, the licensee shall perform a survey to locate and account for all sources that have not been implanted.

b. Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.

c. A licensee shall retain a record of the surveys in accordance with RH-8716.

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RH-8602. **Brachytherapy Sources Inventory**.

a. A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use.

b. Promptly after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.

c. A licensee shall maintain a record of the brachytherapy source accountability in accordance with RH-8717.

RH-8603. **Safety Instruction**.

In addition to the requirements of RH-2803.:

a. The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that are undergoing implant therapy and cannot be released in accordance with RH-8420.- Instruction must be commensurate with the duties of the personnel and shall include the following:

1. Size and appearance of the brachytherapy sources;

2. Safe handling and shielding instructions;

3. Patient or human research subject control;

4. Visitor control, including both:

A. Routine visitation of hospitalized individuals in accordance with RH-1208.a.1.; and

B. Visitation authorized in accordance with RH-1208.c.; and

5. Notification of the Radiation Safety Officer, or his or her designee, and an authorized user if the patient or the human research subject dies or has a medical emergency.

b. Records of individuals receiving instruction shall be maintained in accordance with RH-8715.

RH-8604. **Safety Precautions for Patients or Human Research Subjects Receiving Brachytherapy**.

a. For each patient or human research subject that is receiving brachytherapy and cannot be released in accordance with RH-8420., a licensee shall:

1. Not place the patient or human research subject in the same room as an individual who is not receiving brachytherapy;

2. Visibly post the patent's or human research subject's room with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.

~~RH-8604. (Cont'd)~~

b. A licensee shall have emergency response equipment available near each treatment room to respond to a source that inadvertently becomes:

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1. Dislodged from the patient; or

2. Lodged within the patient following removal of the source applicators.

c. The Radiation Safety Officer, or his or her designee, and the authorized user shall be notified immediately if the hospitalized patient or human research subject dies or has a medical emergency.

RH-8605. **Calibration Measurements of Brachytherapy Sealed Sources**.

a. Prior to the first medical use of a brachytherapy sealed source on or after October 1, 2006, a licensee shall perform the following:

1. Determine the source output or activity using a dosimetry system that meets the requirements of RH-8635.a.;

2. Determine source positioning accuracy within applicators; and

3. Use published protocols accepted by nationally recognized bodies to meet the requirements of paragraphsa.1. and a.2. of this section.

b. A licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with paragraph a. of this section.

c. A licensee shall mathematically correct the outputs or activities determined in paragraph a. of this section for physical decay at intervals consistent with one percent (1%) physical decay.

d. An authorized medical physicist shall perform or review the calculation measurements made pursuant to paragraphs a., b., or c. of this section.

e. Notwithstanding paragraph d. of this section, an ophthalmic physicist, as defined in RH-8100., may perform or review measurements made pursuant to paragraphs a., b., and c. of this section, in relation to strontium-90 sources for ophthalmic treatments.

~~RH-8605. (Cont'd)~~

f. A licensee shall retain a record of each calibration in accordance with RH-8718.

RH-8606. **Therapy-Related Computer Systems**.

The licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

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a. The source-specific input parameters required by the dose calculation algorithm;

b. The accuracy of dose, dwell time, and treatment time calculations at representative points;

c. The accuracy of isodose plots and graphic displays; and

d. The accuracy of the software used to determine radioactive source positions from radiographic images.

RH-8607. **Possession of Survey Instruments**.

A licensee authorized to use manual brachytherapy sources shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of one (1) microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of ten (10) microsieverts (1 mrem) per hour to ten (10) millisieverts (1000 mrems) per hour. -The instruments shall be operable and calibrated in accordance with RH-8402.

RH-8608. **Strontium-90 Sources for Ophthalmic Treatments.**

a. Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in paragraph b. of this section are performed by either:

1. An authorized medical physicist; or

2. An individual who:

~~RH-8608. (Cont'd)~~

A. Is identified as an ophthalmic physicist on a specific medical use license issued by the Nuclear Regulatory Commission or an Agreement State; permit issued by a Nuclear Regulatory Commission or Agreement State broad scope medical use licensee; medical use permit issued by a Nuclear Regulatory Commission master material licensee; or permit issued by a Nuclear Regulatory Commission master material licensee broad scope medical use permittee; -and

B. Holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university; and

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C. Has successfully completed one (1) year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist; and

D. Has documented training in:

i. The creation, modification, and completion of written directives;

ii. Procedures for administrations requiring a written directive; and

iii. Performing the calibration measurements of brachytherapy sources as detailed in RH-8605.

b. The individuals who are identified in paragraph a. of this section must:

1. Calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under RH-8605.; and

~~RH-8608. (Cont'd)~~

2. Assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive. These procedures must include the frequencies that the individual meeting the requirements in paragraph a. of this section will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.

c. Licensees must retain a record of the activity of each strontium-90 source in accordance with RH-8719.

RH-8609. ___ Reserved.

RH-8610. **Training for Use of Manual Brachytherapy Sources**.

Except as provided in RH-8318., the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under RH-8600. to be a physician who:

a. Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State. The names of board certifications that have been recognized by the

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Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page.- To have its certification process recognized, a specialty board shall require all candidates for certification to:

1. Successfully complete a minimum of three (3) years of residency training in a radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association; and

2. Pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or

b. 1. Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:

~~RH-8610.b.1. (Cont'd)~~

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A. 200 hours of classroom and laboratory training in the following areas:

i. Radiation physics and instrumentation;

ii. Radiation protection;

iii. Mathematics pertaining to the use and measurement of radioactivity; and

iv. Radiation biology; and

B. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in RH-8318., RH-8610., or equivalent Nuclear Regulatory Commission or Agreement State requirements, at a medical facility authorized to use radioactive material under RH-8600., involving:

i. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

ii. Checking survey meters for proper operation;

iii. Preparing, implanting, and removing brachytherapy sources;

iv. Maintaining running inventories of material on hand;

v. Using administrative controls to prevent a misadministration involving the use of radioactive material;

vi. Using emergency procedures to control radioactive material; and

~~RH-8610.b. (Cont'd)~~

2. Has completed three (3) years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in RH-8318., RH-8610., or equivalent Nuclear Regulatory Commission or Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association.- This experience may be obtained concurrently with the supervised work experience required by paragraph b.1.B. of this section; and

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs b.1. and b.2., of this section and is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under RH-8600.- The attestation must be obtained from either:

A. A preceptor authorized user who meets the requirements in RH-8318., RH-8610., or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

B. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RH-8318., RH-8610., or equivalent Nuclear Regulatory Commission or Agreement State requirements, and concurs with the attestation provided by the residency program director.

-The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic

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Association and must include training and experience specified in paragraphs b.1. and b.2. of this section.

RH-8611.- RH-8614.– _Reserved.

RH-8615. **Training for Ophthalmic Use of Strontium-90**.

Except as provided in RH-8318., the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who:

a. Is an authorized user under RH-8610. or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

b. 1. Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy.- The training must include:

A. Radiation physics and instrumentation;

B. Radiation protection;

C. Mathematics pertaining to the use and measurement of radioactivity; and

D. Radiation biology; and

2. Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. -This supervised clinical training must involve:

A. Examination of each individual to be treated;

B. Calculation of the dose to be administered;

C. Administration of the dose; and

D. Follow up and review of each individual's case history; and

3. Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in RH-8318., RH-8610., RH-8615., or equivalent Nuclear Regulatory Commission or Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs b.1. and b.2. of this section and is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.

RH-8616.- RH-8619.– _Reserved.

PART H:
SEALED SOURCES FOR DIAGNOSIS

RH-8620. **Use of Sealed Sources and Medical Devices for Diagnosis**.

a. A licensee shall use only sealed sources that are not in medical devices for diagnostic medical uses if the sealed sources are approved in the Sealed Source and Device Registry for diagnostic medicine. -The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

b. A licensee shall only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. -The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.

c. Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of RH-8310.a. are met.

RH-8621. **Training for Use of Sealed Sources and Medical Devices for Diagnosis**.

Except as provided in RH-8318., the licensee shall require the authorized user of a diagnostic sealed source or a device authorized under RH-8620. to be a physician, dentist, or podiatrist who:

a. Is certified by a specialty board whose certification process includes all of the requirements in paragraphs c. and d. of this section and whose certification has been recognized by the Nuclear Regulatory Commission or an Agreement State.- The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page; or

b. Is an authorized user for uses listed in RH-8530. or equivalent Nuclear Regulatory Commission or Agreement State requirements; or

~~RH-8621. (Cont'd)~~

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c. Has completed eight (8) hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include:

1. Radiation physics and instrumentation;

2. Radiation protection;

3. Mathematics pertaining to the use and measurement of radioactivity; and

4. Radiation biology; and

d. Has completed training in the use of the device for the uses requested.

RH-8622. RH-8629. Reserved.

PART I:
PHOTON EMITTING REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS, AND GAMMA STEREOTACTIC RADIOSURGERY UNITS

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RH-8630. **Use of Sealed Sources in a Remote Afterloader Unit, Teletherapy Unit, or Gamma Stereotactic Radiosurgery Unit**.

a. A licensee shall only use sealed sources:

1. Approved and as provided for in the Sealed Source and Device Registry in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units to deliver therapeutic doses for medical uses: or

2. In research involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of RH-8310.a. are met.

b. A licensee shall use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

1. Approved in the Sealed Source and Device Registry to deliver a therapeutic dose for medical use. ~~-~~These devices may be used for therapeutic medical treatments that are not explicitly provided for in the Sealed Source and Device Registry but must be used in accordance with radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

2. In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of RH-8310.a. are met.

RH-8631. **Surveys of Patients and Human Research Subjects Treated with a Remote Afterloader Unit**.

a. Before releasing a patient or a human research subject from licensee control, a licensee shall make a survey of the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe, shielded position.

~~RH-8631. (Cont'd)~~

b. A licensee shall retain a record of the surveys in accordance with

RH-8716.

RH-8632. **Installation, Maintenance, Adjustment, and Repair**.

a. Only a person specifically licensed by the Department, the Nuclear Regulatory Commission or an Agreement State shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

b. Except for low dose-rate remote afterloader units, only a person specifically licensed by the Department, an Agreement State or the Nuclear Regulatory Commission shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units.

c. For a low dose-rate remote afterloader unit, only a person specifically licensed by the Department, an Agreement State or the Nuclear Regulatory Commission, or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.

d. A licensee shall retain a record of the installation, maintenance, adjustment, and repair done on remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with RH-8720.

RH-8633. **Safety Procedures and Instructions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units**.

a. A licensee shall:

1. Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;

2. Permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);

3. Prevent dual operation of more than one radiation producing device in a treatment room, if applicable; and

~~RH-8633.a. (Cont'd)~~

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4. Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient

or human research subject from the radiation field with controls from outside the treatment room. This procedure must include:

A. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;

B. The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

C. The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

b. A copy of the procedures required by paragraph a.4. of this section must be physically located at the unit console.

c. A licensee shall post instructions at the unit console to inform the operator of:

1. The location of the procedures required by paragraph a.4. of this section; and

2. The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

d. 1. Prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, a licensee shall ensure that vendor operational and safety training is provided to all individuals who will operate the unit. The vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training.

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~~RH 8633.d. (Cont'd)~~

2. A licensee shall provide operational and safety instructions initially and at least annually to all individuals who operate the unit at the facility, as appropriate to the individual's assigned duties. The instructions shall include instruction in:

A. The procedures identified in paragraph a.4. of this section; and

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B. The operating procedures for the unit.

e. A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures, initially and at least annually.

f. A licensee shall retain a record of individuals receiving instruction required by paragraph d. of this section, in accordance with RH-8715.

g. A licensee shall retain a copy of the procedures required by paragraphs a.4. and d.2.B. of this section until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit.

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RH-8634. **Safety Precautions for Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units**.

a. A licensee shall control access to the treatment room by a door at each entrance.

b. A licensee shall equip each entrance to the treatment room with an electrical interlock system that will:

1. Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

2. Cause the source(s) to be shielded promptly when an entrance door is opened; and

3. Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.

~~RH-8634.b. (Cont'd)~~

c. A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.

d. Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.

e. For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

f. In addition to the requirements specified in paragraphs a. through e. of this section, a licensee shall:

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1. For low dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units, require:

   A. An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during initiation of all patient treatments involving the unit; and

   B. An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

2. For high dose-rate remote afterloader units, require:

   A. An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

   B. An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.

~~RH-8634.f.2. (Cont'd)~~

3. For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

4. Notify the Radiation Safety Officer, or his or her designee, and an authorized user as soon as possible, if the patient or human research subject has a medical emergency and, immediately, if the patient dies.

g. A licensee shall have emergency response equipment available near each treatment room, to respond to a source that inadvertently:

1. Remains in the unshielded position; or

2. Lodges within the patient following completion of the treatment.

RH-8635. **Dosimetry Equipment**.

a. Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two (2) conditions must be met.

1. The system must have been calibrated using a system or source traceable to the National Institute of Standards and Technology (NIST) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous two (2) years and after any servicing that may have affected system calibration; or

2. The system must have been calibrated within the previous four (4) years; 18 to 30 months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the inter-comparison must have indicated that the calibration factor of the licensee's system had not changed by more than two percent (2%). The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

~~RH-8635.a. (Cont'd)~~

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b. The licensee shall have available for use a dosimetry system for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with RH-8635.a. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in RH-8635.a.

c. The licensee shall retain a record of each calibration, intercomparison, and comparison in accordance with RH-8721.

RH-8636. RH-8639. Reserved.

RH-8640. **Full Calibration Measurements on Teletherapy Units**.

a. A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit:

1. Before the first medical use of the unit; and

2. Before medical use under the following conditions:

   A. Whenever spot-check measurements indicate that the output differs by more than five percent (5%) from the output obtained at the last full calibration corrected mathematically for radioactive decay;

   B. Following replacement of the source or following reinstallation of the teletherapy unit in a new location;

   C. Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

3. At intervals not exceeding one (1) year.

b. To satisfy the requirement of RH-8640.a., full calibration measurements must include determination of:

~~RH-8640.b. (Cont'd)~~

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1. The output within plus or minus three percent (± 3%) for the range of field sizes and for the distance or range of distances used for medical use;

2. The coincidence of the radiation field and the field indicated by the light beam localizing device;

3. The uniformity of the radiation field and its dependence on the orientation of the useful beam;

4. Timer accuracy and linearity over the range of use;

5. On-off error; and

6. The accuracy of all distance measuring and localization devices in medical use.

c. A licensee shall use the dosimetry system described in RH-8635.a. to measure the output for one set of exposure conditions. The remaining radiation measurements required in RH-8640.b.1. may be made using a dosimetry system that indicates relative dose rates.

d. A licensee shall make full calibration measurements required by

RH-8640.a. in accordance with published protocols accepted by nationally recognized bodies.

e. A licensee shall mathematically correct the outputs determined in RH-8640.b.1. for physical decay for intervals not exceeding one (1) month for cobalt-60, six (6) months for cesium-137, or at intervals consistent with one percent (1%) decay for all other nuclides.

f. Full calibration measurements required by RH-8640.a. and physical decay corrections required by RH-8640.e. must be performed by the authorized medical physicist.

g. A licensee shall retain a record of each calibration in accordance with RH-8722.

RH-8641. **Full Calibration Measurements on Remote Afterloader Units**.

a. A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit:

~~RH-8641. (Cont'd)~~

1. Before the first medical use of the unit;

2. Before medical use under the following conditions:

A. Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

B. Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

3. At intervals not exceeding one (1) quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and

4. At intervals not exceeding one (1) year for low dose-rate remote afterloader units.

b. To satisfy the requirement of RH-8641.a., full calibration measurements must include, as applicable, determination of:

1. The output within plus or minus five percent (± 5%);

2. Source positioning accuracy to within plus or minus one (±1) millimeter;

3. Source retraction with backup battery upon power failure;

4. Length of the source transfer tubes;

5. Timer accuracy and linearity over the typical range of use;

6. Length of the applicators; and

7. Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

c. In addition to the requirements for full calibrations for low dose-rate remote afterloader units in RH-8641.b., a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding one (1) quarter.

~~RH-8641. (Cont'd)~~

d. A licensee shall use the dosimetry system described in RH-8635.a. to measure the output.

e. A licensee shall make full calibration measurements required by RH-8641.a. of this section in accordance with published protocols accepted by nationally recognized bodies.

f. For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with RH-8641.a. through RH-8641.e.

g. A licensee shall mathematically correct the outputs determined in RH-8641.b.1. for physical decay at intervals consistent with one percent (1%) physical decay.

h. Full calibration measurements required by RH-8641.a. and physical decay corrections required b RH-8641.g. must be performed by the authorized medical physicist.

i. A licensee shall retain a record of each calibration in accordance with RH-8722.

RH-8642. **Full Calibration Measurements on Gamma Stereotactic Radiosurgery Units**.

a. A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit:

1. Before the first medical use of the unit;

2. Before medical use under the following conditions:

A. Whenever spot-check measurements indicate that the output differs by more than five percent (5%) from the output obtained at the last full calibration corrected mathematically for radioactive decay;

B. Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and

~~RH-8642.a. (Cont'd)~~

C. Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and

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3. At intervals not exceeding one (1) year, with the exception that relative helmet factors need only be determined before the first medical use of a helmet and following any damage to a helmet.

b. To satisfy the requirement of RH-8642.a., full calibration measurements must include determination of:

1. The output within plus or minus three percent (± 3%);

2. Relative helmet factors;

3. Isocenter coincidence;

4. Timer accuracy and linearity over the range of use;

5. On-off error;

6. Trunnion centricity;

7. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

8. Helmet microswitchs;

9. Emergency timing circuits; and

10. Stereotactic frames and localizing devices (trunnions).

c. A licensee shall use the dosimetry system described in RH-8635.a. to measure the output for one (1) set of exposure conditions. The remaining

radiation measurements required in RH-8642.b.1. may be made using a dosimetry system that indicates relative dose rates.

d. A licensee shall make full calibration measurements required by RH-8642.a. in accordance with published protocols accepted by nationally recognized bodies.

~~RH-8642. (Cont'd)~~

e. A licensee shall mathematically correct the outputs determined in RH-8642.b.1. at intervals not exceeding one (1) month for cobalt-60 and at intervals consistent with one percent (1%) physical decay for all other radionuclides.

f. Full calibration measurements required by RH-8642.a. and physical decay corrections required by RH-8642.e. must be performed by the authorized medical physicist.

g. A licensee shall retain a record of each calibration in accordance with RH-8722.

RH-8643. **Periodic Spot-Checks for Teletherapy Units**.

a. A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of:

1. Timer accuracy, and timer linearity over the range of use;

2. On-off error;

3. The coincidence of the radiation field and the field indicated by the light beam localizing device;

4. The accuracy of all distance measuring and localization devices used for medical use;

5. The output for one (1) typical set of operating conditions measured with the dosimetry system described in RH-8635.b.; and

6. The difference between the measurement made in RH-8643.a.5. and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

b. A licensee shall perform measurements required by RH-8643.a. in accordance with procedures established by the authorized medical

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physicist. -That individual need not actually perform the spot check measurements.

~~RH-8643. (Cont'd)~~

c. A licensee shall have the authorized medical physicist review the results of each spot-check within fifteen (15) days. -The authorized medical physicist shall promptly notify the licensee in writing of the results of each spot-check.

d. A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of:

1. Electrical interlocks at each teletherapy room entrance;

2. Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);

3. Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;

4. Viewing and intercom systems;

5. Treatment room doors from inside and outside the treatment room; and

6. Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

e. If the results of the checks required in RH-8643.d. indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

f. A licensee shall retain a record of each spot-check required by RH-8643.a. and RH-8643.d., in accordance with RH-8723.

RH-8644. **Periodic Spot-Checks for Remote Afterloader Units**.

a. A licensee authorized to use remote afterloader units for medical use shall perform spot-checks of each remote afterloader facility and on each unit:

1. At the beginning of each day of use of a high dose-rate, medium dose-rate or pulsed dose-rate remote afterloader unit;

~~RH-8644.a. (Cont'd)~~

2. Prior to each patient treatment with a low dose-rate remote afterloader unit; and

3. After each source installation.

b. The licensee shall have the authorized medical physicist establish written procedures for performing the spot-checks required in RH-8644.a. The authorized medical physicist need not actually perform the spot-check measurements.

c. A licensee shall have the authorized medical physicist review the results of each spot-check within fifteen (15) days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

d. To satisfy the requirements of RH-8644.a., spot-checks must, at a minimum, assure proper operation of:

1. Electrical interlocks at each remote afterloader unit room entrance;

2. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

3. Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;

4. Emergency response equipment;

5. Radiation monitors used to indicate the source position;

6. Timer accuracy;

7. Clock (date and time) in the unit's computer; and

8. Decayed source(s) activity in the unit's computer.

e. If the results of the checks required in RH-8644.d. indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

f. A licensee shall retain a record of each check required by RH-8644.d. in accordance with RH-8724.

RH-8645. **Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units**.

a. A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit:

1. Monthly;

2. At the beginning of each day of use; and

3. After each source installation.

b. The licensee shall have the authorized medical physicist:

1. Establish written procedures for performing the spot-checks required in RH-8645.a.; and

2. Review the results of each spot-check required by RH-8645.a. within fifteen (15) days of the check. The authorized medical physicist need not actually perform the spot-check measurements. The authorized medical physicist shall notify the licensee as soon as possible, in writing, of the results of the spot-check.

c. To satisfy the requirements of RH-8645.a.1., spot-checks must, at a minimum:

1. Assure proper operation of:

A. Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;

B. Helmet microswitchs;

C. Emergency timing circuits; and

D. Stereotactic frames and localizing devices (trunnions).

2. Determine:

A. The output for one (1) typical set of operating conditions measured with the dosimetry system described in RH-8635.b.;

~~RH-8645.c.2. (Cont'd)~~

B. The difference between the measurement made in RH-8645.c.2.A. and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay);

C. Source output against computer calculation;

D. Timer accuracy and linearity over the range of use;

E. On-off error; and

F. Trunnion centricity.

d. To satisfy the requirements of RH-8645.a.2. and RH-8645.a.3., spot-checks must assure proper operation of:

1. Electrical interlocks at each gamma stereotactic radiosurgery room entrance;

2. Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility;

3. Viewing and intercom systems;

4. Timer termination;

5. Radiation monitors used to indicate room exposures; and

6. Emergency off buttons.

e. A licensee shall arrange for prompt repair of any system identified in RH-8645.c. that is not operating properly.

f. If the results of the checks required in RH-8645.d. indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

g. A licensee shall retain a record for each check required by RH-8645.c. and RH-8645.d. in accordance with RH-8725.

RH-8646. **Full-Inspection Servicing for Teletherapy and Gamma Stereotactic Radiosurgery Units**.

a. A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during each source replacement to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full-inspection servicing shall not exceed five (5) years for each teletherapy unit and shall not exceed seven (7) years for each gamma stereotactic radiosurgery unit.

b. This inspection and servicing may only be performed by persons specifically licensed to do so by the Department, the Nuclear Regulatory Commission, or an Agreement State.

c. A licensee shall keep a record of the inspection and servicing in accordance with RH-8728.

RH-8647. **Additional Technical Requirements for Mobile Remote Afterloader Units**.

a. A licensee providing mobile remote afterloader service shall:

1. Check survey instruments for consistent response before medical use at each address of use or on each day of use, whichever is more frequent; and

2. Account for all sources before departure from a client's address of use.

b. In addition to the periodic spot-checks required by RH-8644., a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use.- At a minimum, checks must be made to verify the operation of:

1. Electrical interlocks on treatment area access points;

2. Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

3. Viewing and intercom systems;

4. Applicators, source transfer tubes, and transfer tube-applicator interfaces;

~~RH-8647.b. (Cont'd)~~

5. Radiation monitors used to indicate room exposures;

6. Source positioning (accuracy); and

7. Radiation monitors used to indicate whether the source has returned to a safe shielded position.

c. In addition to the requirements for checks in RH-8647.b., a licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.

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d. If the results of the checks required in RH-8647.b. indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

e. A licensee shall retain a record of each check required by RH-8647.b. in accordance with RH-8726.

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RH-8648. **Therapy-Related Computer Systems**.

The licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

a. The source-specific input parameters required by the dose calculation algorithm;

b. The accuracy of dose, dwell time, and treatment time calculations at representative points;

c. The accuracy of isodose plots and graphic displays;

d. The accuracy of the software used to determine radioactive source positions from radiographic images; and

e. The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

RH-8649. **Possession of Survey Instruments**.

A licensee authorized to use radioactive material in remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units shall possess a portable radiation detection survey instrument capable of detecting dose rates over the range of one (1) microsievert (0.1 mrem) per hour to 500 microsieverts (50 mrems) per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range of ten (10) microsieverts (1 mrem) per hour to ten (10) millisieverts (1000 mrems) per hour. The instruments shall be operable and calibrated in accordance with RH-8402.

RH-8650. **Radiation Surveys**.

a. In addition to the survey requirements in RH-1300.b., a person licensed pursuant to Section 9 shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position does not exceed the levels stated in the Sealed Source and Device Registry.

b. The licensee shall make the survey required by RH-8650.a. at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

c. A licensee shall retain a record of the radiation surveys required by RH-8650.a. in accordance with RH-8727.

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RH-8651.- RH-8659.– _Reserved.

RH-8660. **Training for Use of Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units**.

Except as provided in RH-8318., the licensee shall require an authorized user of a sealed source for a use authorized under RH-8630. to be a physician who:

a. Is certified by a medical specialty board whose certification process has been recognized by the Nuclear Regulatory Commission or an Agreement State and who meets the requirements in paragraph c. of this section. -The names of board certifications that have been recognized by the Nuclear Regulatory Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit web page.- To have its certification process recognized, a specialty board shall require all candidates for certification to:

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1. Successfully complete a minimum of three (3) years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association; and

2. Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders, and external beam therapy; or

b. 1. Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes:

A. 200 hours of classroom and laboratory training in the following areas:

i. Radiation physics and instrumentation;

ii. Radiation protection;

iii. Mathematics pertaining to the use and measurement of radioactivity; and

iv. Radiation biology; and

B. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in RH-8318., RH-8660., or equivalent Nuclear Regulatory Commission or Agreement State requirements, at a medical facility that is authorized to use radioactive material in RH-8630., involving:

i. Reviewing full calibration measurements and periodic spot-checks;

ii. Preparing treatment plans and calculating treatment doses and times;

iii. Using administrative controls to prevent a misadministration involving the use of radioactive material;

~~RH-8660.b.1. (Cont'd)~~

iv. Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

v. Checking and using survey meters; and

vi. Selecting the proper dose and how it is to be administered; and

2. Has completed three (3) years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in RH-8318., RH-8660., or equivalent Nuclear Regulatory Commission or Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association. -This experience may be obtained concurrently with the supervised work experience required by paragraph b.1.B. of this section; and

3. Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs b.1. and b.2. and c. of this section and is able to independently fulfill the

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radiation safety-related duties as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The attestation must be obtained from either:

A. A preceptor authorized user who meets the requirements in RH-8318., RH-8660., or equivalent Nuclear Regulatory Commission or Agreement State requirements for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status; or

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~~RH-8660.b. (Cont'd)~~

B. A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in RH-8318., RH-8660., or equivalent Nuclear Regulatory Commission or Agreement State requirements, for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs b.1. and b.2. of this section.

c. Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.

RH-8661.- RH-8669. Reserved.

PARTS J – K
[RESERVED]

PART L:
OTHER MEDICAL USES OF RADIOACTIVE MATERIAL
OR RADIATION FROM RADIOACTIVE MATERIAL

RH-8670. **Other Medical Uses of Radioactive Material or Radiation from Radioactive Material**.

A licensee may use radioactive material or a radiation source approved for medical use that is not specifically addressed in Section 9 if:

a. The applicant or licensee has submitted the information required by RH-8010.b., RH-8010.c., and RH-8010.d; and

b. The applicant or licensee has received written approval from the Nuclear Regulatory Commission, or an Agreement State in a license and uses the material in accordance with the rules and specific conditions the Nuclear Regulatory Commission or Agreement State considers necessary for the medical use of the material.

RH-8671.- RH-8699.– _Reserved.

PART M:
RECORDS

RH-8700. **Records of Authority and Responsibilities for Radiation Protection Programs**.

a. A licensee shall retain a record of actions taken by the licensee's management in accordance with RH-8300.a. for five (5) years. The record must include a summary of the actions taken and a signature of licensee management.

b. The licensee shall retain a current copy of the authorities, duties and responsibilities of the Radiation Safety Officer as required by RH-8300.d, and a signed copy of each Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by RH-8300.b. The record must include the signature of the Radiation Safety Officer and licensee management.

c. For each Associate Radiation Safety Officer appointed under RH-8300.b., the licensee shall retain, for five (5) years after the Associate Radiation Safety Officer is removed from the license, a copy of the written document appointing the Associate Radiation Safety Officer signed by the licensee's management.

d. The minutes of each Radiation Safety Committee meeting held in accordance with RH-8300.g. shall include:

1. The date of the meeting;

2. Members present;

3. Members absent; and

4. Summary of deliberations and discussions.

RH-8701. **Records of Radiation Protection Program Safety Changes**.

A licensee shall retain a record of each radiation protection program change made in accordance with RH-8301.a. for five (5) years. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the licensee management that reviewed and approved the change.

RH-8702. **Records of Written Directives**.

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A licensee shall retain a copy of each written directive as required by RH-8307. for three (3) years.

RH-8703. **Records of Misadministrations**.

A licensee shall retain a record of misadministrations reported in accordance with RH-8800. for ~~three (3)~~ five (5) years.~~-~~ The record must contain the licensee's name; names of the individuals involved; the social security number or other identification number, if one has been assigned, of the individual who is the subject of the misadministration; a brief description of the event; why it occurred; the effect, if any, on the individual; the actions, if any, taken, or planned, to prevent recurrence; and, whether the licensee notified the individual (or the individual's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

RH-8704. **Record of a Dose to an Embryo/Fetus or a Nursing Child**.

A licensee shall retain a record of a dose to an embryo/fetus or a nursing child reported in accordance with RH-8801 for three (3) years.~~-~~ The record must contain the licensee's name; names of all the individuals involved; social security number or other identification number if one has been assigned to the pregnant individual or nursing child who is the subject of the event; a brief description of the event; why it occurred; the effect, if any, on the embryo/fetus or nursing child; the actions, if any, taken, or planned, to prevent recurrence; and whether the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian) and, if not, whether such failure to notify was based on guidance from the referring physician.

RH-8705. **Records of Checks and Tests of Instruments Used to Measure the Activity of Unsealed Radioactive Material**.

A licensee shall maintain a record of instrument checks and tests required by RH-8401. for three (3) years, excluding geometry test records where only the most current record must be maintained. ~~-~~The records must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

RH-8706. **Records of Survey Instrument Calibrations**.

A licensee shall maintain a record of survey instrument calibrations required by RH-8402. for three (3) years. ~~-~~The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

RH-8707. **Records of Dosages of Unsealed Radioactive Material for Medical Use**.

A licensee shall maintain a record of dosage determinations required by RH-8403. for three (3) years. The record must contain the radioactive drug; the patient's or human research subject's name, or identification number if one has been assigned; prescribed dosage; the determined dosage, or a notation that the total activity is less than 1.1 megabecquerel (30 µCi); the date and time of the dosage determination; and the name of the individual who determined the dosage.

RH-8708. **Records of Possession of Sealed Sources and Brachytherapy Sources**.

A licensee shall retain a record of the quarterly physical inventory of sealed sources and brachytherapy sources required by RH-8405.e. for three (3) years. The inventory record must contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

RH-8709. **Records of Surveys for Ambient Radiation Dose Rate and Contamination**.

A licensee shall retain a record of each survey required by RH-8408. for three (3) years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

RH-8710. **Records of the Release of Individuals Containing Unsealed Radioactive Material or Implants Containing Radioactive Material**.

a. A licensee shall retain a record, signed by the authorized user, of the basis for authorizing the release of an individual pursuant to RH-8420.a., if the total effective dose equivalent is calculated by:

1. Using the retained activity rather than the activity administered;

2. Using an occupancy factor less than 0.25 at 1 meter;

3. Using the biological or effective half-life; or

4. Considering the shielding by tissue.

~~RH-8710. (Cont'd)~~

b. A licensee shall retain a record that the instructions required by RH-8420.b. were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 0.1 rem (1 mSv).

c. Records required by paragraphs a. and b. of this section shall be retained for three (3) years after the date of release of the individual.

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RH-8711. **Records of Administrative and Technical Requirements that Apply to the Provision of Mobile Services**.

a. A licensee shall retain a copy of the letter(s) that permits the use of radioactive material at a client's address of use, as required by RH-8012.b., for three (3) years after the last provision of service.

b. A licensee shall retain the record of each survey required by RH-8425.f. for three (3) years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

RH-8712. **Records of Decay-in-Storage**.

A licensee shall maintain records of the disposal of licensed materials, as required by RH-8410., for three (3) years. The record must include the date the container was sealed, the date of the disposal, the radionuclides disposed, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

RH-8713. **Records of Molybdenum-99, Strontium-82, and Strontium-85 Concentrations**.

A licensee shall maintain a record of the radionuclide contaminant concentration tests required by RH-8531. for three (3) years. The record must include, for each measured elution of radionuclide used to prepare a radioactive drug, the ratio of the measures expressed as kilobecquerel of contaminant per megabecquerel of desired radionuclide (microcuries/millicuries), or microgram of contaminant per megabecquerel of desired radionuclide (microgram/millicuries), the time and date of the measurement, and the name of the individual who made the measurement.

RH-8714. Reserved.

RH-8715. **Records of Safety Instruction and Operational Instruction**.

A licensee shall maintain a record of safety instructions required by RH-8551. and RH-8603. and the operational and safety instructions required by RH-8633. for three (3) years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

RH-8716. **Records of Radiation Surveys of Patients and Human Research Subjects**.

A licensee shall maintain a record of the surveys required by RH-8601. and

RH-8631. for three (3) years. -Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

RH-8717. **Records of Brachytherapy Source Inventory**.

a. A licensee shall maintain a record of brachytherapy source accountability required by RH-8602. for three (3) years.

b. For temporary implants, the record must include:

1. The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use; and

2. The number and activity of sources not implanted, the time and date they were returned to storage, and the name of the individual who returned them to storage.

c. For permanent implants, the record must include:

1. The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage;

2. The number and activity of sources returned to storage, the date they were returned to storage, and the name of the individual who returned them to storage; and

3. The number and activity of sources permanently implanted in the patient or human research subject.

RH-8718. **Records of Calibration Measurements on Brachytherapy Sources**.

A licensee shall maintain a record of the calibrations on brachytherapy sources required by RH-8605. for three (3) years after the last use of the source. -The record must include the date of the calibration; the manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source; the source output or activity; source positioning accuracy within applicators; and the signature of the authorized medical physicist, or ophthalmic physicist, as appropriate.

RH-8719. **Records of Decay of Strontium-90 Sources for Ophthalmic Treatments**.

A licensee shall maintain a record of the activity of a strontium-90 source required by RH- 8608. for the life of the source.- The record must include the date

and initial activity of the source as determined under RH-8605., and for each decay calculation, the date and the source activity as determined under RH-8608., and the signature of the authorized medical physicist, or ophthalmic physicist, as appropriate.

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RH-8720. **Records of Installation, Maintenance, Adjustment, and Repair**.

A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by RH-8632. for three (3) years. For each installation, maintenance, adjustment, and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work.

RH-8721. **Records of Dosimetry Equipment**.

a. A licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with RH-8635. for the duration of the license.

b. For each calibration, intercomparison, or comparison, the record must include:

1. The date;

2. The manufacturer's name, model numbers, and serial numbers of the instruments that were calibrated, intercompared, or compared as required by RH-8635.a. and RH-8635.b.;

~~RH-8721.b. (Cont'd)~~

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3. The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and

4. The names of the individuals who performed the calibration, intercomparison, or comparison.

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RH-8722. **Records of Teletherapy, Remote Afterloader, and Gamma Stereotactic Radiosurgery Full Calibrations**.

a. A licensee shall maintain a record of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations required by RH-8640., RH-8641., and RH-8642. for three (3) years.

b. The record must include:

1. The date of the calibration;

2. The manufacturer's name, model number, and serial number for the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit(s), the source(s), and instruments used to calibrate the unit;

3. The results and assessments of the full calibrations;

4. The results of the autoradiograph required for low dose-rate remote afterloader units; and

5. The signature of the authorized medical physicist who performed the full calibration.

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RH-8723. **Records of Periodic Spot-Checks for Teletherapy Units**.

a. A licensee shall retain a record of each periodic spot-check for teletherapy units required by RH-8643. for three (3) years.

b. The record must include:

1. The date of the spot-check;

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~~RH-8723.b. (Cont'd)~~

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2. The manufacturer's name, model number, and serial number for the teletherapy unit, source, and instrument used to measure the output of the teletherapy unit;

3. An assessment of timer linearity and constancy;

4. The calculated on-off error;

5. A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

6. The determined accuracy of each distance measuring and localization device;

7. The difference between the anticipated output and the measured output;

8. Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure

indicator light, and the viewing and intercom system and doors; and

9. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

RH-8724. **Records of Periodic Spot-Checks for Remote Afterloader Units**.

a. A licensee shall retain a record of each spot-check for remote afterloader units required by RH-8644. for three (3) years.

b. The record must include, as applicable:

1. The date of the spot-check;

2. The manufacturer's name, model number, and serial number for the remote afterloader unit and source;

3. An assessment of timer accuracy;

~~RH-8724.b. (Cont'd)~~

4. Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit's computer; and

5. The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

RH-8725. **Records of Periodic Spot-Checks for Gamma Stereotactic Radiosurgery Units**.

a. A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by RH-8645. for three (3) years.

b. The record must include:

1. The date of the spot-check;

2. The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit;

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3. An assessment of timer linearity and accuracy;

4. The calculated on-off error;

5. A determination of trunnion centricity;

6. The difference between the anticipated output and the measured output;

7. An assessment of source output against computer calculations;

8. Notations indicating the operability of radiation monitors, helmet microswitchs, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and

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~~RH-8725.b. (Cont'd)~~

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9. The name of the individual, who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

RH-8726. **Records of Additional Technical Requirements for Mobile Remote Afterloader Units**.

a. A licensee shall retain a record of each check for mobile remote afterloader units required by RH-8647.b. for three (3) years.

b. The record must include:

1. The date of the check;

2. The manufacturer's name, model number, and serial number of the remote afterloader unit;

3. Notations accounting for all sources before the licensee departs from a facility;

4. Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators and source transfer tubes, and source positioning accuracy; and

5. The signature of the individual who performed the check.

RH-8727. **Records of Surveys of Therapeutic Treatment Units**.

a. A licensee shall maintain a record of radiation surveys of treatment units made in accordance with RH-8650.a. for the duration of use of the unit.

b. The record must include:

1. The date of the measurements;

2. The manufacturer's name, model number, and serial number of the treatment unit, source, and instrument used to measure radiation levels;

3. Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and

~~RH-8727.b. (Cont'd)~~

4. The signature of the individual who performed the test.

RH-8728. **Records of Full-Inspection Servicing for Teletherapy and Gamma Stereotactic Radiosurgery Units**.

a. A licensee shall maintain a record of the full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units required by RH-8646. for the duration of use of the unit.

b. The record must contain:

1. The inspector's radioactive materials license number;

2. The date of inspection;

3. The manufacturer's name and model number and serial number of both the treatment unit and source;

4. A list of components inspected and serviced, and the type of service; and

5. The signature of the inspector.

RH-8729.- RH-8799. _–Reserved.

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PART N:
REPORTS

RH-8800. **Reports and Notifications of Misadministrations**.

a. A licensee shall report any event as a misadministration, except for an event that results from patient intervention, in which:

1. The administration of radioactive material or radiation from radioactive material, except permanent implant brachytherapy, results in:

A. A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sievert (5 rem) effective dose equivalent, 0.5 Sievert (50 rem) to an organ or tissue, or 0.5 Sievert (50 rem) shallow dose equivalent to the skin; and

i. The total dose delivered differs from the prescribed dose by twenty percent (20%) or more;

ii. The total dosage delivered differs from the prescribed dosage by twenty percent (20%) or more or falls outside the prescribed dosage range; or

iii. The fractionated dose delivered differs from the prescribed dose for a single fraction, by fifty percent (50%) or more.

B. A dose that exceeds 0.05 Sievert (5 rem) effective dose equivalent, 0.5 Sievert (50 rem) to an organ or tissue, or 0.5 Sievert (50 rem) shallow dose equivalent to the skin from any of the following:

i. An administration of a wrong radioactive drug containing radioactive material or the wrong radionuclide for a brachytherapy procedure;

ii. An administration of a radioactive drug containing radioactive material by the wrong route of administration;

iii. An administration of a dose or dosage to the wrong individual or human research subject;

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~~RH-8800.a. (Cont'd)~~

iv. An administration of a dose or dosage delivered by the wrong mode of treatment; or

v. A leaking sealed source.

C. A dose to the skin or an organ or tissue other than the treatment site that exceeds by:

i. 0.5 Sievert (50 rem) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and

ii. Fifty percent (50%) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.

2. For permanent implant brachytherapy, the administration of radioactive material or radiation from radioactive material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in:

A. The total source strength administered differing by twenty percent (20%) or more from the total source strength documented in the post-implantation portion of the written directive;

B. The total source strength administered outside of the treatment site exceeding twenty percent (20%) of the total source strength documented in the post-implantation portion of the written directive; or

C. An administration that includes any of the following:

i. The wrong radionuclide;

ii. The wrong individual or human research subject;

iii. Sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive; or

~~RH 8800.a. (Cont'd)~~

iv. A leaking sealed source resulting in a dose that exceeds 0.5 Sievert (50 rem) to an organ or tissue.

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b. A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of radioactive material or radiation from radioactive material results, or will result in, unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

c. The licensee shall notify the Department by telephone no later than the next calendar day after discovery of the misadministration.

d. The licensee shall submit a written report to the Department within fifteen (15) days after discovery of the misadministration.

1. The written report must include:

A. The licensee's name;

B. The name of the prescribing physician;

C. A brief description of the event;

D. Why the event occurred;

E. The effect, if any, on the individual who received the administration;

F. Actions, if any, that have been taken, or are planned, to prevent recurrence; and

G. Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

2. The report may not contain the individual's name or any other information that could lead to identification of the individual.

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~~RH-8800. (Cont'd)~~

e. The licensee shall provide notification of the misadministration to the referring physician and also notify the individual who is the subject of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. -The licensee is not required to notify the individual without first consulting the referring physician. -If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. -The licensee may not delay any appropriate medical care for the individual,

including any necessary remedial care as a result of the misadministration, because of any delay in notification.

To meet the requirements of this paragraph, the notification of the individual who is the subject of the misadministration may be made instead to that individual's responsible relative or guardian. If a verbal notification is made, the licensee shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

f. Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the misadministration, or to that individual's responsible relatives or guardians.

g. A licensee shall retain a record of a misadministration in accordance with RH-8703. A copy of ~~the~~ this record ~~required under RH-8703.~~ shall be:

1. ~~p~~Provided to the referring physician, if other than the licensee, within fifteen (15) days after discovery of the misadministration.~~;~~

2. Maintained as part of the permanent medical record of the individual who is the subject of the misadministration.

RH-8801. **Reports and Notifications of a Dose to an Embryo/Fetus or a Nursing Child**.

a. A licensee shall report any dose to an embryo/fetus that is greater than five (5) millisievert (500 mrem) dose equivalent that is a result of an administration of radioactive material or radiation from radioactive material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.

~~RH-8801. (Cont'd)~~

b. A licensee shall report any dose to a nursing child, that was not specifically approved, in advance, by the authorized user, that is a result of an administration of radioactive material to a breast-feeding individual that:

1. Is greater than five (5) millisievert (500 mrem) total effective dose equivalent; or

2. Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.

Commented [AO88]: RH-8800 From NRC Subpart M—Reports § 35.3045 Report and notification of a medical event.

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c. The licensee shall notify by telephone the Department no later than the next calendar day after discovery of a dose to the embryo/fetus or nursing child that requires a report in RH-8801.a. or RH-8801.b.

d. The licensee shall submit a written report to the Department within fifteen (15) days after discovery of a dose to the embryo/fetus or nursing child that requires a report in RH-8801.a. or RH-8801.b.

1. The written report must include:

A. The licensee's name;

B. The name of the prescribing physician;

C. A brief description of the event;

D. Why the event occurred;

E. The effect, if any, on the embryo/fetus or the nursing child;

F. What actions, if any, have been taken or are planned to prevent recurrence; and

G. Certification that the licensee notified the pregnant individual or mother (or the mother's or child's responsible relative or guardian), and if not, why not.

2. The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.

~~RH-8801. (Cont'd)~~

e. The licensee shall notify the referring physician and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under RH-8801.a. or RH-8801.b., unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful.- The licensee is not required to notify the mother without first consulting with the referring physician.- If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. -The licensee may not delay any appropriate medical care of the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification.

To meet the requirements of this paragraph, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother, when appropriate. If a verbal notification is made, the licensee shall inform the mother, or the mother's or child's responsible relative or guardian, that a written description of the event can be obtained from the licensee upon request. The licensee shall provide such a written description if requested.

f. A licensee shall retain a record of a dose to an embryo/fetus or a nursing child in accordance with RH-8704. A copy of the record required under RH-8704 shall be provided to the referring physician, if other than the licensee, within fifteen (15) days after discovery of the event.

RH-8802. **Reports of Leaking Sources**.

A licensee shall file a report with the Department within five (5) days if a leakage test required by RH-8405. reveals the presence of 185 Becquerel (0.005 μCi) or more of removable contamination. The written report must include the model number and serial number, if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

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RH-8803. Deleted.

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RH-8805. **Report and Notification for an Eluate Exceeding Permissible Molybdenum-99, Strontium-82, and Strontium-85 Concentrations**.

a. The licensee shall notify by telephone the Department and the distributor of the generator within 24 hours after discovery that an eluate exceeded the permissible concentration listed in RH-8531.a. at the time of generator elution. The telephone report to the Department must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects; when the distributor was notified; and the action taken.

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b. The licensee shall submit a written report to the Department within thirty (30) calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; the probable cause and an assessment of failure in the licensee's equipment, procedures, or

training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by paragraph a. of this section.

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RH-8806.- RH-8899.– _Reserved.

PART O:
ENFORCEMENT

RH-8900. **Violations.**

a. An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any rule or order issued thereunder. -Any person who willfully violates any provision of the Act or any rule or order issued thereunder may be guilty of a felony, misdemeanor, or crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law. -Arkansas Code Annotated §20-21-204 describes criminal and civil penalties which may be assessed.

b. **Impounding**.

Sources of radiation shall be subject to impounding pursuant to Section 5 of these Rules.

RH-8901.- RH-8999.– _Reserved.

FOOTNOTES TO SECTION 9

1/ Experience with at least three (3) cases in category vii.(b). also satisfies the requirement in category vii.(a).

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SECTION 10.
~~[RESERVED]~~

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NON-THERAPEUTIC USE OF MACHINE-PRODUCED RADIATION IN THE HEALING ARTS AND VETERINARY MEDICINE

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PART A. GENERAL

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RH-9000. **Purpose and Scope**.

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This Section establishes requirements for the use of diagnostic and interventional x-ray equipment and imaging systems in the healing arts or veterinary medicine. The requirements of this Section are in addition to, and not in substitution for, other applicable requirements of these Rules. The requirements of these Rules apply to applicants and registrants subject to this Section unless specifically exempted. Radiation machines for morgue use are subject to requirements as determined by the Department. Facilities conducting training using non-humans shall comply with all requirements of this Section except for RH-9305.b.2 concerning radiographic entrance exposure rates (air kerma) and RH-9201.b. and c. concerning film processing.

RH-9001. **Communications**.

Except where otherwise specified, all communications concerning these Rules may be addressed to the Arkansas Department of Health, Radiation Control Section, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

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RH-9002. **Interpretations**.

Except as specifically authorized by the Department in writing, no interpretations of the meaning of the rules in this Section by an officer or employee of the Department other than a written interpretation by the Department Director or designee will be recognized as binding upon the Department.

RH-9003. **Specific Exemptions**.

The Department may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the rules in this Section as it determines are authorized by law and will not result in undue hazard to public health and safety or property, and are otherwise in the public interest.

RH-9004.- RH-9099. Reserved.

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PART B.
DEFINITIONS

RH-9100 **Definitions.**

Accessible surface - The external surface of the enclosure or housing of the radiation producing machine as provided by the manufacturer.

Air kerma - Kerma in air. See definition of Kerma.

Air kerma rate (AKR) - The air kerma per unit time.

Alert value - A dose index (e.g., of $CTDI_{vol}$ (mGy) or DLP(mGy-cm)) that is set by the registrant to trigger an alert to the CT operator prior to scanning within an ongoing examination. The Alert value represents a universal dose index value well above the registrant's established range for the examination that warrants more stringent review and consideration before proceeding.

Aluminum equivalent - The thickness of type 1100 aluminum alloy[1/] affording the same attenuation, under specified conditions, as the material in question.

Articulated joint - A joint between two separate sections of a tabletop which joint provides the capacity of one of the sections to pivot on the line segment along which the sections join.

Attenuation block - A block or stack of type 1100 aluminum alloy, or aluminum alloy having equivalent attenuation, with dimensions 20 centimeters or larger by 20 centimeters or larger by 3.8 centimeters, that is large enough to intercept the entire x-ray beam.

Automatic exposure control (AEC) - A device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation.

Automatic exposure rate control (AERC) - A device which automatically controls one or more technique factors in order to obtain, at a preselected location(s), a required quantity of radiation per unit time.

Barrier - See "protective barrier."

Beam axis - A line from the source through the centers of the x-ray fields.

Beam-limiting device - A device which provides a means to restrict the dimensions of the x-ray field.

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Bone densitometry - A noninvasive measurement of certain physical characteristics of bone that reflect bone strength. Test results are typically reported as bone mineral content or density and are used for diagnosing osteoporosis, estimating fracture risk, and monitoring changes in bone mineral content.

Bone densitometer - A device intended for medical purposes to measure bone density and mineral content by x-ray or gamma ray transmission measurements through the bone and adjacent tissues. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

C-arm fluoroscope - A fluoroscopic x-ray system in which the image receptor and the x-ray tube housing assembly are connected or coordinated to maintain a spatial relationship. Such a system allows a change in the direction of the beam axis with respect to the patient without moving the patient.

Cantilevered tabletop - A tabletop designed such that the unsupported portion can be extended at least 100 centimeters beyond the support.

Cassette holder - A device, other than a spot-film device, that supports or fixes the position of the image receptor during a radiographic exposure.

Coefficient of variation (C) - The ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\overline{x}} = \frac{1}{\overline{x}}\left[\frac{\sum_{i=1}^{n}(x_i - \overline{x})^2}{n-1}\right]^{\frac{1}{2}}$$

where:

s = estimated standard deviation of the population;

$\overline{x}$ = mean value of observations in sample;

x_i = ith observation in sample; and

n = number of observations in sample.

Coulomb- SI unit of electric charge, equal to the quantity of electricity conveyed in one second by a current of one ampere.

Computed radiography (CR)(also see DR) - A digital x-ray imaging method in which a photo-stimulable phosphor is used to capture and store a latent image. The latent image is read out by stimulating the phosphor with a laser. Computed radiography systems may use cassettes to house the phosphor, or it may be

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integrated into a digital radiography system.

Computed tomography (CT) - The production of a tomogram by the acquisition and computer processing of x-ray transmission data.

Computed tomography dose index (CTDI) - The average absorbed dose, along the z-axis, from a series of contiguous irradiations. It is measured from one axial CT scan (one rotation of the x-ray tube), and is calculated by dividing the integrated absorbed dose by the nominal total beam collimation. The scattering media for CTDI consist of two (16 and 32 centimeters in diameter) polymethylmethacrylate (PMMA, e.g., acrylic or Lucite) cylinders of 14 centimeters in length. The equation is:

$$CTDI = \frac{1}{NT}\int_{-\infty}^{\infty} D(z)dz$$

where:

$D(z)$ = the radiation dose profile along the z-axis;

N = the number of tomographic sections imaged in a single axial scan. This is equal to the number of data channels used in a particular scan. The value of N may be less than or equal to the maximum number of data channels available on the system; and

T = the width of the tomographic section along the z-axis imaged by one data channel. In multiple-detector-row (multislice) CT scanners, several detector elements may be grouped together to form one data channel. In single-detector-row (single-slice) CT, the z-axis collimation (T) is the nominal scan width.

$CTDI_{100}$ - The accumulated multiple scan dose at the center of a 100-milllimeter scan and underestimates the accumulated dose for longer scan lengths. It is thus smaller than the equilibrium dose. The $CTDI_{100}$ requires integration of the radiation dose profile from a single axial scan over specific integration limits. In the case of $CTDI_{100}$, the integration limits are +50 millimeters, which corresponds to the 100-millimeter length of the commercially available "pencil" ionization chamber. $CTDI_{100}$ is acquired using a 100-millimeter long, 3-cubic centimeter active volume CT "pencil" ionization chamber and one of the two standard CTDI acrylic phantoms (16 and 32 centimeter diameters) and a stationary patient table. The equation is:

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$$CTDI_{100} = \frac{1}{NT}\int_{-50\ mm}^{50\ mm} D(z)dz$$

$CTDI_{vol}$ - See "Volume Computed Tomography Dose Index ($CTDI_{vol}$)."

$CTDI_{w}$ - See "Weighted Computed Tomography Dose Index ($CTDI_{w}$)."

Cone Beam Computed Tomography (CBCT) - A volumetric imaging modality. Volumetric data are acquired using two-dimensional digital detector arrays and a cone-shaped x-ray beam (instead of fan-shaped) that rotates around the patient. Reconstruction algorithms can be used to generate images of any desired plane.

Control panel - That part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, keypads, touchscreens, and other hardware necessary for manually setting the technique factors.

Cradle -

1. A removable device which supports and may restrain a patient above an x-ray table; or

2. A device -

   A. Whose patient support structure is interposed between the patient and the image receptor during normal use;

   B. Which is equipped with means for patient restraint; and

   C. Which is capable of rotation about its long (longitudinal) axis.

CT - See "computed tomography."

CT conditions of operation - All selectable parameters governing the operation of a CT x-ray system including nominal tomographic section thickness, filtration, and the technique factors as defined in RH-9100.

CT gantry - Tube housing assemblies, beam-limiting devices, detectors, and the supporting structures, frames, and covers which hold or enclose these components within a computed tomography system.

CT number (CTN) - The number used to represent the x-ray attenuation associated with each elemental area of the CT image. The equation is:

$$\overline{CTN} = \frac{k(\mu_{x-}\mu_w)}{\mu_w}$$

where:

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k = a constant, a normal value of 1,000 when the Houndsfield scale of CT number is used;

μ_x = linear attenuation coefficient of the material of interest; and

μ_w = linear attenuation coefficient of water.

Cumulative air kerma - The total air kerma accrued from the beginning of an examination or procedure and includes all contributions from fluoroscopic and radiographic irradiation.

Detector - See "radiation detector."

Diagnostic reference level (DRL) - An investigational level used to identify unusually high radiation doses or dose rates for common medical X-ray imaging procedures. DRLs are suggested action levels above which a facility should review its methods and determine if acceptable image quality can be achieved at lower doses. DRLs should not be applied to an individual patient.

Diagnostic source assembly - The tube housing assembly with a beam-limiting device attached.

Diagnostic x-ray system - An x-ray system designed for irradiation of any part of the human [or animal] body for the purpose of diagnosis or visualization.

Digital radiography (DR) - An x-ray imaging method (or radiography) which produces a digital rather than analog image. DR includes both computed radiography and direct digital radiography.

Direct digital radiography (DDR)(also see CR and DR) - An x-ray imaging method in which a digital sensor, usually incorporating a thin-film transistor, is used to capture an x-ray image. Some DDR systems use a scintillator to convert x-rays to light and a photodiode array to convert light to charge, while others use a photoconductor to convert x-rays directly to charge, which is stored on the thin-film transistor.

Direct scattered radiation - That scattered radiation which has been deviated in direction only by materials irradiated by the useful beam. See "scattered radiation."

Direct supervision - A qualified practitioner must exercise general supervision and be present in the facility and immediately available to furnish assistance and direction throughout the performance of the procedure or service. Direct supervision does not mean that the qualified practitioner must be present in the room when the procedure or service is being performed.

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Dose - The absorbed dose as defined by the International Commission on Radiation Units and Measurements. The absorbed dose, D, is the quotient of de by dm, where de is the mean energy imparted to matter of mass dm; thus D=de/dm, in units of J/kg, where the special name of the unit of absorbed dose is gray (Gy).

Dose area product (DAP) (essentially kerma-area product (KAP)) The product of the air kerma and the area of the irradiated field and is typically expressed in $Gy \cdot cm^2$, so it does not change with distance from the x-ray tube.

Dose length product (DLP) - The indicator of the integrated radiation dose from a complete CT examination. DLP addresses the total scan length by the formula:

$$DLP\ (mGy \cdot cm) = CTDI_{vol}\ (mGy) \times \text{scan length (cm)}$$

Dose profile - The dose as a function of position along a line.

Effective dose (E) - The sum of the tissue-weighted equivalent doses for the radiosensitive tissues and organs of the body. Effective dose is given by the expression $E = \Sigma_T (w_T H_T)$, in which H_T is the equivalent dose in tissue or organ T and w_T is the tissue weighting factor for tissue or organ T. The unit of E and H_T is joule per kilogram ($J \cdot kg^{-1}$), with the special name sievert (Sv).

Equipment - See "x-ray equipment."

Exposure (X) - The quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the electrons and positrons liberated or created by photons in air of mass dm are completely stopped in air; thus X=dQ/dm, in units of C/kg. A second meaning of exposure is the process or condition during which the x-ray tube produces x-ray radiation.
Field emission equipment - Equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

Filter - Material placed in the useful beam to preferentially absorb selected radiations.

Fluoroscopic imaging assembly - A subsystem in which x-ray photons produce a set of fluoroscopic images or radiographic images recorded from the fluoroscopic image receptor. This term includes the image receptor(s), electrical interlocks, if any, and structural material providing linkage between the image receptor and diagnostic source assembly.

Fluoroscopic irradiation time - The cumulative duration during an examination or procedure of operator-applied continuous pressure to the device, enabling x-ray tube activation in any fluoroscopic mode of operation.

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Fluoroscopically-Guided Interventional (FGI) procedure - An interventional diagnostic or therapeutic procedure performed via percutaneous or other access routes, usually with local anesthesia or intravenous sedation, which uses external ionizing radiation in the form of fluoroscopy to localize or characterize a lesion, diagnostic site, or treatment site, to monitor the procedure, and to control and document therapy.

Fluoroscopy - A technique for generating x-ray images and presenting them simultaneously and continuously as visible images. This term has the same meaning as the term "radioscopy" in the standards of the International Electrotechnical Commission.

Focal spot (actual) - The area projected on the anode of the x-ray tube bombarded by the electrons accelerated from the cathode and from which the useful beam originates.

General purpose radiographic x-ray system - Any radiographic x-ray system which, by design, is not limited to radiographic examination of specific anatomical regions.

General supervision - The procedure or service is performed under the overall direction and control of the qualified practitioner. The qualified practitioner's presence is not required during the performance of the procedure or service.

Half-value layer (HVL) - The thickness of specified material which attenuates the beam of radiation to an extent such that the air kerma rate is reduced by one-half of its original value. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

Hand-held x-ray equipment - See "x-ray equipment."

Healing arts screening - The testing of human beings using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.

Heat unit - A unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, i.e., kVp x mA x second.

HVL - See "half-value layer."

Image intensifier - A device, installed in its housing, which instantaneously converts an x-ray pattern into a corresponding light image of higher intensity.

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Image receptor - Any device, such as a fluorescent screen, radiographic film, x-ray image intensifier tube, solid-state detector, or gaseous detector which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations. In those cases where means are provided to preselect a portion of the image receptor, the term "image receptor" shall mean the preselected portion of the device.

Irradiation - The exposure of matter to ionizing radiation.

Isocenter - The center of the smallest sphere through which the beam axis passes when the equipment moves through a full range of rotations about its common center.

Kerma - The quantity defined by the International Commission on Radiation Units and Measurements. The kerma, K, is the quotient of dEtr by dm, where dEtr is the sum of the initial kinetic energies of all the charged particles liberated by uncharged particles in a mass dm of material; thus K=dEtr/dm, in units of J/kg, where the special name for the unit of kerma is gray (Gy). When the material is air, the quantity is referred to as "air kerma."

Kerma-area product (KAP) - See "dose area product."

Kilovolts peak - See "peak tube potential."

kV - Kilovolts.

kVp - See "peak tube potential."

kWs - Kilowatt second.

Last-image hold (LIH) radiograph - An image obtained either by retaining one or more fluoroscopic images, which may be temporarily integrated, at the end of a fluoroscopic exposure or by initiating a separate and distinct radiographic exposure automatically and immediately in conjunction with termination of the fluoroscopic exposure.

Lead equivalent - The thickness of lead affording the same attenuation, under specified conditions, as the material in question.

Leakage radiation - Radiation emanating from the diagnostic source assembly except for:

1. The useful beam; and

2. Radiation produced when the exposure switch or timer is not activated.

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Leakage technique factors - The technique factors associated with the diagnostic source assembly which are used in measuring leakage radiation. The factors are defined as follows:

1. For diagnostic source assemblies intended for capacitor energy storage equipment, the maximum-rated peak tube potential and the maximum-rated number of exposures in an hour for operation at the maximum-rated peak tube potential with the quantity of charge per exposure being ten (10) millicoulombs (or 10 mAs) or the minimum obtainable from the unit, whichever is larger;

2. For diagnostic source assemblies intended for field emission equipment rated for pulsed operation, the maximum-rated peak tube potential and the maximum-rated number of x-ray pulses in an hour for operation at the maximum-rated peak tube potential; and

3. For all other diagnostic source assemblies, the maximum-rated peak tube potential and the maximum-rated continuous tube current for the maximum-rated peak tube potential.

Light field - That area of the intersection of the light beam from the beam-limiting device and one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the illumination is one-fourth of the maximum in the intersection.

Line-voltage regulation - The difference between the no-load and the load line potentials expressed as a percent of the load line potential; that is,

Percent line-voltage regulation = $100 (V_n - V_l)/V_l$

where:

V_n = no-load line potential; and

V_l = load line potential.

mA - Milliampere.

mAs - Milliampere second.

Misadministration - An event that meets the criteria in RH-9202.a.

Mobile x-ray equipment - See "x-ray equipment."

Mode of operation - For fluoroscopic systems, a distinct method of fluoroscopy or radiography provided by the manufacturer and selected with a set of several

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technique factors or other control settings uniquely associated with the mode. The set of distinct technique factors and control settings for the mode may be selected by the operation of a single control. Examples of distinct modes of operation include normal fluoroscopy (analog or digital), high-level control fluoroscopy, cineradiography (analog and digital), digital subtraction angiography, electronic radiography using the fluoroscopic image receptor, and photospot recording. In a specific mode of operation, certain system variables affecting kerma, air kerma rate (AKR), or image quality, such as image magnification, x-ray field size, pulse rate, pulse duration, number of pulses, source-image receptor distance (SID), or optical aperture, may be adjustable or may vary; their variation per se does not comprise a mode of operation different from the one that has been selected.

Multiple tomogram system - A computed tomography x-ray system which obtains x-ray transmission data simultaneously during a single scan to produce more than one tomogram.

Noise in CT - The standard deviation of the fluctuations in CT number expressed as a percentage of the attenuation coefficient of water. Its estimate (S_n) is calculated using the following expression:

$$S_n = \frac{100 \cdot \overline{CS} \cdot s}{\mu_w}$$

where:

$\overline{CS}$ = contrast scale;

μ_w = linear attenuation coefficient of water; and

s = estimated standard deviation of the CT numbers of picture elements in a specified area of the CT image.

Nominal tomographic section thickness - The full width at half-maximum of the sensitivity profile taken at the center of the cross-sectional volume over which x-ray transmission data are collected.

Notification value - A protocol-specific dose index (e.g. $CTDI_{vol}$(mGy) or of DLP(mGy·cm)) that is set by the registrant to trigger a notification to the CT operator prior to scanning when the dose index exceeds the established range for the examination.

Patient - An individual or animal subjected to healing arts examination, diagnosis or treatment.

Picture element - An elemental area of a tomogram.

PBL - See "positive beam limitation."

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Peak tube potential - The maximum value of the potential difference across the x-ray tube during an exposure.

Personal supervision - A qualified practitioner must exercise general supervision and be present in the room or adjacent control area during the performance of the procedure or service.

Phantom - A volume of material behaving in a manner similar to tissue with respect to the attenuation and scattering of radiation. This requires that both the atomic number (Z) and the density of the material be similar to that of tissue.

Photostimulable storage phosphor (PSP) - A material used to capture and store radiographic images in computed radiography systems.

PID - See "position indicating device."

Pitch - The table incrementation, in CT, per x-ray tube rotation, divided by the nominal x-ray beam width at isocenter.

Portable x-ray equipment - See "x-ray equipment."

Position indicating device (PID) - A device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

Positive beam limitation - The automatic or semi-automatic adjustment of an x-ray beam to the size of the selected image receptor, whereby exposures cannot be made without such adjustment.

Primary protective barrier - The material, excluding filters, placed in the useful beam to reduce the radiation exposure [beyond the patient and cassette holder] for protection purposes.

Protective apron - An apron made of radiation absorbing materials used to reduce radiation exposure.

Protocol - A collection of settings and parameters that fully describe an examination.

Pulsed mode - Operation of the x-ray system such that the x-ray tube current is pulsed by the x-ray control to produce one or more exposure intervals of duration less than one-half second.

Qualified Expert - An individual specifically approved by the Department as having the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection matters.

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Individuals shall be certified in an appropriate field, commensurate with his or her duties, either by the American Board of Radiology, the American Board of Health Physics, the American Board of Medical Physics, or the Canadian College of Physicists in Medicine, or individuals may have equivalent qualifications. An individual that meets the qualifications in RH-10200.d. for a Qualified Medical Physicist also meets the qualifications of a Qualified Expert.

Quality assurance - A program providing for verification by written procedures such as testing, auditing, and inspection to ensure that deficiencies, deviations, defective equipment, or unsafe practices, or a combination thereof, relating to the use, disposal, management, or manufacture of radiation devices are identified, promptly corrected, and reported to the appropriate regulatory authorities as required.

Radiation detector - A device which in the presence of radiation provides a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

Radiation machine - Any device emitting or capable of producing radiation, but excluding particle accelerators (for the purposes of this Section), devices with radioactive material as the only source of radiation, and devices exempted by Part E of Section 1.

Radiation Protocol Committee (RPC) - The representative group of qualified individuals in a CT or FGI facility responsible for the ongoing review and management of CT or FGI protocols to ensure that exams being performed achieve the desired diagnostic image quality at the lowest radiation dose possible while properly exploiting the capabilities of the equipment being used.

Radiation Safety Officer (RSO) - An individual responsible for the overall radiation protection program (RH-1004.), on behalf of the registrant.

Radiation therapy simulation system - A radiographic or fluoroscopic x-ray system intended for localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field.

Radiograph - An image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

Radiography - A technique for generating and recording an x-ray pattern for the purpose of providing the user with an image(s) after termination of the exposure.

Recording - Producing a retrievable form of an image resulting from x-ray photons.

Reference plane - A plane which is parallel to and which can be offset (as

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specified in manufacturer information provided to users) from the location of the tomographic plane(s).

Scan - The complete process of collecting x-ray transmission data for the production of a tomogram. Data may be collected simultaneously during a single scan for the production of one or more tomograms.

Scan increment - The amount of relative displacement of the patient with respect to the CT x-ray system between successive scans measured along the direction of such displacement.

Scan sequence - A pre-selected set of two or more scans performed consecutively under pre-selected CT conditions of operation.

Scan time - The time elapsed during the accumulation of x-ray transmission data for a single scan.

Scattered radiation - Radiation that, during passage through matter, has been deviated in direction. See "direct scattered radiation."

Sensitivity profile - The relative response of the CT x-ray system as a function of position along a line perpendicular to the tomographic plane.

Single tomogram system - A CT x-ray system which obtains x-ray transmission data during a scan to produce a single tomogram.

Shutter - A device attached to the tube housing assembly which can intercept the entire cross-sectional area of the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

SID - See "source-image receptor distance."

Size-specific dose estimate (SSDE) - A patient dose estimate which takes into consideration corrections based on the size of the patient, using linear dimensions measured on the patient or patient images.

Source - The focal spot of the x-ray tube.

Source-image receptor distance - The distance from the source to the center of the input surface of the image receptor.

Source-skin distance (SSD) - The distance from the source to the center of the entrant x-ray field in the plane tangent to the patient skin surface.

Spot-film - A radiograph which is made during a fluoroscopic examination to permanently record conditions which exist during that fluoroscopic procedure.

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Spot-film device - A device intended to transport or position a radiographic image receptor between the x-ray source and fluoroscopic image receptor. It includes a device intended to hold a cassette over the input end of the fluoroscopic image receptor for the purpose of producing a radiograph.

Stationary x-ray equipment - See "x-ray equipment."

Stray radiation - The sum of leakage and scattered radiation.

Substantial radiation dose level (SRDL) - An appropriately-selected dose level used to trigger additional dose-management actions during a procedure and medical follow-up for a radiation level that might produce a clinically-relevant injury in an average patient.

Technique factors - The following conditions of operation:

1. For capacitor energy storage equipment, peak tube potential in kilovolts (kV) and quantity of charge in milliampere-seconds (mAs);

2. For field emission equipment rated for pulsed operation, peak tube potential in kV, and number of x-ray pulses;

3. For CT equipment designed for pulsed operation, peak tube potential in kV, scan time in seconds, and either tube current in milliamperes (mA), x-ray pulse width in seconds, and the number of x-ray pulses per scan, or the product of tube current, x-ray pulse width, and the number of x-ray pulses in mAs;

4. For CT equipment not designed for pulsed operation, peak tube potential in kV, and either tube current in mA and scan time in seconds, or the product of tube current and exposure time in mAs and the scan time when the scan time and exposure time are equivalent; and

5. For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

These Rules -The Arkansas State Board of Health Rules for Control of Sources of Ionizing Radiation.

Tomogram - The depiction of the x-ray attenuation properties of a section through the body.

Tomographic plane - That geometric plane which the manufacturer identified as corresponding to the output tomogram.

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Tomographic section - The volume of an object whose x-ray attenuation properties are imaged in a tomogram.

Tube - An x-ray tube, unless otherwise specified.

Tube housing assembly - The tube housing with tube installed. It includes high-voltage or filament transformers and other appropriate elements when such are contained within the tube housing.

Unintended radiation dose in diagnostic or interventional x-ray - A patient or human research subject radiation dose resulting from a human error or equipment malfunction during the procedure.

Useful beam - The radiation which passes through the tube housing port and the aperture of the beam limiting device when the exposure switch or timer is activated.

Visible area - That portion of the input surface of the image receptor over which incident x-ray photons are producing a visible image.

Volume Computed Tomography Dose Index ($CTDI_{vol}$) - A radiation dose parameter derived from the $CTDI_w$ (weighted or average CTDI given across the field of view). The formula is:

$$CTDI_{vol} = (N)(T)(CTDI_w) / I,$$ where:

N = number of simultaneous axial scans per x-ray source rotation;

T = thickness of one (1) axial scan (mm); and

I = table increment per axial scan (mm).

Thus, $CTDI_{vol} = CTDI_w / pitch$.

Weighted Computed Tomography Dose Index ($CTDI_w$) - The estimated average $CTDI_{100}$ across the field of view (FOV). The equation is:

$$CTDI_w = \frac{1}{3} CTDI_{100,center} + \frac{2}{3} CDTI_{100,edge}$$

Where 1/3 and 2/3 approximate the relative areas represented by the center and edge values derived using the 16 or 32 centimeters acrylic phantom. $CTDI_w$ uses $CTDI_{100}$ and an f-factor for air (0.87 rad/R or 1.0 mGy/mGy).

X-ray control - A device which controls input power to the x-ray high-voltage

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generator or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure.

X-ray exposure control - A device, switch, button, or other similar means by which an operator initiates or terminates the radiation exposure. The x-ray exposure control may include such associated equipment as timers and back-up timers.

X-ray equipment - An x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

1. Mobile x-ray equipment - X-ray equipment mounted on a permanent base with wheels or casters for moving while completely assembled;

2. Portable x-ray equipment - X-ray equipment designed to be hand-carried but not hand-held during operation;

3. Stationary x-ray equipment - X-ray equipment which is installed in a fixed location; and

4. Hand-held x-ray equipment - X-ray equipment that is designed to be hand-held during operation.

X-ray field - That area of the intersection of the useful beam and any one of a set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the air kerma rate (AKR) is one-fourth of the maximum in the intersection.

X-ray high-voltage generator - A device which transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high-voltage switches, electrical protective devices, and other appropriate elements.

X-ray system - An assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high-voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

X-ray table - A patient support device with its patient support structure (tabletop) interposed between the patient and the image receptor during radiography or fluoroscopy. This includes, but is not limited to, any stretcher equipped with a

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radiolucent panel and any table equipped with a cassette tray (or bucky), cassette tunnel, fluoroscopic image receptor, or spot-film device beneath the tabletop.

X-ray tube - Any electron tube which is designed for the conversion of electrical energy into x-ray energy.

RH-9101.- RH-9199. Reserved.

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PART C.
ADMINISTRATIVE REQUIREMENTS

RH-9200. **Radiation Safety Requirements**.

The registrant shall be responsible for directing the operation of the x-ray system(s) under his or her administrative control and shall assure that the requirements of these Rules are met in operation of the x-ray system(s).

a. The registrant shall have a radiation safety program as referenced in RH-1004. The radiation safety program shall include but not be limited to the following:

1. The use of ionizing radiation within its purview is performed in accordance with existing laws and rules.

2. All individuals are protected as required by Section 3, "Standards for Protection Against Radiation," of these Rules.

b. An x-ray system which does not meet the provisions of these Rules shall not be operated for diagnostic purposes unless the Department or a Qualified Expert determines that the non-compliance shall not pose a significant radiation risk or significantly affect image quality, and arrangements have been made to correct the non-compliance within thirty (30) calendar days.

c. The Qualified Expert, shall complete initial and routine compliance evaluations following nationally recognized procedures or those recognized by the Department. These evaluations shall include a review of the required quality control (QC) tests.

d. All x-ray equipment shall be installed and used in accordance with the equipment manufacturer's specifications.

e. 1. Individuals operating x-ray equipment shall meet the appropriate Radiologic Technology Licensure requirements, unless specifically exempted by the Rules Pertaining to Radiologic Technology Licensure promulgated under the authority of Act 1071 of 1999, as amended – codified at Arkansas Code Annotated §§17-106-101 – 17-106-111 and 17-106-201 – 17-106-204.

2. Operators, prior to use of the x-ray equipment, shall be adequately instructed in the safe operating procedures of the equipment and shall be competent in the safe use of the equipment.

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3. Operators shall receive refresher training addressing relevant radiation safety topics and appropriate x-ray equipment use at intervals not to exceed twelve (12) months and when a change occurs in duties, rules, or terms of the registration. Additional training requirements specific to fluoroscopy are detailed in RH-9305.l.

f. A sufficient number of protective apparel (e.g., aprons, gloves, collars) and shields shall be available to provide the necessary radiation protection for all patients and personnel who are involved with x-ray operations.

g. All protective apparel and auxiliary shields shall be evaluated annually for integrity and clearly labeled with their lead equivalence.

h. Each registrant shall have a mechanism in place for the referring physician to access information on selecting the most appropriate diagnostic procedure to answer the clinical question.

i. Nationally recognized diagnostic reference levels (DRLs) shall be utilized when applicable.

j. The registrant shall use auxiliary equipment designed to minimize patient and personnel exposure commensurate with the needed diagnostic information.

k. Portable or mobile x-ray equipment shall be used only for examinations where it is impractical to transfer the patient to a stationary x-ray installation.

l. Neither the x-ray tube housing nor the collimating device shall be held during an exposure. Exceptions are allowed for Department-approved devices specifically designed to be hand-held.

m. The useful x-ray beam shall be limited to the area of clinical interest.

n. Consideration shall be given to selecting the appropriate technique and employing available dose reduction methods and technologies across all patient sizes and clinical indications.

o. A facility shall have a documented procedure in place for verification of patient identity and exam to be performed, including identification of the appropriate body part.

p. For general radiographic systems not equipped with an operational anatomic programming option, protocols shall be documented and readily available to the operator. At a minimum, these protocols shall include:

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1. Patient's (adult and pediatric, if appropriate) body part and anatomical size;

2. Technique factors;

3. Type of image receptor used;

4. Source to image receptor distance used (except for dental intraoral radiography); and

5. Type of grid, if any.

q. The registrant shall create and make available to x-ray operators written safety procedures, including instructions for patient holding and any restrictions of the operating technique required for the safe operation of the particular x-ray system. The operator shall be able to demonstrate familiarity with these procedures.

r. The registrant shall restrict the presence of individuals in the immediate area of the patient being examined to those required or in training for the medical procedure, or the parent or guardian of a patient while the x-ray tube is energized. The following applies to all individuals, other than the patient being examined:

1. All persons shall be positioned such that no part of the body will be struck by the useful beam unless protected by not less than 0.5 millimeter lead equivalent material;

2. All persons shall be protected from the secondary radiation by protective garments or whole body protective barriers of not less than 0.25 millimeter lead equivalent material; and

3. Instances may warrant having human patients other than the one being examined in the room during the exam. If the procedure results in scatter radiation in excess of 2 mrem (0.02 mSv) in any one hour at the position of these patients, they shall be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 millimeter lead equivalent material or shall be positioned so that the 2 mrem (0.02 mSv) in any one hour limit is met.

s. Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

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1. Exposure of an individual for training, demonstration, or other non-healing arts purposes; and

2. Exposure of an individual for the purpose of healing arts screening except as authorized by the Department.

t. In cases where a patient or image receptor must be provided with auxiliary support, mechanical support devices shall be used whenever possible. If a patient or image receptor must be provided with auxiliary support during a radiation exposure:

1. Written safety procedures, as required by paragraph q. of this section, shall indicate the requirements for selecting a holder and the procedure the holder shall follow;

2. The human holder shall be instructed in personal radiation safety and protected as required by paragraph r. of this section;

3. No individual shall be used routinely to hold the image receptor or patient during a radiation exposure; and

4. In those cases where the patient must hold the image receptor, except during intraoral examinations, any portion of the body other than the area of clinical interest struck by the useful beam shall be protected by not less than 0.5 millimeter lead equivalent material.

u. All individuals who are associated with the operation of an x-ray system are subject to the requirements of Section 3, "Standards for Protection Against Radiation."

v. A facility shall be in compliance with shielding and safety design requirements as described in RH-59.

w. **Healing arts screening.**

Any person proposing to conduct a healing arts screening program shall not initiate such a program without prior approval of the Department. When requesting such an approval, that person shall submit to the Department the information outlined in Appendix C to Section 1. Registration requirements pursuant to Part C of Section 1 shall also be met. The Department shall be notified in writing prior to any changes that would render the submitted information no longer accurate.

x. **Maintenance of x-ray system records.**

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The registrant shall maintain the following information on each x-ray system for inspection by the Department:

1. Model and serial numbers of all major components, and user's manuals for those components, including software, for the life of the system;

2. Records of surveys, calibrations, maintenance, and modifications (e.g., major software and hardware upgrades) performed on the x-ray system(s), for five (5) years; and

3. A copy of all correspondence with the Department regarding the x-ray system, for five (5) years.

v. **X-ray utilization record**.

Each facility shall maintain a record containing the patient's name, the type of examinations, and the dates the examinations were performed.

RH-9201. **Quality Assurance**.

a. The registrant shall establish and maintain a quality assurance (QA) program. In addition to the requirements in the modality specific sections, the registrant shall:

1. Maintain documentation of minimum qualifications for practitioners, Qualified Experts, and x-ray equipment operators.

2. Designate an appropriately trained individual to manage the QA program.

3. Establish and maintain written QA and quality control (QC) procedures, including evaluation frequencies and tolerances.

4. Check each study for artifacts. If an artifact is present, the source shall be identified and appropriate action taken.

5. Perform repeat and reject analysis of radiographic images at least quarterly following specifications of a nationally recognized organization.

6. Complete preventative maintenance on the x-ray systems in accordance with manufacturer specifications at intervals not to exceed twelve (12) months.

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7. Maintain documentation showing the testing instruments used in determining compliance with the provisions of this section are properly calibrated and maintained in accordance with the Department minimum standard or accepted professional standards when no Department minimum is defined.

8. Complete and document an annual review of the QA program.

9. Retain QA and QC records of evaluations and reviews for three (3) years after it is made.

b. **X-ray film processing facilities**.

A registrant using analog image receptors (e.g. radiographic film) shall have available suitable equipment for handling and processing radiographic film in accordance with the following provisions:

1. Manually developed film:

A. Processing tanks shall be constructed of mechanically rigid, corrosion resistant material.

B. Developing solutions shall be prepared, replenished, and replaced following manufacturer recommendations.

C. The temperature of solutions in the tanks shall be maintained within the range of 60° F to 80° F (16° C to 27° C). Film shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer, or, in the absence of such recommendations, with the following time-temperature chart:

Manual Film Developing Technique Chart				
Developer Temperature °C / °F	Developing Time (Minutes)		Developer Temperature °C / °F	Developing Time (Minutes)
26.7 / 80	2.0		20.6 / 69	4.5
26.1 / 79	2.0		20.0 / 68	5.0
25.6 / 78	2.5		19.4 / 67	5.5
25.0 / 77	2.5		18.9 / 66	5.5
24.4 / 76	3.0		18.3 / 65	6.0
23.9 / 75	3.0		17.8 / 64	6.5
23.3 / 74	3.5		17.2 / 63	7.0
22.8 / 73	3.5		16.7 / 62	8.0

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22.2 / 72	4.0		16.1 / 61	8.5
21.7 / 71	4.0		15.6 / 60	9.5
21.1 / 70	4.5			

D. Devices shall be utilized which will indicate the actual temperature of the developer solution and signal the passage of a preset time.

2. Automatic processors and other closed processing systems:

A. Automatic processors shall be operated and maintained following manufacturer specifications.

B. Films shall be developed in accordance with the time-temperature relationships recommended by the film manufacturer; in the absence of such recommendations, the film shall be developed using the following chart:

Developer Temperature		Minimum Immersion Time[a]
ºC	ºF	Seconds
35.5	96	19
35	95	20
34.5	94	21
34	93	22
33.5	92	23
33	91	24
32	90	25
31.5	89	26
31	88	27
30.5	87	28
30	86	29
29.5	85	30

[a] Immersion time only, no crossover time included.

C. Processing deviations from the requirements in paragraph b. of this section shall be documented by the registrant in such manner that the requirements are shown to be met or

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exceeded (e.g., extended processing and special rapid chemistry).

c. **Additional requirements for facilities using x-ray film.**

1. Pass boxes, if provided, shall be so constructed as to exclude light from the darkroom when cassettes are placed in or removed from the boxes and shall incorporate adequate shielding from stray radiation to prevent exposure of undeveloped film.

2. Darkrooms typically used by more than one individual shall be provided a method to prevent accidental entry while undeveloped films are being handled or processed.

3. Film shall be stored in a cool, dry place and shall be protected from exposure to stray radiation. Film in open packages shall be stored in a light tight container.

4. Film cassettes and intensifying screens shall be inspected periodically and shall be cleaned and replaced as necessary.

5. Outdated x-ray film shall not be used for diagnostic radiographs.

6. The film and intensifying screen shall be spectrally compatible.

7. Facilities shall maintain a light-tight darkroom, use proper safelighting and safeguards, and evaluate darkroom integrity and daylight loading systems for film fog every six months and after a change that may impact film fog.

8. Facilities other than dental, podiatry, and veterinary shall:

   A. Have a continuous and documented sensitometric quality control program, including quality control tests for speed, contrast, and fog. These tests shall be performed according to specifications of the manufacturer, a Qualified Expert, or a nationally recognized organization.

   B. Maintain a light-tight darkroom and use proper safelighting and safeguards such that any film type in use exposed in a cassette to x-radiation sufficient to produce an optical density from 1 to 2 when processed shall not suffer an increase in optical density greater than 0.1 when exposed in the darkroom for 2 minutes with all safelights on. If used, daylight film handling boxes shall preclude fogging of the film.

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C. Limit the base plus fog of unexposed film to an optical density less than 0.25 when developed by the routine procedure used by the facility.

d. **Facilities using computed radiography (CR) or direct digital radiography (DDR).**

1. When exposure indicators are available, the facility shall establish and document an acceptable range for the exposure values for examinations routinely performed at the facility. The indicated exposure values for each image shall be compared to the established range. Consistent deviations from established ranges shall be investigated, corrective actions taken as necessary, and results documented.

2. Facilities shall establish and follow an image quality control program in accordance with the recommendations of a Qualified Expert, the system manufacturer, or a nationally recognized organization.

3. Facilities other than dental, podiatric, and veterinary shall quarterly complete phantom image evaluation using a phantom approved by a Qualified Expert, system manufacturer, or the Department. The analysis at a minimum shall include artifacts, spatial resolution, contrast or noise, workstation monitors, and exposure indicator constancy.

4. In addition to paragraphs d.1. through d.3. of this section, CR facilities shall perform erasure of all CR cassettes at least on a weekly basis.

RH-9202. **Reports, Notifications, and Records.**

a. **Reports, notifications, and records of misadministrations.**

1. A registrant shall report any event resulting from intervention of a patient or human research subject in which the administration of radiation results, or will result in, unintended permanent functional damage to an organ or a physiological system as determined by a physician.

2. Other than events that result from intervention by a patient or human research subject, a registrant shall report any event in which

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the administration of radiation from diagnostic or interventional radiography results in:

A. Unintended skin dose to the same area in a single procedure greater than 200 rads (2 Gy); or

B. Unintended dose, other than skin dose, in a single procedure greater than:

i. Five (5) times the facility's established protocol, and greater than fifty (50) rads (0.5 Gy) to any organ; or

ii. Five (5) times the facility's established protocol, and greater than five (5) rem (0.05 Sv) effective dose; or

C. Dose, for a wrong patient or wrong site, greater than:

i. Fifty (50) rads (0.5 Gy) to any organ; or

ii. Five (5) rem (0.05 Sv) effective dose; or

iii. 200 rads (2 Gy) to skin in the same area.

3. The registrant shall notify the Department by telephone no later than the next business day after the discovery of a misadministration.

4. The registrant shall provide notification of the event to the referring physician and also notify the individual who is the subject of the misadministration no later than twenty-four (24) hours after its discovery, unless the referring physician personally informs the registrant either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. The registrant is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within twenty-four (24) hours, the registrant shall notify the individual as soon as possible thereafter. The registrant may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification. To meet the requirements of this subparagraph, the notification of the individual who is the subject of the misadministration may be made instead to that

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individual's responsible relative or guardian. If a verbal notification is made, the registrant shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the registrant upon request. The registrant shall provide such a written description if requested.

5. The registrant shall submit to the Department a written report, prepared by a Qualified Expert, within fifteen (15) calendar days after the discovery of a misadministration. The report shall not contain the individual's name or any other information that could lead to the identification of the individual. The written report shall include the following:

   A. The registrant's name;

   B. The name of the prescribing physician;

   C. A brief description of the event;

   D. Why the event occurred;

   E. The effect, if any, on the individual who received the administration;

   F. What actions, if any, that have been taken, or are planned, to prevent recurrence;

   G. Certification that the registrant notified the individual (or the individual's responsible relative or guardian), and if not, why not; and

   H. What information was provided to the individual (or the individual's responsible relative or guardian) when notified.

6. The registrant shall retain a record of a misadministration in accordance with paragraph a.8. of this section. A copy of this record shall be:

   A. Provided to the referring physician, if other than the registrant, within fifteen (15) calendar days after discovery of the misadministration; and

   B. Maintained as part of the permanent medical record of the individual who is the subject of the misadministration.

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7. Aside from the notification requirement in paragraph a.4. of this section, nothing in paragraph a. affects any rights or duties of registrants and physicians in relation to each other, to individuals affected by the misadministration, or to that individual's responsible relatives or guardians.

8. A registrant shall retain a record of misadministrations reported in accordance with paragraph a. of this section for five (5) years. The record shall contain the following:

A. The registrant's name;

B. The names of all persons involved (including the individual who is the subject of the misadministration);

C. The social security number or other identification number, if one has been assigned, of the individual who is the subject of the misadministration;

D. A brief description of the event; why it occurred; the effect, if any, on the individual;

E. The actions, if any, that have been taken, or are planned, to prevent recurrence; and

F. Whether the registrant notified the individual (or the individual's responsible relative or guardian), and if not, why not.

b. **Reports, notifications, and records of a dose to an embryo/fetus**.

1. A registrant shall report any dose to an embryo/fetus that is greater than five (5) millisievert (500 mrem) dose equivalent that is a result of an administration of radiation to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the referring physician.

2. The registrant shall notify the Department by telephone no later than the next calendar day after discovery of a dose to the embryo/fetus that requires a report pursuant to paragraph b.1. of this section.

3. The registrant shall submit a written report to the Department within fifteen (15) calendar days after discovery of a dose to the

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embryo/fetus that requires a report pursuant to paragraph b.1. of this section.

A. The written report shall include:

i. The registrant's name and registration number;

ii. The name of the referring physician and of the prescribing physician;

iii. A brief description of the event;

iv. Why the event occurred;

v. The effect, if any, on the embryo/fetus;

vi. What actions, if any, have been taken or are planned to prevent recurrence; and

vii. Certification that the registrant notified the pregnant individual (or the pregnant individual's responsible relative or guardian), and if not, why not.

B. The report must not contain the individual's name or any other information that could lead to identification of the individual.

4. The registrant shall provide notification of the event to the referring physician and also to the pregnant individual, no later than 24 hours after discovery of an event that would require reporting under paragraph b.1. of this section, unless the referring physician personally informs the registrant either that he or she will inform the pregnant individual or that, based on medical judgment, telling the pregnant individual would be harmful. The registrant is not required to notify the pregnant individual without first consulting with the referring physician. If the referring physician or pregnant individual cannot be reached within 24 hours, the registrant shall make the appropriate notifications as soon as possible thereafter. The registrant may not delay any appropriate medical care for the embryo/fetus, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this subparagraph, the notification may be made to the pregnant individual's responsible relative or guardian instead of to the pregnant individual. If a verbal notification is made, the registrant shall inform the pregnant individual, or the pregnant individual's

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responsible relative or guardian, that a written description of the event can be obtained from the registrant upon request. The registrant shall provide such a written description if requested.

5. A registrant shall retain a record of a dose to an embryo/fetus for five (5) years. The record must contain the information required by paragraph b.3.A. of this section plus the name of the pregnant individual who is the subject of the event and her social security number or other identification number, if one has been assigned. A copy of this record shall be provided to the referring physician, if other than the registrant, within fifteen (15) calendar days after the discovery of the event.

RH-9203. Reserved.

RH-9204. **Exemptions**.

a. **Dental facilities**.

Dental facilities performing only intra-oral, panoramic, cephalometric, or volumetric dental imaging are exempt from the following provisions of this Part: RH-9200.h. (information available to referring physician) and RH-9201.a.5. (repeat analysis).

b. **Podiatry facilities**.

Podiatry facilities are exempt from the following provisions of this Part: RH-9200.h. (information available to referring physician) and RH-9201.a.5. (repeat analysis).

c. **Veterinary facilities**.

Veterinary facilities are exempt from the following provisions of this Part: RH-9200.h. (information available to referring physician), RH-9200.i. (use of reference levels), RH-9200.n. (use of dose reduction techniques), RH-9200.o. (patient identification), RH-9200.p. (protocol control), RH-9200.t.3. (routine holding of patient), RH-9200.w. (healing arts screening), and RH-9201.a.5. (repeat analysis).

RH-9205.- 9299. Reserved.

PART D.
TECHNICAL REQUIREMENTS

RH-9300. **Diagnostic and Interventional X-Ray Systems**.

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In addition to other requirements of this Section, all diagnostic and interventional x-ray systems shall meet the following requirements. Requirements specific to dental intra-oral, panoramic, cephalometric, and volumetric dental imaging equipment are included in RH-9320.

a. **Warning label**.

1. On systems manufactured on or before June 10, 2006, the control panel containing the main power switch shall bear the warning statement, or the warning statement in paragraph a.2. of this section, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

2. On systems manufactured after June 10, 2006, the control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions, and maintenance schedules are observed."

b. **Leakage radiation from the diagnostic source assembly**.

The leakage radiation from the diagnostic source assembly measured at a distance of one (1) meter in any direction from the source shall not exceed 0.88 milligray (mGy) air kerma (vice 100 milliroentgen (mR) exposure) in one (1) hour when the x-ray tube is operated at its leakage technique factors. If the maximum rated peak tube potential of the tube housing assembly is greater than the maximum rated peak tube potential for the diagnostic source assembly, positive means shall be provided to limit the maximum x-ray tube potential to that of the diagnostic source assembly. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than twenty (20) centimeters.

c. **Radiation from components other than the diagnostic source assembly**.

The radiation emitted by a component other than the diagnostic source assembly shall not exceed an air kerma of 18 microgray (vice 2 milliroentgens exposure) in one (1) hour at five (5) centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than twenty (20) centimeters.

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d. **Technique indicators**.

1. For x-ray equipment capable of displaying technique factors, the technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated.

2. The requirement in paragraph d.1. of this section may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

3. The accuracy of the indicated kilovoltage peak (kVp) shall meet manufacturer specifications. In the absence of a manufacturer specification, kVp accuracy shall be within plus or minus ten percent (±10 %).

e. **Beam quality**.

1. The half value layer (HVL) of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table I to RH-9300. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Table I of this section, linear interpolation or extrapolation may be made. Positive means shall be provided to ensure that at least the minimum filtration needed to achieve beam quality requirements is in the useful beam during each exposure. In the case of a system which is to be operated with more than one thickness of filtration, this requirement can be met by a filter interlocked with the kilovoltage selector which will prevent x-ray emissions if the minimum required filtration is not in place.

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TABLE I TO RH-9300.

X-Ray Tube Voltage (kilovolt peak)				
Design Operating Range	**Measured Operating Potential**	**Minimum HVL (mm of Aluminum)**		
		Specified Dental Systems[a]	Other X-Ray Systems[b]	Other X-Ray Systems[c]
Below 51	30	1.5	0.3	0.3
	40	1.5	0.4	0.4
	50	1.5	0.5	0.5
51 to 70	51	1.5	1.2	1.3
	60	1.5	1.3	1.5
	70	1.5	1.5	1.8
Above 70	71	2.1	2.1	2.5
	80	2.3	2.3	2.9
	90	2.5	2.5	3.2
	100	2.7	2.7	3.6
	110	3.0	3.0	3.9
	120	3.2	3.2	4.3
	130	3.5	3.5	4.7
	140	3.8	3.8	5.0
	150	4.1	4.1	5.4

[a] Dental x-ray systems designed for use with intraoral image receptors and manufactured after December 1, 1980.

[b] Dental x-ray systems designed for use with intraoral image receptors and manufactured before or on December 1, 1980, and all other x-ray systems subject to this section and manufactured before June 10, 2006.

[c] All x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006.

2. **Optional filtration on fluoroscopic systems.**

Fluoroscopic systems manufactured on or after June 10, 2006, incorporating an x-ray tube(s) with a continuous output of one (1) kilowatt or more and an anode heat storage capacity of one (1) million heat units or more shall provide the option of adding x-ray filtration to the diagnostic source assembly in addition to the amount needed to meet the half-value layer provisions of this subsection. The selection of this additional x-ray filtration shall be either at the option of the user or automatic as part of the selected mode of operation. A means of indicating which combination of additional filtration is in the x-ray beam shall be provided.

3. **Measuring compliance.**

For capacitor energy storage equipment, compliance shall be determined with the maximum selectable quantity of charge per exposure.

f. **Aluminum equivalent of material between patient and image receptor.**

Except when used in a CT x-ray system, the aluminum equivalent of each of the items listed in Table II to RH-9300, which are used between the patient and the image receptor, may not exceed the indicated limits. Compliance shall be determined by x-ray measurements made at a potential of 100 kilovolts peak and with an x-ray beam that has an HVL specified in Table I to RH-9300 for the potential. This requirement applies to front panel(s) of image receptors and film changers provided by the manufacturer for patient support or for prevention of foreign object intrusions. The requirement does not apply to screens and their associated mechanical support panels or grids.

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TABLE II TO RH-9300.

Item	Maximum Aluminum Equivalent (millimeters)
1. Front panel(s) of image receptor (total of all)	1.2
2. Film panel(s) of film changer (total of all)	1.2
3. Cradle	2.3
4. Tabletop, stationary, without articulated joints	1.2
5. Tabletop, movable, without articulated joint(s) (including stationary subtop)	1.7
6. Tabletop, with radiolucent panel having one articulated joint	1.7
7. Tabletop, with radiolucent panel having two or more articulated joints	2.3
8. Tabletop, cantilevered	2.3
9. Tabletop, radiation therapy simulator	5.0

g. **Battery charge indicator.**

On battery-powered generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

h. **Modification of certified diagnostic x-ray components and systems.**

In addition to the requirements of this Section, the registrant shall not make, nor cause to be made, any modification of components or installations of components certified in accordance with the U.S. Food and Drug Administration (FDA) Title 21 of the Code of Federal Regulations, Part 1020, in any manner that could cause the installations or the components to fail to meet the requirements of the applicable parts of the standards specified in 21 CFR Part 1020, except where a variance has been granted by the Director, Center for Devices and Radiological Health, U.S. FDA. A copy of the variance shall be maintained by the registrant for inspection by the Department until termination of the registration.

i. **Multiple tubes.**

Where two or more radiographic tubes are controlled by one exposure switch, the tube which has been selected shall be clearly indicated prior to initiation of the exposure. Only the selected tube can be energized. This indication shall be both on the x-ray control panel and at or near the tube housing assembly which has been selected.

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j. **Mechanical support of tube head**.

The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the x-ray system.

k. **Locks**.

All position locking, holding, and centering devices on x-ray system components and systems shall function as intended.

l. **Maintaining compliance**.

Diagnostic x-ray systems and their associated components used on humans and certified pursuant to 21 CFR Part 1020, "Performance Standards for Ionizing Radiation Emitting Products," shall be maintained in compliance with applicable requirements of these standards.

RH-9301.- 9304. Reserved.

RH-9305. **Fluoroscopic Equipment**.

The provisions of this section apply to equipment for fluoroscopic imaging or for recording images from the fluoroscopic image receptor.

a. Only image-intensified or direct-digital receptor fluoroscopic equipment shall be used for fluoroscopy.

b. **Primary protective barrier**.

1. **Limitation of useful beam**.

The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any source-image receptor distance (SID). The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam. The air kerma rate (AKR) due to transmission through the barrier with the attenuation block in the useful beam combined with radiation from the fluoroscopic imaging receptor shall not exceed 3.34×10^{-3} percent of the entrance AKR, at a distance of 10 cm from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor. Radiation therapy simulation systems shall be exempt from this requirement provided the systems are intended only for remote control operation.

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2. **Measuring compliance**.

The AKR shall be measured in accordance with RH-9305.e. The AKR due to transmission through the primary barrier combined with radiation from the fluoroscopic image receptor shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 cm. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 cm above the tabletop. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 cm. Movable grids and compression devices shall be removed from the useful beam during the measurement. For all measurements, the attenuation block shall be positioned in the useful beam 10 cm from the point of measurement of entrance AKR and between this point and the input surface of the fluoroscopic imaging assembly.

c. **Field limitation**.

1. **Angulation**.

For fluoroscopic equipment manufactured after February 25, 1978, when the angle between the image receptor and the beam axis of the x-ray beam is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor. Compliance with paragraphs c.4. and c.5. of this section shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

2. **Further means for limitation**.

Means shall be provided to permit further limitation of the x-ray field to sizes smaller than the limits of paragraphs c.4. and c.5. of this section. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID or capability of a visible area of greater than 300 square centimeters, shall be provided with means for stepless adjustment of the x-ray field. Equipment with a fixed SID and the capability of a visible area of no greater than 300 square centimeters shall be provided with either stepless adjustment of the x-ray field or with a means to further limit the x-ray field size at the plane of the image receptor to 125 square centimeters or less. Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size containable in a square of 5 cm by 5 cm.

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3. **Spot-film devices**.

In addition to applicable rules in RH-9310., "Radiographic Equipment," the following requirements shall apply to spot-film devices, except when the spot-film device is provided for use with a radiation therapy simulation system:

A. Means shall be provided between the source and the patient for adjustment of the x-ray field size in the plane of the image receptor to the size of that portion of the image receptor which has been selected on the spot-film selector. Such adjustment shall be accomplished automatically when the x-ray field size in the plane of the image receptor is greater than the selected portion of the image receptor. If the x-ray field size is less than the size of the selected portion of the image receptor, the field size shall not open automatically to the size of the selected portion of the image receptor unless the operator has selected that mode of operation.

B. Neither the length nor width of the x-ray field in the plane of the image receptor shall differ from the corresponding dimensions of the selected portion of the image receptor by more than three percent (3%) of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum, without regard to sign, of the length and width differences shall not exceed four percent (4%) of the SID. On spot-film devices manufactured after February 25, 1978, if the angle between the plane of the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, and compliance shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

C. The center of the x-ray field in the plane of the image receptor shall be aligned with the center of the selected portion of the image receptor to within two percent (2%) of the SID.

D. Means shall be provided to reduce the x-ray field size in the plane of the image receptor to a size smaller than the selected portion of the image receptor such that:

i. For spot-film devices used on fixed-SID fluoroscopic systems which are not required to, and

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do not provide stepless adjustment of the x-ray field, the minimum field size, at the greatest SID, does not exceed 125 square centimeters; or

ii. For spot-film devices used on fluoroscopic systems that have a variable SID or stepless adjustment of the field size, the minimum field size, at the greatest SID, shall be containable in a square of 5 cm by 5 cm.

a. A capability may be provided for overriding the automatic x-ray field size adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position shall indicate whenever the automatic x-ray field size adjustment override is engaged. Each such system failure override switch shall be clearly labeled as follows:

"**FOR X-RAY FIELD LIMITATION SYSTEM FAILURE**."

4. **Fluoroscopy and radiography using the fluoroscopic imaging assembly with inherently circular image receptors**.

A. For fluoroscopic equipment manufactured before June 10, 2006, other than radiation therapy simulation systems, the following applies:

i. Neither the length nor width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than three percent (3%) of the SID. The sum of the excess length and the excess width shall be no greater than four percent (4%) of the SID.

ii. For rectangular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

B. For fluoroscopic equipment manufactured on or after June 10, 2006, other than radiation therapy simulation systems, the maximum area of the x-ray field in the plane of the

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image receptor shall conform with one of the following requirements:

i. When any linear dimension of the visible area of the image receptor measured through the center of the visible area is less than or equal to 34 cm in any direction, at least 80 percent (80%) of the area of the x-ray field overlaps the visible area of the image receptor; or

ii. When any linear dimension of the visible area of the image receptor measured through the center of the visible area is greater than 34 cm in any direction, the x-ray field measured along the direction of greatest misalignment with the visible area of the image receptor does not extend beyond the edge of the visible area of the image receptor by more than 2 cm.

5. **Fluoroscopy and radiography using fluoroscopic imaging assembly with inherently rectangular image receptors.**

For x-ray systems manufactured on or after June 10, 2006, the following applies:

A. Neither the length nor width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than three percent (3%) of the SID. The sum of the excess length and the excess width shall be no greater than four percent (4%) of the SID.

B. The error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

6. **Override capability**.

If the fluoroscopic x-ray field size is adjusted automatically as the SID or image receptor size is changed, a capability may be provided for overriding the automatic adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position shall indicate whenever the automatic field adjustment is overridden. Each such system failure override switch shall be clearly labeled as follows:

"**FOR X-RAY FIELD LIMITATION SYSTEM FAILURE.**"

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d. **Activation of tube**.

X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the operator for the entire time of any exposure. When recording serial radiographic images from the fluoroscopic image receptor, the operator shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

e. **Air kerma rates**.

For fluoroscopic equipment, the following requirements apply:

1. Fluoroscopic equipment manufactured before May 19, 1995.

A. Equipment provided with automatic exposure rate control (AERC) shall not be operable at any combination of tube potential and current that will result in an air kerma rate (AKR) in excess of 88 mGy per minute (vice 10 R/min exposure rate) at the measurement point specified in paragraph e.4. of this section, except as specified in paragraph e.1.E. of this section.

B. Equipment provided without AERC shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 44 mGy per minute (vice 10 R/min exposure rate) at the measurement point specified in paragraph e.4. of this section, except as specified in paragraph e.1.E. of this section.

C. Equipment provided with both an AERC mode and a manual mode shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (vice 10 R/min exposure rate) in either mode at the measurement point specified in paragraph e.4. of this section, except as specified in paragraph e.1.E. of this section.

D. Equipment may be modified in accordance with 21 CFR 1020.30(q) to comply with paragraph e.2. of this section. When the equipment is modified, it shall bear a label indicating the date of the modification and the statement:

"MODIFIED TO COMPLY WITH 21 CFR 1020.32(d)(2)."[3/]

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E. Exceptions:

During recording of fluoroscopic images.

2. Fluoroscopic equipment manufactured on or after May 19, 1995.

A. Equipment shall be equipped with AERC if operable at any combination of tube potential and current that results in an AKR greater than 44 mGy per minute (vice 5 R/min exposure rate) at the measurement point specified in paragraph e.4. of this section. Provision for manual selection of technique factors may be provided.

B. Equipment shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 88 mGy per minute (vice 10 R/min exposure rate) at the measurement point specified in paragraph e.4. of this section, except as specified in paragraph e.2.C. of this section.

C. Exceptions:

i. For equipment manufactured prior to June 10, 2006, during the recording of images from a fluoroscopic image receptor using photographic film or a video camera when the x-ray source is operated in a pulsed mode.

ii. For equipment manufactured on or after June 10, 2006, during the recording of images from the fluoroscopic image receptor for the purpose of providing the user with a recorded image(s) after termination of the exposure. Such recording does not include images resulting from a last-image-hold feature that are not recorded.

3. **Fluoroscopy equipment with optional high-level control.**

When high-level control is selected and the control is activated, in which case the equipment shall not be operable at any combination of tube potential and current that will result in an AKR in excess of 176 mGy per minute (vice 20 R/min exposure rate) at the measurement point specified in paragraph e.4. of this section. Special means of activation of high-level controls shall be required. The high-level control shall be operable only when

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continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is employed.

4. **Measuring compliance**.

Compliance with paragraph e. of this section shall be determined as follows:

A. If the source is below the x-ray table, the AKR shall be measured at 1 cm above the tabletop or cradle.

B. If the source is above the x-ray table, the AKR shall be measured at 30 cm above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

C. In a C-arm type of fluoroscope, the AKR shall be measured at 30 cm from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 cm from the input surface of the fluoroscopic imaging assembly.

D. In a C-arm type of fluoroscope having an SID less than 45 cm, the AKR shall be measured at the minimum source-skin distance.

E. In a lateral type of fluoroscope, the AKR shall be measured at a point 15 cm from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 cm to the centerline of the x-ray table.

5. Exemptions.

Fluoroscopic radiation therapy simulation systems are exempt from the requirements set forth in paragraph e. of this section when used for therapy simulation purposes.

f. **Indication of potential and current**.

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During fluoroscopy and cinefluorography, x-ray tube potential and current shall be continuously indicated. Deviation of x-ray tube potential and current from the indicated value shall not exceed the maximum deviation as stated by the manufacturer.

g. **Source-skin distance**.

1. Means shall be provided to limit the source-skin distance to not less than 38 cm on stationary fluoroscopes and to not less than 30 cm on mobile and portable fluoroscopes. In addition, for fluoroscopes intended for specific surgical or interventional applications that would be prohibited at the source-skin distances specified in this paragraph g.1., provisions may be made for operating at shorter source-skin distances but in no case less than 20 cm.

2. For stationary, mobile, or portable C-arm fluoroscopic systems manufactured on or after June 10, 2006, having a maximum source-image receptor distance of less than 45 cm, means shall be provided to limit the source-skin distance to not less than 19 cm. Such systems shall be labeled for extremity use only. In addition, for those systems intended for specific surgical application that would be prohibited at the source-skin distance specified in this paragraph g.2., provisions may be made for operation at shorter source-skin distances but in no case less than 10 cm.

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3. The registrant's written operating and safety procedures shall provide precautionary measures to be adhered to during the use of the shorter source-skin distance, in accordance with manufacturer's precautions, if provided.

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h. **Fluoroscopic irradiation time, display, and signal**.

1. Fluoroscopic equipment manufactured before June 10, 2006.

A. Equipment shall be provided with means to preset the cumulative irradiation time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed five (5) minutes without resetting. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative irradiation time. Such signal shall continue to sound while x-rays are produced until the timing device is reset. Fluoroscopic equipment may be modified in accordance with 21 CFR 1020.30(q) to comply with the requirements of paragraph h.2. of this section.

When the equipment is modified, it shall bear a label indicating the statement:

"MODIFIED TO COMPLY WITH 21 CFR 1020.32(h)(2)."

B. As an alternative to the requirements of paragraph h.1.A., radiation therapy simulation systems may be provided with a means to indicate the total cumulative exposure time during which x-rays were produced, and which is capable of being reset between x-ray examinations.

2. For x-ray controls manufactured on or after June 10, 2006, there shall be provided for each fluoroscopic tube:

A. A display of the fluoroscopic irradiation time at the fluoroscopist's working position. This display shall function independently of the audible signal described in paragraph h.2.B. of this section. The following requirements apply:

i. When the x-ray tube is activated, the fluoroscopic irradiation time in minutes and tenths of minutes shall be continuously displayed and updated at least once every six (6) seconds.

ii. The fluoroscopic irradiation time shall also be displayed within six (6) seconds of termination of an exposure and remain displayed until reset.

iii. Means shall be provided to reset the display to zero prior to the beginning of a new examination or procedure.

B. A signal audible to the fluoroscopist shall sound for each passage of five (5) minutes of fluoroscopic irradiation time during an examination or procedure. The signal shall sound until manually reset or, if automatically reset, for at least two (2) seconds.

i. **Display of last-image-hold.**

Fluoroscopic equipment manufactured on or after June 10, 2006, shall be equipped with means to display last-image-hold (LIH) image following termination of the fluoroscopic exposure.

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1. For an LIH image obtained by retaining pretermination fluoroscopic images, if the number of images and method of combining images are selectable by the user, the selection shall be indicated prior to initiation of the fluoroscopic exposure.

2. For an LIH image obtained by initiating a separate radiographic-like exposure at the termination of fluoroscopic imaging, the technique factors for the LIH image shall be selectable prior to the fluoroscopic exposure, and the combination selected shall be indicated prior to initiation of the fluoroscopic exposure.

3. Means shall be provided to clearly indicate to the user whether a displayed image is the LIH radiograph or fluoroscopy. Display of the LIH radiograph shall be replaced by the fluoroscopic image concurrently with re-initiation of fluoroscopic exposure, unless separate displays are provided for the LIH radiograph and fluoroscopic images.

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j. **Displays of values of AKR and cumulative air kerma**.

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Fluoroscopic equipment manufactured on or after June 10, 2006, shall display at the fluoroscopist's working position the AKR and cumulative air kerma. The following requirements apply for each x-ray tube used during an examination or procedure:

1. When the x-ray tube is activated and the number of images produced per unit time is greater than six (6) images per second, the AKR in mGy/min shall be continuously displayed and updated at least once every second.

2. The cumulative air kerma in units of mGy shall be displayed either within five (5) seconds of termination of an exposure or displayed continuously and updated at least once every five (5) seconds.

3. The display of the AKR shall be clearly distinguishable from the display of the cumulative air kerma.

4. The AKR and cumulative air kerma shall represent the value for conditions of free-in-air irradiation at one of the following reference locations specified according to the type of fluoroscope.

   A. For fluoroscopes with x-ray source below the x-ray table, x-ray source above the table, or of lateral type, the reference location shall be the respective locations specified in paragraphs e.4.A., e.4.B., or e.4.E. of RH-9305.

B. For C-arm fluoroscopes, the reference location shall be 15 cm from the isocenter toward the x-ray source along the beam axis. Alternatively, the reference location shall be at a point specified by the manufacturer to represent the location of the intersection of the x-ray beam with the patient's skin.

5. Means shall be provided to reset to zero the display of cumulative air kerma prior to the commencement of a new examination or procedure.

6. The displayed AKR and cumulative air kerma shall not deviate from the actual values by more than plus or minus thirty five percent (±35%) over the range of 6 mGy/min and 100 mGy to the maximum indication of AKR and cumulative air kerma, respectively. Compliance shall be determined with an irradiation time greater than three (3) seconds.

k. **Protection from scatter radiation**.

1. Fluoroscopic system configuration, including fluoroscopic table designs, shall not permit any portion of any individual's body, except the head, neck, and extremities, to be exposed to scattered radiation emanating from above or below the tabletop unless the radiation has passed through not less than a total of 0.25 mm lead equivalent material. The material may be, but is not limited to, drapes, self-supporting curtains, or viewing shields, in addition to any lead equivalency provided by a protective apron.

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2. Where sterile fields or special procedures prohibit the use of normal protective barriers or drapes, all of the following conditions shall be met.

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A. Shielding required under paragraph k.1. of this section shall be maintained to the degree possible under the clinical conditions.

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B. All persons, except the patient, in the room where fluoroscopy is performed shall wear protective aprons that provide a lead equivalent shielding of at least 0.25 mm.

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C. The fluoroscopic field size shall be reduced to the minimum required for the procedure being performed (area of clinical interest).

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D. Operating and safety procedures shall reflect the above conditions, and fluoroscopy personnel shall exhibit awareness of situations requiring the use or non-use of the protective drapes.

l. **Operator training**.

1. All persons operating, or supervising the operation of, fluoroscopy systems shall have completed a minimum of four (4) hours of training that includes, but is not limited to, the following:

A. Basic properties of radiation;

B. Biological effects of x-ray;

C. Radiation protection methods for patients and staff;

D. Units of measurement and dose, including dose-area product (DAP) values & air kerma;

E. Factors affecting fluoroscopic outputs;

F. High level control options;

G. Dose management including dose reduction techniques, monitoring, and recording;

H. Principles and operation of the specific fluoroscopic x-ray system(s) to be used;

I. Fluoroscopic and fluorographic outputs of each mode of operation on the system(s) to be used clinically; and

J. Applicable requirements of these Rules.

2. All persons operating, or supervising the operation of, fluoroscopy systems during fluoroscopically-guided interventional (FGI) procedures shall have completed a minimum of eight (8) hours of training approved by the Department. The topics shall include:

A. Topics provided in paragraph l.2. of this section;

B. Methods to reduce patient dose using advanced imaging and recording features;

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C. Procedures for recording pertinent data specified in paragraph p. of this section; and

D. Hands-on fluoroscopic machine training, a minimum of one (1) hour, demonstrating application of topics required in paragraph l.2. of this section.

3. The training required in paragraphs l.1. and l.2. of this section shall be provided by a Qualified Expert or another entity approved by the Department. The hands-on training shall be given by a Qualified Expert, a radiologist, or a physician, any of whom must meet the training requirements in paragraph l. of this section.

4. Two years after [effective date], the registrant shall ensure that prior to performing fluoroscopy procedures, each person operating, or supervising the operation of, fluoroscopy systems has completed the training required in paragraphs l.1. or l.2. of this section, as applicable.

5. The registrant shall either provide a minimum of two (2) hours in-service training every two (2) years for all individuals operating, or supervising the operation of, fluoroscopy systems used or shall require evidence of continuing education meeting the objectives of paragraphs l.1. or l.2. of this section, as applicable.

6. Training records pursuant to the requirements in paragraph l. of this section shall be maintained for inspection by the Department for three (3) years beyond the last date the individual was subject to paragraph l.

m. **Equipment operation**.

1. All fluoroscopic images shall be viewed, directly or indirectly, and interpreted by a licensed practitioner of the healing arts.

2. Overhead fluoroscopy shall not be used as a positioning tool for general purpose radiographic examinations.

3. Operators shall be competent in the standard operating procedures of the unit in use, including the use of available dose-saving features and the relative radiation output rates of the various modes of operation.

4. Procedure planning for fluoroscopic procedures on pregnant patients shall include feasible modifications to minimize the dose to the conceptus.

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5. Procedure planning for fluoroscopic procedures on pediatric patients shall include feasible modifications to minimize dose.

6. The registrant shall use all methods available on the fluoroscopy system to monitor dose during a fluoroscopic procedure.

7. The registrant shall establish a written policy regarding patient dose management in fluoroscopically-guided procedures in conformance with the "ACR-AAPM Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures" (revised 2018), NCRP Report No. 168, or equivalent.

n. **Equipment performance evaluations**.

1. Fluoroscopic equipment performance evaluations shall be performed by a Qualified Expert within thirty (30) calendar days of installation and of any maintenance of the system that may affect the exposure rate. An evaluation by, or under the personal supervision of, a Qualified Expert shall also be performed at intervals not to exceed twelve (12) months from the date of the prior evaluation. At a minimum, these evaluations shall include:

A. A measurement of entrance exposure rates that covers the full range of patient thicknesses, including those that are expected to drive the system to maximum output in all modes clinically used, including fluoroscopy, high-level control, acquisition, digital subtraction and CINE, when available. These measurements shall:

i. For systems without automatic exposure control, be made utilizing a milliamperage and kVp typical of the clinical use of the fluoroscopic system;

ii. For systems with automatic exposure control, be made utilizing sufficient attenuating material in the useful beam to produce a milliamperage and kVp typical of the clinical use of the fluoroscopic system;

B. A measurement and verification of compliance of maximum AKR for fluoroscopy and high-level control, if available. Measurements shall be made in accordance with RH-9305.e.4.;

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C. An evaluation of high contrast resolution and low contrast resolution in both fluoroscopic and spot-film modes;

D. An evaluation of the operation of the 5-minute timer, warning lights, interlocks, and collision sensors;

E. An evaluation of the beam quality and collimation in the fluoroscopy and spot-film modes;

F. An evaluation of the availability and accuracy of technique indicators and integrated radiation dose displays; and

G. An evaluation of any changes that may impact patient and personnel protection devices.

2. Measurements required in paragraph n.1. of this section shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding twenty-four (24) months and after any servicing that may have affected system calibration.

3. Records pursuant to paragraph n. of this section shall be maintained for inspection by the Department for five (5) years. Performance evaluation reports shall contain the signature of the Qualified Expert responsible for the evaluation.

o. **Fluoroscopically-guided interventional Radiation Protocol Committee.**

A registrant performing fluoroscopically-guided interventional (FGI) procedures shall develop and maintain an FGI Radiation Protocol Committee (RPC) in accordance with the following:

1. **RPC members.**

A. Membership of the RPC shall include the following individuals:

i. A physician who meets the requirements in paragraph l. of this section;

ii. A Qualified Expert;

iii. The Radiation Safety Officer; and

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iv. Other individuals as deemed necessary by the registrant (e.g., member of Administration, Radiology Department manager, lead radiologic technologist, etc.).

B. The registrant may establish a system-wide committee if the registrant has more than one site performing FGI procedures.

C. Two or more registrants may form a cooperative RPC as long as each facility has a representative on the committee.

D. If the registrant has established a radiation safety committee, the requirements of this paragraph may be delegated to that committee if the membership meets the requirements of paragraph o.1. of this section.

2. **Responsibilities of the RPC**.

The RPC shall:

A. Establish and implement written protocols, or protocols documented in an electronic report system, that include, but are not limited to, the following:

i. Identification of individuals who are authorized to use fluoroscopic systems for interventional purposes, who have fulfilled the requirements in paragraph 1. of this section;

ii. A method to be used to monitor patient radiation dose during FGI procedures;

iii. Dose notification levels, as appropriate, at which the physician is notified and appropriate actions are taken for patient safety;

iv. Substantial Radiation Dose Level (SRDL) values following nationally recognized standards; and

v. Actions to be taken for cases when an SRDL is exceeded which may include patient follow-up;

B. Maintain a record of each RPC protocol for inspection by the Department. If the RPC revises a protocol,

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documentation shall be maintained that includes the justification for the revision and the previous protocol;

C. Review the established protocols at an interval not to exceed twelve (12) months;

D. Meet as often as necessary to accomplish the responsibilities in paragraph o.2. of this section, with, at a minimum, the members in paragraphs o.1.A.i. through iii. of this section present, but at intervals not to exceed twelve (12) months. Interim meetings may be conducted by electronic means;

E. Provide an annual report to the radiation safety committee, if such a committee has been established pursuant to Department requirements and if the committee is not performing the functions of the RPC as described in paragraph o.1.D. of this section; and

F. Review patient procedures meeting misadministration criteria detailed in RH-9202.a. and patient procedures exceeding protocol-specified SRDL's. For misadministrations, the report prepared by the Qualified Expert in accordance with RH-9202.a.5. shall be discussed. For exceedance of an SRDL, the RPC shall discuss, at a minimum, why the SRDL was exceeded and actions taken. Such procedure reviews shall be documented, including within records required by paragraph o.3. of this section.

3. **Record of RPC meetings**.

A record of each RPC meeting shall be maintained and shall include the date, names and titles of individuals in attendance, minutes of the meeting, and any actions taken.

p. **Records of radiation output information for estimating dose**.

The registrant shall maintain a record of radiation output information so that radiation dose may be estimated in accordance with the facility's established FGI protocols and so as to determine actions necessary pursuant to RH-9202.a. regarding misadministrations.

1. The record shall include the following:

A. Patient identification;

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B. Type and date of examination;

C. Identification of the fluoroscopic system used; and

D. Peak skin dose, cumulative air kerma, or dose area product used if the information is available on the fluoroscopic system.

2. If the peak skin dose, cumulative air kerma, or dose area product are not displayed on the fluoroscopic system, records shall include other information necessary to estimate radiation dose in accordance with this paragraph, or the following, as necessary:

A. Fluoroscopic mode, such as high-level or pulsed mode of operation;

B. Cumulative fluoroscopic exposure time; and

C. Number of films or recorded exposures.

3. The registrant shall maintain records required by this paragraph in accordance with record retention policies of the facility.

RH-9306.- RH-9309. Reserved.

RH-9310. **Radiographic Equipment.**

The following rules apply to all non-dental registrants using diagnostic x-ray equipment. Requirements specific to using dental intra-oral, hand-held, panoramic, and cephalometric equipment are in RH-9320.

a. Digital radiographic systems shall be evaluated by a Qualified Expert within thirty (30) calendar days of clinical use and by or under the direct supervision of a Qualified Expert at intervals not to exceed twelve (12) months unless otherwise determined by the Department. The evaluation shall follow nationally recognized procedures or those recognized by the Department. Unless otherwise specified in this Section, dental, podiatric, and veterinary systems are exempt from this requirement.

b. **Control and indication of technique factors**.

1. **Timers**.

Means shall be provided to terminate the exposure at a preset time interval, a preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.

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A. Except during serial radiography, the operator shall be able to terminate the exposure at any time during an exposure of greater than one-half second. Except during panoramic dental radiography, termination of exposure shall cause automatic resetting of the timer to its initial setting or to zero. It shall not be possible to make an exposure when the timer is set to a zero or off position if either position is provided.

B. During serial radiography, the operator shall be able to terminate the x-ray exposure(s) at any time but means may be provided to permit completion of any single exposure of the series in process.

2. **Automatic exposure controls**.

When an automatic exposure control is provided:

A. Indication shall be made on the control panel when this mode of operation is selected;

B. When the x-ray tube potential is equal to or greater than 51 emission equipment rated for pulse operation shall be equal to or less than a time interval equivalent to two (2) pulses and the minimum exposure time for all other equipment shall be equal to or less than one-sixtieth second or a time kilovolts peak (kVp), the minimum exposure time for field interval required to deliver five (5) milliampere-seconds (mAs), whichever is greater;

C. Either the product of peak x-ray tube potential, current, and exposure time shall be limited to not more than 60 kilowatt-seconds (kWs) per exposure or the product of x-ray tube current and exposure time shall be limited to not more than 600 mAs per exposure, except when the x-ray tube potential is less than 51 kVp, in which case the product of x-ray tube current and exposure time shall be limited to not more than 2,000 mAs per exposure; and

D. A visible signal shall indicate when an exposure has been terminated at the limits described in paragraph b.2.C. of this section, and manual resetting shall be required before further automatically timed exposures can be made.

3. **Accuracy**.

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Deviation of technique factors under paragraph b. of this section from indicated values shall not exceed the limits given by the manufacturer.

c. **Reproducibility**.

1. **Coefficient of variation**.

For any specific combination of selected technique factors, the estimated coefficient of variation of the air kerma shall be no greater than 0.05.

2. **Measuring compliance**.

Determination of compliance shall be based on ten (10) consecutive measurements taken within a time period of one (1) hour. Equipment manufactured after September 5, 1978, shall be subject to the additional requirement that all variable controls for technique factors shall be adjusted to alternate settings and reset to the test setting after each measurement. The percent line-voltage regulation shall be within ±1 of the mean value for all measurements. For equipment having automatic exposure controls, compliance shall be determined with a sufficient thickness of attenuating material in the useful beam such that the technique factors can be adjusted to provide individual exposures of a minimum of twelve (12) pulses on field emission equipment rated for pulsed operation or no less than one-tenth second per exposure on all other equipment.

d. **Linearity**.

The following requirements apply for any fixed x-ray tube potential within the range of thirty percent (30%) to one hundred percent (100%) of the maximum rated.

1. **Equipment having independent selection of x-ray tube current (mA).**

The average ratios of air kerma to the indicated milliampere-seconds product (mGy/mAs) obtained at any two (2) consecutive tube current settings shall not differ by more than 0.10 times their sum, where X_1 and X_2 are the average mGy/mAs values obtained at each of two (2) consecutive mAs selector settings or at two (2) settings differing by no more than a factor of 2 where the mAs selector provides continuous selection:

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$$|\bar{X}_1 - \bar{X}_2| \leq 0.10(\bar{X}_1 + \bar{X}_2)$$

2. **Equipment having selection of x-ray tube current-exposure time product (mAs).**

For equipment manufactured after May 3, 1994, the average ratios of air kerma to the indicated milliampere-seconds product (mGy/mAs) obtained at any two (2) consecutive mAs selector settings shall not differ by more than 0.10 times their sum, where X_1 and X_2 are the average mGy/mAs values obtained at each of two (2) consecutive mAs selector settings or at two (2) settings differing by no more than a factor of 2 where the mAs selector provides continuous selection:

$$|\bar{X}_1 - \bar{X}_2| \leq 0.10(\bar{X}_1 + \bar{X}_2)$$

3. **Measuring compliance.**

Determination of compliance will be based on ten (10) exposures, made within one (1) hour, at each of the two (2) settings. These two (2) settings may include any two (2) focal spot sizes except where one (1) is equal to or less than 0.45 millimeters and the other is greater than 0.45 millimeters. For purposes of this requirement, focal spot size is the focal spot size specified by the x-ray tube manufacturer. The percent line-voltage regulation shall be determined for each measurement. All values for percent line-voltage regulation at any one (1) combination of technique factors shall be within ±1 of the mean value for all measurements at these technique factors.

e. **Field limitation and alignment for mobile, portable, and stationary general purpose x-ray systems.**

Except when spot-film devices are in service, mobile, portable, and stationary general purpose radiographic x-ray systems shall meet the following requirements:

1. **Variable x-ray field limitation.**

A means for stepless adjustment of the size of the x-ray field shall be provided. Each dimension of the minimum field size at an SID of 100 centimeters shall be equal to or less than 5 centimeters.

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2. **Visual definition**.

A. Means for visually defining the perimeter of the x-ray field shall be provided. The total misalignment of the edges of the visually defined field with the respective edges of the x-ray field along either the length or width of the visually defined field shall not exceed two percent (2%) of the distance from the source to the center of the visually defined field when the surface upon which it appears is perpendicular to the axis of the x-ray beam.

B. When a light localizer is used to define the x-ray field, it shall provide an average illuminance of not less than 160 lux (15 footcandles) at 100 centimeters or at the maximum SID, whichever is less. The average illuminance shall be based on measurements made in the approximate center of each quadrant of the light field. Radiation therapy simulation systems are exempt from this requirement.

C. The edge of the light field at 100 centimeters or at the maximum SID, whichever is less, shall have a contrast ratio, corrected for ambient lighting, of not less than four (4) in the case of beam-limiting devices designed for use on stationary equipment, and a contrast ratio of not less than three (3) in the case of beam-limiting devices designed for use on mobile and portable equipment. The contrast ratio is defined as I_1/I_2, where I_1 is the illuminance three (3) millimeters from the edge of the light field toward the center of the field; and I_2 is the illuminance three (3) millimeters from the edge of the light field away from the center of the field. Compliance shall be determined with a measuring aperture of one (1) millimeter.

f. **Field indication and alignment on stationary general purpose x-ray equipment**.

Except when spot-film devices are in service, stationary general purpose x-ray systems shall meet the following requirements in addition to those prescribed in paragraph e. of this section:

1. Means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor, to align the center of the x-ray field with respect to the center of the image receptor to within two percent (2%) of the SID, and to indicate the SID to within two percent (2%);

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2. The beam-limiting device shall numerically indicate the field size in the plane of the image receptor to which it is adjusted;

3. Indication of field size dimensions and SIDs shall be specified in centimeters, inches, or both, and shall be such that aperture adjustments result in x-ray field dimensions in the plane of the image receptor which correspond to those indicated by the beam-limiting device to within two percent (2%) of the SID when the beam axis is indicated to be perpendicular to the plane of the image receptor; and

4. Compliance measurements will be made at discrete SIDs and image receptor dimensions in common clinical use (such as SIDs of 100, 150, and 200 centimeters or 36, 40, 48, 72 inches and nominal image receptor dimensions of 13, 18, 24, 30, 35, 40, and 43 centimeters or 5, 7, 8, 9, 10, 11, 12, 14, and 17 inches) or at any other specific dimensions at which the beam-limiting device or its associated diagnostic x-ray system is uniquely designed to operate.

g. **Field limitation on x-ray equipment other than general purpose radiographic systems.**

1. **X-ray systems designed for one image receptor size.**

Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of image receptor to within two percent (2%) of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond the edge of the image receptor.

2. **Other x-ray systems.**

Radiographic systems not specifically covered in paragraphs e., f., F.6g.ii., and systems covered in F.6g.i., which are also designed for use with extraoral image receptors and when used with an extraoral image receptor, shall be provided with means to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than two percent (2%) of the SID, when the axis of the x-ray beam is perpendicular to the plane of the image receptor.

In addition, means shall be provided to align the center of the x-ray field with the center of the image receptor to within two percent

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(2%) of the SID, or means shall be provided to both size and alignment the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor. These requirements may be met with:

A. A system which performs in accordance with paragraphs e. and f.; or when alignment means are also provided, may be met with either;

B. An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Each such device shall have clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

C. A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

h. **Positive beam limitation (PBL).**

The requirements of this paragraph shall apply to radiographic systems which contain PBL.

1. **Field size.**

When a PBL system is provided, it shall prevent x-ray production when:

A. Either the length or width of the x-ray field in the plane of the image receptor differs from the corresponding image receptor dimension by more than three percent (3%) of the SID; or

B. The sum of the length and width differences stated in paragraph h.1.A. of this section without regard to sign exceeds four percent (4%) of the SID.

C. The beam-limiting device is at an SID for which PBL is not designed for sizing.

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2. **Conditions for PBL**.

When provided, the PBL system shall function as described in paragraph h.1. of this section whenever all the following conditions are met:

A. The image receptor is inserted into a permanently mounted cassette holder;

B. The image receptor length and width are less than 50 centimeters;

C. The x-ray beam axis is within ±3 degrees of vertical and the SID is 90 centimeters to 130 centimeters inclusive; or the x-ray beam axis is within ±3 degrees of horizontal and the SID is 90 centimeters to 205 centimeters inclusive;

D. The x-ray beam axis is perpendicular to the plane of the image receptor to within ±3 degrees; and

E. Neither tomographic nor stereoscopic radiography is being performed.

3. **Measuring compliance**.

Compliance with the requirements of paragraph h.1. of this section shall be determined when the equipment indicates that the beam axis is perpendicular to the plane of the image receptor and the provisions of paragraph h.2. of this section are met. Compliance shall be determined no sooner than five (5) seconds after insertion of the image receptor.

4. **Operator initiated undersizing**.

The PBL system shall be capable of operating such that, at the discretion of the operator, the size of the field may be made smaller than the size of the image receptor through stepless adjustment of the field size. Each dimension of the minimum field size at an SID of 100 centimeters shall be equal to or less than five (5) centimeters. Return to PBL function as described in paragraph h.1. of this section shall occur automatically upon any change of image receptor size or SID.

5. **Override of PBL**.

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A capability may be provided for overriding PBL in case of system failure and for servicing the system. This override may be for all SIDs and image receptor sizes. A key shall be required for any override capability that is accessible to the operator. It shall not be possible to remove the key while PBL is overridden. Each such key switch or key shall be clearly and durably labeled as follows: For X-Ray Field Limitation System Failure

The override capability is considered accessible to the operator if it is referenced in the operator's manual or in other material intended for the operator or if its location is such that the operator would consider it part of the operational controls.

6. **Disabling of PBL**.

A facility has the option to permanently functionally disable a PBL system. When this option is chosen, the standards for manual collimation apply.

i. **Source-skin distance**.

The minimum source-skin distance shall not be less than thirty (30) centimeters, except intraoral dental equipment covered under RH-9320.p.2. and veterinary equipment.

j. **Radiation from capacitor energy storage equipment**.

Radiation emitted from the x-ray tube shall not exceed:

1. An air kerma of 0.26 microGy (vice 0.03 mR exposure) in one (1) minute at five (5) centimeters from any accessible surface of the diagnostic source assembly, with the beam-limiting device fully open, the system fully charged, and the exposure switch, timer, or any discharge mechanism not activated. Compliance shall be determined by measurements averaged over an area of 100 square centimeters, with no linear dimensions greater than twenty (20) centimeters; and

2. An air kerma of 0.88 mGy (vice 100 mR exposure) in one (1) hour at 100 centimeters from the x-ray source, with beam-limiting device fully open, when the system is discharged through the x-ray tube either manually or automatically by use of a discharge switch or deactivation of the input power.

Compliance shall be determined by measurements of the maximum air kerma per discharge multiplied by the total number of

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discharges in one (1) hour (duty cycle). The measurements shall be averaged over an area of 100 square centimeters with no linear dimension greater than twenty (20) centimeters.

k. **Radiation exposure control.**

1. **Exposure initiation.**

Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action. In addition, it shall not be possible to initiate an exposure when the timer is set to a zero or off position if either position is provided.

2. **Exposure indication.**

Means shall be provided for visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

3. **Operator protection, except veterinary systems.**

A. **Stationary radiographic systems.**

Stationary radiographic systems shall be required to have the x-ray control, including the exposure switch, permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure.

B. **Mobile and portable systems.**

Mobile and portable x-ray systems which are:

i. Used continuously for greater than one week in the same location, i.e., a room or suite, shall meet the requirements of paragraph k.3.A. of this section;

ii. Used for less than one week at the same location shall be provided with either a protective barrier at least two (2) meters (6.5 feet) high for operator protection during exposures, or means shall be

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provided to allow the operator to be at 1.83 meters (6 feet) from the tube housing assembly during the exposure.

C. **Podiatry systems.**

Podiatry facilities shall meet the protection requirements in paragraph k.3.B.ii. of this section.

4. **Operator and ancillary personnel protection for veterinary systems.**

All stationary, mobile, or portable x-ray systems used for veterinary work shall be provided with either a two (2) meter (6.5 feet) high protective barrier for operator protection during exposures, or shall be provided with means to allow the operator to be at least 1.83 meters (6 feet) from the tube housing assembly during exposures. Otherwise, in cases where animals are held, the operator and ancillary personnel shall be protected by a minimum of 0.25 mm lead equivalent from scatter radiation and 0.5 mm from the useful beam. Refer to RH-9320. for hand-held intraoral dental x-ray units used in veterinary practice.

l. **Tube stands for portable x-ray systems.**

Except during veterinary field operations where it is impractical to do so, a tube stand or other mechanical support shall be used for portable x-ray systems, so that the x-ray tube housing assembly need not be hand-held during an exposure.

m. **Systems designed for mammography.**

1. All systems designed for mammography shall comply with the Mammography Quality Standards Act of 1994, 42 USC 263b, as in effect on January 1, 2025.

2. Quality Assurance for Diagnostic Mammography Pursuant to Act 854 of 2025.

A. An interpreting physician is not required to be on site but shall be immediately available via telecommunication to interpret diagnostic mammography to adhere to the quality standard requirements under subdivision (a)(2) of this section.

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B. A patient shall sign a waiver acknowledging that a diagnostic evaluation performed via telemedicine or remotely may have limitations compared to an in-person diagnostic evaluation.

C. The results of the diagnostic evaluation shall be provided to the patient before the patient leaves the facility after the completion of the diagnostic evaluation.

RH-9311. **Reserved.**

RH-9312. **Bone Densitometry (Dual-Energy X-ray Absorptiometry).**

a. Bone densitometry systems shall be:

1. Certified by the manufacturer pursuant to the Medical Device Act and Part C, "Electronic Product Radiation Control," of Chapter V of the Federal Food, Drug, and Cosmetic Act;

2. Registered in accordance with Section 1 of these Rules; and

3. At a minimum, maintained and operated in accordance with the manufacturer's specifications, including, but not limited to, that of periodic surveys.

b. All operators of bone densitometry systems shall complete training specific to patient positioning and operation of the system. A minimum of eight (8) hours of training must be completed by individuals other than those licensed as a practitioner of the healing arts or as a radiologic technologist pursuant to the Rules Pertaining to Radiologic Technology Licensure, radiography license type. Training shall be specific to the manufacturer of the equipment to be utilized.

c. In the absence of a survey performed by or under the supervision of a Qualified Expert determining the minimum distance the operator may be from the patient and radiation source, the operator, ancillary personnel, and members of the general public shall be positioned at least two (2) meters from the patient and bone densitometry system during the examination. If distance is limited, shielding of not less than 0.25 mm lead equivalent shall be provided.

d. A facility performing bone densitometry shall follow the quality assurance recommendations of the system's manufacturer and of recognized professional societies such as the International Society for Clinical Densitometry or the American College of Radiology.

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e. The registrant shall keep maintenance and quality assurance records described in paragraphs a.3. and d. of this section for five (5) years.

f. Bone densitometry on humans shall be conducted only under:

1. A prescription of a licensed practitioner of the healing arts; or

2. A screening program approved by the Department.

g. Any person proposing to conduct a bone densitometry screening program shall meet the requirements in RH-9200.w.

RH-9313.- RH-9314. Reserved.

RH-9315. **Computed Tomography Equipment**.

a. **Requirements for CT equipment**.

1. **Technical and safety information**.

The technical and safety information relating to the conditions of operation, dose information, and imaging performance provided by the CT manufacturer shall be maintained by the facility.

2. **Termination of exposure**.

A. Means shall be provided to terminate the x-ray exposure automatically by either de-energizing the x-ray source or shuttering the x-ray beam in the event of equipment failure affecting data collection. Such termination shall occur within an interval that limits the total scan time to no more than 110 percent (110%) of its preset value through the use of either a backup timer or devices which monitor equipment function.

B. A visible signal shall indicate when the x-ray exposure has been terminated through the means required by paragraph a.2.A. of this section.

C. The operator shall be able to terminate the x-ray exposure at any time during a scan, or series of scans under CT x-ray system control, of greater than one-half second duration.

3. **Tomographic plane indication and alignment**.

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A. For any single tomogram system, means shall be provided to permit visual determination of the tomographic plane or a reference plane offset from the tomographic plane.

B. For any multiple tomogram system, means shall be provided to permit visual determination of the location of a reference plane. This reference plane can be offset from the location of the tomographic planes.

C. If a mechanism using a light source is used to satisfy the requirements of paragraph a.3.A. or a.3.B. of this section, the light source shall allow visual determination of the location of the tomographic plane or reference plane under ambient light conditions of up to 500 lux.

4. **Beam-on and shutter status indicators and control switches**.

A. The CT x-ray control and gantry shall provide visual indication whenever x-rays are produced and, if applicable, whether the shutter is open or closed.

B. Each emergency button or switch shall be clearly labeled as to its function.

5. **Indication of CT conditions of operation**.

The CT x-ray system shall be designed such that the CT conditions of operation to be used during a scan or a scan sequence shall be indicated prior to the initiation of a scan or a scan sequence. On equipment having all or some of these conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of CT conditions of operation shall be visible from any position from which scan initiation is possible.

6. **Additional requirements applicable to CT x-ray systems containing a gantry manufactured after September 3, 1985.**

A. The total error in the indicated location of the tomographic plane or reference plane shall not exceed 5 millimeters.

B. If the x-ray production period is less than one-half second, the indication of x-ray production shall be actuated for at least one-half second. Indicators at or near the gantry shall be discernible from any point external to the patient opening where insertion of any part of the human body into the primary beam is possible.

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C. The deviation of indicated scan increment versus actual increment shall not exceed plus or minus one (±1) millimeter with any mass from 0 to 100 kilograms resting on the support device. The patient support device shall be incremented from a typical starting position to the maximum incremented distance or thirty (30) centimeters, whichever is less, and then returned to the starting position. Measurement of actual versus indicated scan increment may be taken anywhere along this travel.

D. Premature termination of the x-ray exposure by the operator shall necessitate resetting of the CT conditions of operation prior to the initiation of another scan.

b. **CT facility design requirements**.

1. **Aural communication**.

Provision shall be made for two-way aural communication between the patient and the operator at the control panel.

2. **Viewing systems**.

A. Windows, mirrors, closed-circuit television, or an equivalent shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

B. When the primary viewing system is by electronic means, an alternate viewing system (which may be electronic) shall be available for use in the event of failure of the primary viewing system.

c. **CT surveys, performance evaluations, routine QC, operator training, and operating procedures**.

1. **Radiation protection surveys**.

A. All CT x-ray systems installed after [effective date] shall have a radiation protection survey completed by, or under the direct supervision of, a Qualified Expert within 30 calendar days of installation. Systems installed on or before [effective date] shall have completed such an initial survey,

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though not required within 30 calendar days of installation. In addition, such a survey shall be done after any change in the facility or equipment or in the occupancy of areas adjacent to the CT system that might cause:

1. Radiation levels in restricted areas likely to contribute to personnel exposures in excess of the limits specified in RH-1200.a.; and

2. Radiation levels in unrestricted areas in excess of the limits specified in RH-1208.a. and b.

B. The registrant shall obtain a written report of the survey from the Qualified Expert. The report shall contain the signature of the Qualified Expert responsible for the survey. A copy of the report shall be made available to the Department upon request.

2. **System performance evaluations.**

A. CT x-ray system performance evaluations shall be performed by a Qualified Expert after initial installation and before use on human patients, and within thirty (30) calendar days after any change or replacement of components which, in the opinion of the Qualified Expert, could cause a change in the radiation output or image quality. An evaluation by, or under the personal supervision of, a Qualified Expert shall also be performed at intervals not to exceed twelve (12) months from the date of the prior evaluation.

B. Evaluation standards and tolerances shall be established by the Qualified Expert and maintained by the facility. These standards and tolerances shall meet nationally recognized standards and tolerances for the CT x-ray system.

C. The evaluation shall include but not be limited to:

i. Geometric factors and alignment including:

(a). Alignment light accuracy; and

(b). Table increment accuracy;

ii. Image localization from scanned projection radiograph (localization image);

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iii. Radiation beam width;

iv. Image quality including:

(a). High-contrast (spatial) resolution;

(b). Low-contrast resolution;

(c). Image uniformity;

(d). Noise; and

(e). Artifact evaluation;

v. CT number accuracy;

vi. Image quality for acquisition workstation display devices;

vii. A review of the results of the routine QC required under RH-9315.c.3.;

viii. A safety evaluation of audible and visual signals, posting requirements; and

ix. Dosimetry.

D. The measurement of the radiation output of a CT x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The dosimetry system shall have been calibrated within the preceding twenty-four (24) months and after any servicing that may have affected system calibration.

E. Records pursuant to paragraph c.2. of this section shall be maintained for inspection by the Department for five (5) years. Performance evaluation reports shall contain the signature of the Qualified Expert responsible for the evaluation.

3. **Routine quality control.**

A. A routine quality control program on the CT system shall:

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i. Be developed by a Qualified Expert and include acceptable tolerances for points evaluated.

ii. Incorporate the use of a water equivalent phantom. At a minimum, noise, CT number, and artifacts shall be evaluated.

B. Quality control checks shall:

i. Be completed at time intervals and under system conditions specified by the Qualified Expert. The interval shall not exceed one (1) week.

ii. Be documented and maintained for inspection by the Department for five (5) years.

4. **Operator training**.

The CT x-ray system shall not be operated except by an individual who has been specifically trained on the operational features of the system. This training shall be given by a manufacturer's applications specialist, Qualified Expert, or someone deemed qualified by the Department.

5. **Operating procedures**.

A. The following information shall be readily available to the CT operator:

i. Instructions on performing routine quality control, including the use of the CT phantom(s), a schedule of routine QC appropriate for the system, allowable variations set by the Qualified Expert for the indicated parameters, and the results of at least the most recent routine QC completed on the system; and

ii. Scanning protocols established by the Radiation Protocol Committee, including instructions on reporting deviations.

B. If the Qualified Expert evaluation or routine QC of the CT x-ray system identifies that a system operating parameter has exceeded a tolerance established by the Qualified Expert, use of the CT x-ray system on patients shall be limited to those uses permitted by established written instructions of the Qualified Expert.

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C. Any individual who is in the room during a CT exposure shall stand clear of the gantry bore and shall stand behind a whole-body protective barrier or wear a protective lead apron of not less than 0.25 millimeter lead equivalent.

D. Mobile CT x-ray systems, except for stationary CT x-ray systems installed in a van, trailer, or mobile vehicle and operator behind a protective control booth, shall be provided with protective curtains of not less than 0.25 millimeter lead equivalent that completely surround the gantry bore during exposures, unless the protective curtains interfere with the sterile field of a surgical procedure.

d. **Specific CT systems.**

1. **CT systems used in treatment planning.**

CT systems solely used for treatment planning in radiation oncology shall also meet the requirements in RH-10306.

2. **Positron Emission Tomography CT and Single-Photon Emission Control Tomography CT systems.**

CT systems solely used to calculate attenuation coefficients in nuclear medicine studies shall meet the requirements in RH-9315.a. through e. except as provided below.

A. In lieu of RH-9315.c.2., a Qualified Expert shall complete a performance evaluation on the CT system following nationally recognized guidelines or manufacturer's instructions at intervals recommended by the nationally recognized guidelines or manufacturer's instructions but not to exceed twelve (12) months.

B. In lieu of RH-9315.c.3., a Qualified Expert shall establish and document routine QC check procedures following nationally recognized guidelines or manufacturer's instructions. These checks shall be completed at intervals recommended by the nationally recognized guidelines or manufacturer's instructions but not to exceed one (1) week.

C. Scanning protocols referenced in RH-9315.c.5.A.ii. are not required for CT systems subject to paragraph f.2.

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D. Shielding described in RH-9315.c.5.C. and c.5.D. is not required for CT systems subject to paragraph f.2.

3. **Cone beam computed tomography systems**.

A. CBCT facilities shall meet RH-9300., RH-9310.i. and k., and paragraphs a. and c.1. of this section, as applicable.

B. **Beam alignment**.

The x-ray field in the plane of the image receptor shall not exceed beyond the edge of the image receptor by more than two percent (2%) of the SID, when the axis of the x-ray beam is perpendicular to the plane of the image receptor. In addition, the center of the x-ray field shall be aligned with the center of the image receptor to within two percent (2%) of the SID.

C. **System performance evaluations**.

A performance evaluation shall be performed by, or under the direct supervision of, a Qualified Expert. The evaluation shall follow nationally recognized standards and tolerances or those recognized by the manufacturer. The evaluation shall be performed within thirty (30) calendar days of initial installation, at intervals not to exceed twelve (12) months or an interval recommended by the manufacturer, and within thirty (30) calendar days after any change or replacement of components which, in the opinion of the Qualified Expert, could cause a change in the radiation output or image quality. Performance evaluation reports shall contain the signature of the Qualified Expert responsible for the evaluation. The facility shall maintain documentation of the established standards and tolerances and testing results.

D. **Routine quality control**.

The registrant shall follow the QC recommendations provided by the CBCT manufacturer. In the absence of manufacturer-provided QC recommendations, the registrant shall implement and document QC guidelines established by a Qualified Expert in accordance to nationally recognized guidelines.

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E. The registrant or CT Radiation Protocol Committee, if established, shall implement and document a policy addressing deviations from established protocols.

F. **Training**.

The CBCT x-ray system shall only be operated by an individual who has been specifically trained in its operation.

G. The following information shall be readily available to the CBCT operator:

i. Instructions on performing routine QC, including the use of the CBCT phantom(s);

ii. A schedule of routine QC appropriate for the system;

iii. Allowable variations set by the Qualified Expert, if use of a Qualified Expert was required, for the indicated parameters; and

iv. The results of at least the most recent routine QC completed on the system.

H. **Fluoroscopy systems capable of CBCT**.

The registrant using fluoroscopy systems capable of CBCT shall meet paragraph f.3. of this section, except paragraph a. referenced in paragraph f.3.A. of this section.

4. **Micro-CT systems.**

Micro-CT systems equipped with an x-ray tube enclosure designed to exclude personnel from its interior during x-ray generation shall be exempt from RH-9315. and shall comply with the requirements set forth in Part C of Section 13 for closed-beam machines.

5. **Veterinary CT systems.**

CT systems, including CBCT systems, solely used in non-human imaging shall meet the requirements of paragraph c.1. of this section (radiation protection surveys) and are otherwise exempt from this section.

RH-9316.- RH-9319. Reserved.

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RH-9320. **Dental Radiographic Systems**.

In addition to the applicable provisions of Part C of this Section, the requirements of RH-9320. apply to dental facilities using intraoral, panoramic, and cephalometric x-ray equipment. Dental facilities using cone beam computed tomography (CBCT) technology shall follow RH-9315.f.3.

a. **Quality assurance**.

In addition to the general quality assurance provisions in Part C of this Section, the following requirements apply to a dental facility:

1. If using film, maintain a light-tight darkroom, use proper safelighting and safeguards, and evaluate darkroom integrity and daylight loading systems for film fog every six (6) months and after a change that may impact film fog.

2. If using a filmless system, maintain and operate PSP and DDR systems according to manufacturer specifications.

3. The registrant shall provide initial training and annual evaluations of x-ray operators to include but not limited to: positioning of the x-ray tube, image processing, operator location during x-ray exposure, source to skin distance, radiation protection, appropriate radiographic protocol, and applicable regulatory requirements. Records of training and annual evaluations shall be maintained for inspection by the Department.

b. **Warning label**.

1. On systems manufactured on or before June 10, 2006, the control panel containing the main power switch shall bear the warning statement, or the warning statement in paragraph b.2. of this section, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

2. On systems manufactured after June 10, 2006, the control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions, and maintenance schedules are observed."

c. **Radiation exposure control**.

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Means shall be provided to initiate the radiation exposure by a deliberate action on the part of the operator, such as the depression of a switch. Radiation exposure shall not be initiated without such an action.

d. **Exposure control location and operator protection**.
Except for units designed to be hand-held, the exposure control shall allow the operator to be:

1. Behind a protective barrier at least two (2) meters (6.5 feet) tall; or

2. At least two (2) meters (6.5 feet) from the tube housing assembly, outside the path of the useful x-ray beam, while making exposures.

e. **Administrative controls**.

1. Patient and image receptor holding devices shall be used when the techniques permit.

2. Except for units designed to be hand-held, the tube housing and position indicating device (PID) shall not be hand-held during an exposure.

3. Dental fluoroscopy without image intensification shall not be used.

f. **Hand-held intraoral equipment**.

In addition to the requirements in this section, the following applies specifically to hand-held devices:

1. The hand-held x-ray system shall be equipped with a backscatter shield of not less than 0.25 mm lead equivalent and 15.2 cm (6 inches) in diameter that is positioned as close as practicable to the distal end of the position indication device.

2. The facility shall maintain documentation that each operator has completed training as specified by the manufacturer and approved by the Department.

3. The facility shall adopt and follow protocols provided by the manufacturer, and approved by the Department, regarding the safe operation of the device.

4. If the operator has difficulty in holding the device stationary during the exposure, the operator shall use a stand to immobilize the device.

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5. The registrant shall secure the hand-held device from unauthorized removal or use.

g. **Beam-on indicators**.

The x-ray control shall provide visual indication whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

h. **Multiple tubes**.

Where two or more radiographic tubes are controlled by one exposure switch, the tube which has been selected shall be clearly indicated prior to initiation of the exposure. Only the selected tube can be energized. This indication shall be both on the x-ray control panel and at or near the tube housing assembly which has been selected.

i. **Mechanical support of tube head**.

The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the x-ray system.

j. **Battery charge indicator**.

On battery-powered generators, visual means shall be provided on the control panel to indicate whether the battery is in a state of charge adequate for proper operation.

k. **Locks**.

All position locking, holding, and centering devices on x-ray system components and systems shall function as intended.

l. **Technique indicators**.

1. For x-ray equipment capable of displaying technique factors, the technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated.

2. The requirement of paragraph l.1. of this section may be met by permanent markings on equipment having fixed technique factors.

m. **Exposure reproducibility**.

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For any specific combination of selected technique factors, the estimated coefficient of variation of the air kerma shall be no greater than 0.05.

n. **Timers**.

Means shall be provided to terminate the exposure at a preset time interval, a preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor.

o. **Kilovolt peak**.

Deviation of technique factors from indicated values shall not exceed the limits provided by the manufacturer. At a minimum, the kVp on variable kVp units shall be accurate to within ten percent (10%) and within twenty percent (20%) on fixed kVp units.

p. **X-ray beam alignment**.

1. The useful x-ray beam shall be limited to the area of clinical interest.

2. **Intraoral dental units**.

A. X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit the source-to-skin distance (SSD) to not less than 18 centimeters.

B. The x-ray field at the minimum SSD shall be containable in a circle having a diameter of no more than 7 centimeters.

3. **Extraoral, panoramic, and cephalometric units**.

A. X-ray systems designed for use with extraoral image receptors and when used with an extraoral image receptor, shall be provided with means to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than two percent (2%) of the SID, when the axis of the x-ray beam is perpendicular to the plane of the image receptor. In addition, means shall be provided to align the center of the x-ray field with the center of the image receptor to within two percent (2%) of the SID, or means shall be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond

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any edge of the image receptor. These requirements may be met with:

i. An assortment of removable, fixed-aperture, beam-limiting devices sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Each such device shall have clear and permanent markings to indicate the image receptor size and SID for which it is designed; or

ii. A beam-limiting device having multiple fixed apertures sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed. Permanent, clearly legible markings shall indicate the image receptor size and SID for which each aperture is designed and shall indicate which aperture is in position for use.

q. **Beam quality**.

The half value layer (HVL) of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table I to RH-9320. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Table I of this section, linear interpolation or extrapolation may be made. Positive means shall be provided to ensure that at least the minimum filtration needed to achieve beam quality requirements is in the useful beam during each exposure.

In the case of a system which is to be operated with more than one thickness of filtration, this requirement can be met by a filter interlocked with the kilovoltage selector which will prevent x-ray emissions if the minimum required filtration is not in place.

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TABLE I TO RH-9320.

X-Ray Tube Voltage (kilovolt peak)				
Design Operating Range	**Measured Operating Potential**	**Minimum HVL (mm of Aluminum)**		
		Specified Dental Systems[a]	Other X-Ray Systems[b]	Other X-Ray Systems[c]
Below 51	30	1.5	0.3	0.3
	40	1.5	0.4	0.4
	50	1.5	0.5	0.5
51 to 70	51	1.5	1.2	1.3
	60	1.5	1.3	1.5
	70	1.5	1.5	1.8
Above 70	71	2.1	2.1	2.5
	80	2.3	2.3	2.9
	90	2.5	2.5	3.2
	100	2.7	2.7	3.6
	110	3.0	3.0	3.9
	120	3.2	3.2	4.3
	130	3.5	3.5	4.7
	140	3.8	3.8	5.0
	150	4.1	4.1	5.4

[a] Dental x-ray systems designed for use with intraoral image receptors and manufactured after December 1, 1980.

[b] Dental x-ray systems designed for use with intraoral image receptors and manufactured before or on December 1, 1980, and all other x-ray systems subject to this section and manufactured before June 10, 2006.

[c] All x-ray systems, except dental x-ray systems designed for use with intraoral image receptors, subject to this section and manufactured on or after June 10, 2006.

r. Intraoral dental x-ray machines shall not be operated at less than a measured 51 kVp effective two (2) years after [effective date].

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s. **Modification of certified diagnostic x-ray components and systems**.

In addition to the requirements of this Section, the registrant shall not make, nor cause to be made, any modification of components or installations of components certified in accordance with the U.S. Food and Drug Administration (FDA) Title 21 of the Code of Federal Regulations, Part 1020, in any manner that could cause the installations or the components to fail to meet the requirements of the applicable parts of the standards specified in 21 CFR Part 1020, except where a variance has been granted by the Director, Center for Devices and Radiological Health, U.S. FDA. A copy of the variance shall be maintained by the registrant for inspection by the Department until termination of the registration.

t. **Leakage radiation from the diagnostic source assembly**.

The leakage radiation from the diagnostic source assembly measured at a distance of one (1) meter in any direction from the source shall not exceed 0.88 milligray (mGy) air kerma (vice 100 milliroentgen (mR) exposure) in one (1) hour when the x-ray tube is operated at its leakage technique factors. If the maximum rated peak tube potential of the tube housing assembly is greater than the maximum rated peak tube potential for the diagnostic source assembly, positive means shall be provided to limit the maximum x-ray tube potential to that of the diagnostic source assembly. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than twenty (20) centimeters.

u. **Radiation from components other than the diagnostic source assembly**.

The radiation emitted by a component other than the diagnostic source assembly shall not exceed an air kerma of 18 microgray (vice 2 milliroentgens exposure) in one (1) hour at five (5) centimeters from any accessible surface of the component when it is operated in an assembled x-ray system under any conditions for which it was designed. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than twenty (20) centimeters.

v. **Maintaining compliance**.

Diagnostic x-ray systems and their associated components used on humans and certified pursuant to 21 CFR Part 1020, "Performance Standards for Ionizing Radiation Emitting Products," shall be maintained in compliance with applicable requirements of these standards.

RH-9321.- RH-9399. Reserved.

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PART E.
[RESERVED]

RH-9400.- 9499. Reserved.

PART F.
[RESERVED]

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PART G.
ENFORCEMENT

RH-9600. **Violations**.

a. An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any rule or order issued thereunder. Any person who willfully violates any provision of the Act or any rule or order issued thereunder may be guilty of a felony, misdemeanor, or crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law. Arkansas Code Annotated §20-21-204 describes criminal and civil penalties which may be assessed.

b. **Impounding**.

Sources of radiation shall be subject to impounding pursuant to Section 5 of these Rules.

RH-9601.- RH-9999. Reserved.

FOOTNOTES TO SECTION 10

1/ The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper.

2/ Digital image receptors used in place of film with spot-film devices should be considered "spot-film."

3/ "MODIFIED TO COMPLY WITH 21 CFR 1020.32(d)(2)."

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SECTION 11.
THERAPEUTIC RADIATION MACHINES

PART A.
GENERAL

RH-10000. **Purpose and Scope**.

a. This Section establishes requirements, for which the licensee or registrant is responsible, for use of therapeutic radiation machines. -The provisions of this Section are in addition to, and not in substitution for, other applicable provisions of these Rules.

b. Therapeutic radiation machines meeting the definition of a particle accelerator are subject to Section 6, "Licenses and Radiation Safety Requirements for Particle Accelerators." -Electronic brachytherapy devices and other therapeutic radiation machines not meeting the definition of a particle accelerator are subject to Section 1, "Registration of Radiation Machine Facilities and Vendor Services." -RH-10308. devices are licensed or registered as determined by the Department.

c. The use of therapeutic radiation machines shall be by, or under the supervision of, a licensed practitioner of the healing arts who meets the training and experience criteria in RH-10200.c.

RH-10001. **Provisions for Research Involving Human Subjects**.

A licensee or registrant may use therapeutic radiation machines to conduct research involving human subjects, provided the research is conducted, funded, supported, or regulated by a Federal Agency that has implemented the Federal Policy for the Protection of Human Subjects. -Otherwise, a licensee or registrant shall apply for and receive approval of a specific amendment to its Department license or registration before conducting such research. -Both types of licensees~~/~~ or registrants shall, at a minimum, obtain prior informed consent from the human subjects and obtain prior review and approval of the research activities by an Institutional Review Board in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects.

RH-10002. **U.S. Food and Drug Administration, Federal, and State Requirements**.

Nothing in this Section relieves the licensee or registrant from complying with applicable U.S. Food and Drug Administration, other Federal, and State requirements governing therapeutic radiation machines or auxiliary devices.

RH-10003. **Communications**.

Except where otherwise specified, all communications concerning these Rules may be addressed to the Arkansas Department of Health, Radiation Control Section, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

RH-10004. **Interpretations**.

Except as specifically authorized by the Department in writing, no interpretations of the meaning of the rules in this Section by an officer or employee of the Department other than a written interpretation by the Department Director or designee will be recognized as binding upon the Department.

RH-10005. **Specific Exemptions**.

The Department may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the rules in this Section as it determines are authorized by law and will not result in undue hazard to public health and safety or property, and are otherwise in the public interest.

RH-10006.- RH-10099. _–Reserved.

PART B.
DEFINITIONS

RH-10100. **Definitions**.

Absorbed dose (D) - The mean energy imparted by ionizing radiation to matter. Absorbed dose is determined as the quotient of dE by dM, where dE is the mean energy imparted by ionizing radiation to matter of mass dM. The SI unit of absorbed dose is joule per kilogram, and the special name of the unit of absorbed dose is the gray (Gy). The previously used special unit of absorbed dose (rad) is being replaced by the gray.

Absorbed dose rate - Absorbed dose per unit time, for machines with timers, or dose monitor unit per unit time for linear accelerators.

Accessible surface - Surface of equipment or of an equipment part that can be easily or accidentally touched by persons without the use of a tool.

Act - Act 8 of Second Extraordinary Session of 1961, as amended.

Added filtration - Any filtration which is in addition to the inherent filtration.

Air kerma (K) - The kinetic energy released in air by ionizing radiation. Kerma is determined as the quotient of dE by dM, where dE is the sum of the initial kinetic energies of all the charged ionizing particles liberated by uncharged ionizing particles in air of mass dM. The SI unit of air kerma is joule per kilogram and the special name for the unit of kerma is the gray (Gy).

Barrier - See "protective barrier."

Beam axis - The axis of rotation of the beam limiting device.

Beam-limiting device - A field defining collimator, integral to the therapeutic radiation machine, which provides a means to restrict the dimensions of the useful beam.

Beam monitoring system - A system designed and installed in the radiation head to detect and measure the radiation present in the useful beam.

Beam scattering foil - A thin piece of material (usually metallic) placed in the beam to scatter a beam of electrons in order to provide a more uniform electron distribution in the useful beam.

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Bent beam linear accelerator - A linear accelerator geometry in which the accelerated electron beam must change direction by passing through a bending magnet.

Beam quality - A term that describes the penetrating power of the x-ray beam. This is identified numerically by half-value layer and is influenced by kilovolt peak (kVp) and filtration.

Beam quality (accelerator) - A term that describes the type and penetrating power of the ionizing radiation produced for certain machine settings.

Central axis of the beam - An imaginary line passing through the center of the useful beam and the center of the plane figure formed by the edge of the first beam-limiting device.

Changeable filters - Any filter, exclusive of inherent filtration, which can be removed from the useful beam through any electronic, mechanical, or physical process.

Collimator - A device or mechanism by which the x-ray beam is restricted in size.

Contact therapy system - A therapeutic radiation machine with a short target-skin distance (TSD), usually less than 5 centimeters.

Conventional simulator - Any x-ray system designed to reproduce the geometric conditions of the radiation therapy equipment.

Detector - See "radiation detector."

Diaphragm - A device or mechanism by which the x-ray beam is restricted in size.

Direct supervision – A qualified practitioner must exercise general supervision and be present in the facility and immediately available to furnish assistance and direction throughout the performance of the procedure or service. Direct supervision does not mean that the qualified practitioner must be present in the room when the procedure or service is being performed.

Dose monitor unit (DMU) - A unit response from the beam monitoring system from which the absorbed dose can be calculated.

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Dosimetry system - A system of devices used for the detection, measurement, and display of qualitative and quantitative radiation exposures.

Electronic brachytherapy - A method of radiation therapy where an electrically generated source of ionizing radiation is placed in or near the tumor or target tissue to deliver therapeutic radiation ~~dosage~~dose.

~~RH-10100. (Cont'd)~~

Electronic brachytherapy device - The system used to produce and deliver therapeutic radiation including the x-ray tube, the control mechanism, the cooling system, and the power source.

Electronic brachytherapy source - The x-ray tube component used in an electronic brachytherapy device.

External beam radiation therapy - Therapeutic irradiation in which the source of radiation is at a distance from the body.

Field-flattening filter - A filter used to homogenize the absorbed dose rate over the radiation field.

Field size - The dimensions along the major axes of an area in a plane perpendicular to the central axis of the beam at the normal treatment or examination source to image distance and defined by the intersection of the major axes and the 50% isodose line.

Filter - Material placed in the useful beam to change beam quality in therapeutic radiation machines subject to RH-10301.

Gantry - That part of a radiation therapy system supporting and allowing movements of the radiation head about a center of rotation.

General supervision – The procedure or service is performed under the overall direction and control of the qualified practitioner. The qualified practitioner's presence is not required during the performance of the procedure or service.

Gray (Gy) - The SI unit of absorbed dose, kerma, and specific energy imparted equal to 1 joule per kilogram. The previous unit of absorbed dose (rad) is being replaced by the gray (1 Gy=100 rad).

Half-value layer (HVL) - The thickness of a specified substance which, when introduced into the path of a given beam of radiation, reduces the radiation field quantity to one-half its original value.

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Healing arts - Any treatment, operation, diagnosis, prescription, or practice for the ascertainment, cure, relief, palliation, adjustment, or correction of any human disease, ailment, deformity, injury, or unhealthy or abnormal physical or mental condition.

Institutional Review Board (IRB) - Any board, committee, or other group formally designated by an institution to review, approve the initiation of, and conduct periodic review of biomedical research involving human subjects.

Intensity Modulated Radiation Therapy (IMRT) - Radiation therapy that uses non-uniform radiation beam intensities which have been determined by various computer-based optimization techniques.

~~RH 10100. (Cont'd)~~

Interlock - A device preventing the start or continued operation of equipment unless certain predetermined conditions prevail.

Interruption of irradiation - The stopping of irradiation with the possibility of continuing irradiation without resetting of operating conditions at the control panel.

Irradiation - The exposure of a living being or matter to ionizing radiation.

Isocenter - The center of the sphere through which the useful beam axis passes while the gantry moves through its full range of motions.

Kilovolt (kV) [kilo electron volt (keV)] - The energy equal to that acquired by a particle with one electron charge in passing through a potential difference of one thousand volts in a vacuum. ~~(~~Note: current convention is to use kV for photons and keV for electrons.)

Kilovolt peak (kVp) - See "peak tube potential."

Lead equivalence - The thickness of lead affording the same attenuation, under specified conditions, as the material in question.

Leakage radiation - Radiation emanating from the radiation therapy system except for the useful beam.

Light field - The area illuminated by light, simulating the radiation field.

mA - Milliampere.

Megavolt (MV) [mega electron volt (MeV)] -The energy equal to that acquired by a particle with one electron charge in passing through a potential difference of

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one million volts in a vacuum. (Note: current convention is to use MV for photons and MeV for electrons.)

Misadministration - An event that meets the criteria in RH-10201.b.

Mobile Electronic Brachytherapy Service - Transportation of an electronic brachytherapy device to provide electronic brachytherapy at an address that is not the address of record.

Monitor unit (MU) - See "dose monitor unit."

~~RH-10100. (Cont'd)~~

Moving beam radiation therapy - Radiation therapy with any planned displacement of radiation field or patient relative to each other, or with any planned change of absorbed dose distribution. It includes arc, skip, conformal, intensity modulation, and rotational therapy.

Nominal treatment distance -

a. For electron irradiation, the distance from the scattering foil, virtual source, or exit window of the electron beam to the entrance surface of the irradiated object along the central axis of the useful beam.

b. For x-ray irradiation, the virtual source or target to isocenter distance along the central axis of the useful beam. For non-isocentric equipment, this distance shall be that specified by the manufacturer.

Output - The exposure rate (air kerma rate), dose rate, or a quantity related to these rates from a therapeutic radiation machine.

Patient - An individual subjected to machine produced radiation for the purposes of medical therapy. The term "patient" also applies to a human research subject.

Patient intervention - Actions by the patient or human research subject, whether intentional or unintentional, such as prematurely terminating the administration.

Peak tube potential - The maximum value of the potential difference in kilovolts across the x-ray tube during an exposure.

Periodic quality assurance check - A procedure which is performed to ensure that a previous parameter or condition continues to be valid.

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Personal supervision – A qualified practitioner must exercise general supervision and be present in the room or adjacent control area during the performance of the procedure or service.

Phantom - An object behaving in essentially the same manner as tissue, with respect to absorption or scattering of the ionizing radiation in question.

Physician - A doctor of medicine or doctor of osteopathy licensed by the Arkansas State Medical Board to prescribe drugs in the practice of medicine.

Prescribed dose - The total dose and dose per fraction as documented in the written directive. The prescribed dose is an estimation from measured data from a specified therapeutic machine using assumptions that are clinically acceptable for that treatment technique and historically consistent with the clinical calculations previously used for patients treated with the same clinical technique.

~~RH-10100. (Cont'd)~~

Primary dose monitoring system - A system that will monitor the useful beam during irradiation and that will terminate irradiation when a pre-selected number of dose monitor units have been delivered.

Primary protective barrier - See "protective barrier."

Protective barrier - A barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

a. Primary protective barrier - The radiation absorbing material, excluding filters, placed in the useful beam.

b. Secondary protective barrier - The radiation absorbing material that attenuates stray radiation.

Qualified Medical Physicist - An individual qualified in accordance with RH-10200.d.

Radiation detector - A device that in the presence of radiation provides, by either direct or indirect means, a signal or other indication suitable for use in measuring one or more quantities of incident radiation.

Radiation field - See "useful beam."

Radiation head - The structure from which the useful beam emerges.

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Radiation therapy system - An x-ray system that utilizes prescribed doses of ionizing radiation for treatment.

Redundant beam monitoring system - A combination of two independent dose monitoring systems in which each system is designed to terminate irradiation in accordance with a pre-selected number of dose monitor units.

Scattered radiation - Ionizing radiation emitted by interaction of ionizing radiation with matter, the interaction being accompanied by a change in direction of the radiation. Scattered primary radiation means that scattered radiation which has been deviated in direction only by materials irradiated by the useful beam.

Secondary dose monitoring system - A system which will terminate irradiation in the event of failure of the primary dose monitoring system.

Secondary protective barrier - See "protective barrier."

~~RH 10100. (Cont'd)~~

Shutter - A device attached to the tube housing assembly which can totally intercept the useful beam and which has a lead equivalency not less than that of the tube housing assembly.

Sievert (Sv) - The SI unit of dose equivalent. The unit of dose equivalent is the joule per kilogram. The previous unit of dose equivalent (rem) is being replaced by the sievert (1 Sv=100 rem).

Simulator (radiation therapy simulation system) - Any x-ray system intended for localizing the volume to be exposed during radiation therapy and establishing the position and size of the therapeutic irradiation field. (See "conventional simulator" and "virtual simulator.")

Source - The region ~~and/or~~ or material from which the radiation emanates.

Source-skin distance (SSD) - See "target-skin distance."

Stationary beam radiation therapy - Radiation therapy without displacement of one or more mechanical axes relative to the patient during irradiation.

Stray radiation - The sum of leakage and scattered radiation.

Target - That part of an x-ray tube or accelerator onto which a beam of accelerated particles is directed to produce ionizing radiation or other particles.

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Target-skin distance (TSD) - The distance measured along the beam axis from the center of the front surface of the x-ray target ~~and/or~~ or electron virtual source to the surface of the irradiated object or patient.

Tenth-value layer (TVL) - The thickness of a specified substance which, when introduced into the path of a given beam of radiation, reduces the radiation field quantity to one-tenth of its original value.

Termination of irradiation - The stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

Therapeutic radiation machine - X-ray or electron-producing equipment designed and used for external beam radiation therapy. For the purpose of these Rules, devices used to administer electronic brachytherapy shall also be considered therapeutic radiation machines.

Tube - An x-ray tube, unless otherwise specified.

~~RH-10100. (Cont'd)~~

Tube housing assembly - The tube housing with tube installed. It includes high-voltage ~~and/or~~ or filament transformers and other appropriate elements when such are contained within the tube housing.

Useful beam - The radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam limiting device when the exposure controls are in a mode to cause the therapeutic radiation machine to produce radiation.

Virtual simulator - A computed tomography (CT) unit used in conjunction with relevant software which recreates the treatment machine; and that allows import, manipulation, display, and storage of images from CT ~~and/or~~ or other imaging modalities.

Virtual source - A point from which radiation appears to originate.

Wedge filter - A filter which effects continuous change in transmission over all or a part of the useful beam.

Written directive - An order in writing for the administration of radiation to a specific patient or human research subject. Written directives shall meet the requirements in RH-10201.

X-ray tube - Any electron tube which is designed to be used primarily for the production of x-rays.

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RH-10101.- RH-10199. _–Reserved.

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PART C.
ADMINISTRATIVE REQUIREMENTS

RH-10200. **General Administrative Requirements for Facilities Using Therapeutic Radiation Machines**.

a. **Administrative controls**.

The licensee or registrant shall be responsible for directing the operation of the therapeutic radiation machines that have been licensed~~/~~ or registered with the Department.~~-~~ The licensee or registrant or an agent of the licensee~~/~~ or registrant shall ensure that the requirements of Section 11 are met in the operation of the therapeutic radiation machine(s).

b. A therapeutic radiation machine that does not meet the provisions of these Rules shall not be used for irradiation of patients.

c. **Training for therapeutic radiation machine Authorized Users**.

1. The licensee or registrant for any therapeutic radiation machine shall require the Authorized User to be a physician who:

A. Is certified by:

i. The American Board of Radiology in Radiation Oncology or Therapeutic Radiology; or

ii. The American Board of Radiology in Radiology, prior to 1976 (combined diagnostic and therapeutic radiology program); or

iii. The American Osteopathic Board of Radiology in Radiation Oncology; or

iv. The Faculty of Radiologists of the Royal College of Surgeons in Ireland in Radiation Oncology; or

v. The Royal College of Radiologists in Clinical Oncology; or

vi. The Royal College of Physicians and Surgeons of Canada in Radiation Oncology or Therapeutic Radiology; or

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B. Is in the active practice of therapeutic radiology, and has completed 200 hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, five hundred (500) hours of supervised work experience, and a minimum of three (3) years of supervised clinical experience.

i. To satisfy the requirement for instruction, the classroom and laboratory training shall include:

(a). Radiation physics and instrumentation;

(b). Radiation protection;

(c). Mathematics pertaining to the use and measurement of ionization radiation; and

(d). Radiation biology.

ii. To satisfy the requirement for supervised work experience, training shall be under the supervision of an Authorized User and shall include:

(a). Review of the full calibration measurements and periodic quality assurance checks;

(b). Evaluation of prepared treatment plans and calculation of treatment times/patient treatment settings;

(c). Using administrative controls to prevent misadministrations;

(d). Implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console; and

(e). Checking and using radiation survey meters.

~~RH-10200.c.1.B. (Cont'd)~~

iii. To satisfy the requirement for a period of supervised clinical experience, training shall include

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one (1) year in a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education (ACGME) or the Council on Postdoctoral Training (COPT) of the American Osteopathic Association and an additional two (2) years of clinical experience in therapeutic radiology under the supervision of an Authorized User. ~~-~~The supervised clinical experience shall include:

(a). Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations ~~/~~ or contraindications;

(b). Selecting proper dose and how it is to be administered;

(c). Calculating the therapeutic radiation machine doses and collaborating with the Authorized User in the review of patients' progress and consideration of the need to modify originally prescribed doses ~~and/or~~ or treatment plans as warranted by patients' reaction to radiation; and

(d). Post-administration follow-up and review of case histories.

2. Notwithstanding the requirements of RH-10200.c.1., the registrant for any therapeutic radiation machine subject to RH-10301. or RH-10307. may also submit the training and experience of the prospective Authorized User physician for Department review on a case-by-case basis, provided the training and experience is substantially equivalent to that described in RH-10200.c.1. and includes significant emphasis on dosimetry calculation.

3. A physician shall not act as an Authorized User for any therapeutic radiation machine until such time as said physician's training has been reviewed and approved by the Department.

~~RH-10200. (Cont'd)~~

d. **Training for Qualified Medical Physicists**.

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1. The licensee or registrant for any therapeutic radiation machine shall require the Qualified Medical Physicist to be an individual who:

   A. Is certified by:

      i. The American Board of Radiology in:

         (a). Therapeutic Medical Physics; or

         (b). Therapeutic Radiologic Physics; or

         (c). Roentgen-Ray & Gamma-Ray Physics; or

         (d). X-ray and Radium Physics; or

         (e). Radiologic Physics; or

      ii. The American Board of Medical Physics in Radiation Oncology Physics; or

      iii. The Canadian College of Physicists in Medicine in Radiation Oncology Physics; or

   B. Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed one (1) year of full time training in medical physics; and an additional year of full time work experience under the supervision of an individual who meets the requirements for a Qualified Medical Physicist.

      This training and work experience shall be conducted in clinical radiation facilities that provide high-energy external beam radiation therapy (photons and electrons with energies greater than or equal to one MV/one MeV). During the year of work experience, the tasks listed in RH-10300.a., RH-10301.p./RH-10302.t., and RH-10301.q./RH-10302.u. shall have been performed under the supervision of an individual who meets the requirements for a Qualified Medical Physicist.

~~RH-10200.d. (Cont'd)~~

2. An individual identified as a qualified expert on an Arkansas medical particle accelerator license on or before November 30,

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2014 shall be considered as meeting the requirements for a Qualified Medical Physicist for the purposes of these Rules.

3. An individual shall not act as a Qualified Medical Physicist for any therapeutic radiation machine until such time as said individual's training has been reviewed and approved by the Department.

e. **Qualifications of operators**.

1. Individuals who operate therapeutic radiation machines for human use shall meet the appropriate Radiologic Technology Licensure requirements issued in accordance with the Rules Pertaining to Radiologic Technology Licensure promulgated under the authority of Act 1071 of 1999, as amended – codified at Arkansas Code Annotated §§ 17-106-101 –17-106-111 and 17-106-201 – 17-106-204. A copy of the license ~~The original licensure~~ document ~~or a notarized copy of the document~~ shall be maintained at the location(s) where the individual is working.

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2. Operator qualifications of all personnel currently operating a therapeutic radiation machine shall be kept on file at the facility. Information on former operators shall be retained for a period of at least five (5) years beyond the last date they were authorized to operate a therapeutic radiation machine at that facility.

f. Written operating and safety procedures shall be developed by a Qualified Medical Physicist and shall include any restrictions required for the safe operation of the particular therapeutic radiation machine. These procedures shall be available in the control area of the therapeutic radiation machine. The operator shall be able to demonstrate familiarity with these procedures. Written operating and safety procedures for a therapeutic radiation machine subject to RH-10301. shall be in accordance with RH-10301.r. Procedures for a therapeutic radiation machine subject to RH-10302. shall be in accordance with RH-10302.s. Procedures for an electronic brachytherapy device shall be in accordance with RH-10307.h.

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g. Individuals shall not be exposed to the useful beam except for medical therapy purposes and unless such exposure has been ordered in writing by a therapeutic radiation machine Authorized User. This provision specifically prohibits deliberate exposure of an individual for training, demonstration, or other non-healing-arts purposes.

~~RH-10200. (Cont'd)~~

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h. **Visiting Authorized User**.

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Notwithstanding the provisions of RH-10200.g., a licensee or registrant may permit any physician to act as a Visiting Authorized User under the terms of the licensee's or registrant's license~~/~~ or registration for up to sixty (60) days per calendar year under the following conditions:

1. The Visiting Authorized User has the prior written permission of the licensee's~~/~~ or registrant's management and, where applicable, the facility's Radiation Safety Committee; and

2. The Visiting Authorized User meets the training requirements established for Authorized Users in RH-10200.c.1.; and

3. The licensee or registrant maintains copies of all records generated pursuant to RH-10200.h.1. and h.2. for five (5) years from the date of the last visit.

i. All individuals associated with the operation of a therapeutic radiation machine shall be instructed in and shall comply with the provisions of the licensee's or registrant's quality management program.~~-~~ In addition to the requirements of Section 11, these individuals are also subject to the requirements of RH-1200., RH-1302., and RH-1500.d.

j. **Information and maintenance record and associated information**.

The licensee or registrant shall maintain the following information in a separate file for each therapeutic radiation machine, for inspection by the Department:

1. Report of acceptance testing;

2. Records of all surveys, calibrations, and periodic quality assurance checks required by this Section for the therapeutic radiation machine, including the names of persons who performed the activities;

3. Records of maintenance ~~and~~/ or modifications performed on the therapeutic radiation machine, including the names of persons who performed the services; and

4. Signature of person authorizing the return of the therapeutic radiation machine to clinical use after service, repair, or upgrade.

~~RH-10200. (Cont'd)~~

k. **Report and notification of a dose to an embryo/fetus**.

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1. A licensee or registrant shall report any dose to an embryo/fetus that is greater than five (5) millisievert (500 mrem) dose equivalent that is a result of an administration of radiation to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the referring physician.

2. The licensee or registrant shall notify the Department by telephone no later than the next calendar day after discovery of a dose to the embryo/fetus that requires a report pursuant to RH-10200.k.1.

3. The licensee or registrant shall submit a written report to the Department within fifteen (15) calendar days after discovery of a dose to the embryo/fetus that requires a report pursuant to RH-10200.k.1.

   A. The written report shall include:

      i. The licensee's or registrant's name and license~~/~~ or registration number;

      ii. The name of the referring physician and of the prescribing physician;

      iii. A brief description of the event;

      iv. Why the event occurred;

      v. The effect, if any, on the embryo/fetus;

      vi. What actions, if any, have been taken or are planned to prevent recurrence; and

      vii. Certification that the licensee or registrant notified the pregnant individual (or the pregnant individual's responsible relative or guardian), and if not, why not.

   B. The report must not contain the individual's name or any other information that could lead to identification of the individual.

~~RH-10200.k. (Cont'd)~~

4. ~~4.~~ The licensee or registrant shall provide notification of the event to the referring physician and also to the pregnant individual,

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no later than 24 hours after discovery of an event that would require reporting under RH-10200.k.1., unless the referring physician personally informs the licensee or registrant either that he or she will inform the pregnant individual or that, based on medical judgment, telling the pregnant individual would be harmful. The licensee or registrant is not required to notify the pregnant individual without first consulting with the referring physician. If the referring physician or pregnant individual cannot be reached within 24 hours, the licensee or registrant shall make the appropriate notifications as soon as possible thereafter.

The licensee or registrant may not delay any appropriate medical care for the embryo/fetus, including any necessary remedial care as a result of the event, because of any delay in notification. To meet the requirements of this subparagraph, the notification may be made to the pregnant individual's responsible relative or guardian instead of to the pregnant individual. If a verbal notification is made, the licensee or registrant shall inform the pregnant individual, or the pregnant individual's responsible relative or guardian, that a written description of the event can be obtained from the licensee/ or registrant upon request. The licensee or registrant shall provide such a written description if requested.

5. A licensee or registrant shall retain a record of a dose to an embryo/fetus for five (5) years. The record must contain the information required by RH-10200.k.3.A. plus the name of the pregnant individual who is the subject of the event and her social security number or other identification number, if one has been assigned. A copy of this record shall be provided to the referring physician, if other than the licensee or registrant, within fifteen (15) calendar days after the discovery of the event.

l. **Training**.

The licensee or registrant shall provide instruction initially, at least annually, and upon significant procedural changes to all individuals who operate a therapeutic radiation machine, as appropriate to the individual's assigned duties. Instruction shall be provided in the operating and safety procedures described in RH-10200.f. and in the therapeutic radiation machine's emergency procedures. If the interval between patients exceeds one (1) year, retraining of the individuals shall be provided. Training is further detailed in RH-5401. for operators of particle accelerators and in RH-10307.m. for operators of electronic brachytherapy devices.

lm. Licensees or registrants with equipment that has been issued variances by the United States Food and Drug Administration (FDA) to Title 21, CFR

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Part 1020 shall maintain copies of those variances at the pertinent authorized use locations until transfer or disposal of the therapeutic radiation machine or termination of the license or registration.

~~RH-10200. (Cont'd)~~

~~m~~n. **Record retention periods**.

1. Each licensee or registrant shall retain each record that is required by this Section or by ~~license~~ a condition in the license or registration for the period specified by the appropriate rule or ~~license~~ condition in the license or registration.~~-~~ If a retention period is not otherwise specified by rule or ~~license~~ by a condition in the license or registration, the record must be retained until the Department terminates each license or registration that authorizes the activity that is subject to the recordkeeping requirement.

2. If there is a conflict between the Department's rules in this Section, ~~license~~ condition in the license or registration, or other written Department approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the rules in this Section for such records shall apply unless the Department, pursuant to RH-10005., has granted a specific exemption from the record retention requirements specified in the rules in this Section.

~~n~~o. **Record maintenance**.

Each record required by this Section must be legible throughout the specified retention period. ~~-~~The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. ~~-~~The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records, such as letters, drawings, and specifications, must include all pertinent information, such as stamps, initials, and signatures. ~~-~~The licensee or registrant shall maintain adequate safeguards against tampering with and loss of records.

RH-10201. **Quality Management Program**.

Each licensee, registrant, or applicant subject to RH-10301., RH-10302., or RH-10307. shall develop, implement, and maintain a quality management program to provide high confidence that radiation will be administered as directed by the Authorized User.

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a. **Scope and applicability**.

The quality management program shall address, at a minimum, the following specific objectives:

~~RH 10201. (Cont'd)~~

1. **Written directives**.

A. A written directive must be dated and signed by an Authorized User prior to the administration of radiation.

If because of the ~~patient's/human~~ patient's or human research subject's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the ~~patient's/human~~patient's or human research subject's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented as soon as possible in writing in the ~~patient's/human~~ patient's or human research subject's record and a revised written directive is signed by an Authorized User within 48 hours of the oral revision.

B. The written directive must contain the patient or human research subject's name, the type and energy of the beam, the total dose, dose per fraction, treatment site, and number of fractions.

C. A written revision to an existing written directive may be made, provided that the revision is dated and signed by an Authorized User prior to the administration of the therapeutic radiation machine dose, or the next fractional dose.

D. The licensee or registrant shall retain a copy of the written directive for five (5) years.

2. **Procedures for administrations**.

The licensee or registrant shall develop, implement, and maintain written procedures to provide high confidence that:

A. Prior to the administration of each course of radiation treatments, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;

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B. Each administration is in accordance with the written directive;

~~RH 10201.a. (Cont'd)~~

C. Therapeutic radiation machine final plans of treatment and related calculations are in accordance with the respective written directives by:

i. Checking both manual and computer generated dose calculations to verify they are correct and in accordance with the written directive; and

ii. Verifying that any computer-generated calculations are correctly transferred into the consoles of authorized therapeutic medical units;

D. Any unintended deviation from the written directive is identified, evaluated, and appropriate action is taken; and

E. The licensee or registrant retains a copy of the procedures for administrations for the duration of the license or registration.

b. **Reports and notifications of misadministrations**.

1. A licensee or registrant shall report any event resulting from intervention of a patient or human research subject in which the administration of therapeutic radiation machine radiation results, or will result in, unintended permanent functional damage to an organ or a physiological system as determined by a physician.

2. Other than events that result from intervention by a patient or human research subject, a licensee or registrant shall report any event in which the administration of a therapeutic radiation machine therapy dose:

A. Involves the wrong patient, wrong treatment modality, or wrong treatment site; or

B. Consists of three (3) or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than ten percent (10%) of the total prescribed dose; or

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C. The calculated weekly administered dose differs from the weekly prescribed dose by more than thirty percent (30%) of the weekly prescribed dose;- or

~~RH-10201.b.2. (Cont'd)~~

D. The calculated total administered dose differs from the total prescribed dose by more than twenty percent (20%) of the total prescribed dose.

3. The licensee or registrant shall notify the Department by telephone no later than the next calendar day after the discovery of a misadministration.

4. ~~4.~~ The licensee or registrant shall provide notification of the event to the referring physician and also notify the individual who is the subject of the misadministration no later than twenty-four (24) hours after its discovery, unless the referring physician personally informs the licensee or registrant either that he or she will inform the individual or that, based on medical judgment, telling the individual would be harmful. -The licensee or registrant is not required to notify the individual without first consulting the referring physician.- If the referring physician or the affected individual cannot be reached within twenty-four (24) hours, the licensee or registrant shall notify the individual as soon as possible thereafter.

-The licensee or registrant may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification. -To meet the requirements of this subparagraph, the notification of the individual who is the subject of the misadministration may be made instead to that individual's responsible relative or guardian.- If a verbal notification is made, the licensee or registrant shall inform the individual, or appropriate responsible relative or guardian, that a written description of the event can be obtained from the licensee~~/~~ or registrant upon request. The licensee or registrant shall provide such a written description if requested.

5. The licensee or registrant shall submit a written report to the Department within fifteen (15) calendar days after the discovery of a misadministration.- The report shall not contain the individual's name or any other information that could lead to the identification of the individual. -The written report shall include the following:

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RH-10201.b. (Cont'd)

A. The licensee's or registrant's name;

B. The name of the prescribing physician;

C. A brief description of the event;

D. Why the event occurred;

E. The effect, if any, on the individual who received the administration;

F. What actions, if any, that have been taken, or are planned, to prevent recurrence;

G. Certification that the licensee or registrant notified the individual (or the individual's responsible relative or guardian), and if not, why not; and

H. What information was provided to the individual (or the individual's responsible relative or guardian) when notified.

6. The licensee or registrant shall retain a record of a misadministration in accordance with RH-10201.c. A copy of this record shall be:

A. ~~p~~Provided to the referring physician, if other than the licensee or registrant, within fifteen (15) calendar days after discovery of the misadministration.; and

B. Maintained as part of the permanent medical record of the individual who is the subject of the misadministration.

7. Aside from the notification requirement in RH-10201.b.4., nothing in this section affects any rights or duties of licensees or registrants and physicians in relation to each other, to individuals affected by the misadministration, or to that individual's responsible relatives or guardians.

c. **Records of misadministrations**.

A licensee or registrant shall retain a record of misadministrations reported in accordance with RH-10201.b. for five (5) years. The record shall contain the following:

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1. The licensee's or registrant's name;

2. The names of all persons involved (including the individual who is the subject of the misadministration);

3. The social security number or other identification number, if one has been assigned, of the individual who is the subject of the misadministration;

~~RH-10201. (Cont'd)~~

4. A brief description of the event; why it occurred; the effect, if any, on the individual;

5. The actions, if any, that have been taken, or are planned, to prevent recurrence; and

6. Whether the licensee or registrant notified the individual (or the individual's responsible relative or guardian), and if not, why not.

RH-10202.- RH-10299.– _Reserved.

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PART D.
TECHNICAL REQUIREMENTS

RH-10300. **General Technical Requirements for Facilities Using Therapeutic Radiation Machines**.

a. **Radiation ~~P~~protection surveys**.

1. The licensee or registrant shall ensure that radiation protection surveys of all new facilities, and existing facilities not previously surveyed are performed with an operable radiation measurement survey instrument calibrated in accordance with RH-10304. ~~-~~The radiation protection survey shall be performed by, or under the ~~direction~~ direct supervision of, a Qualified Medical Physicist and shall verify, via the use of nationally recognized shielding evaluation survey procedures, that:

   A. Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in RH-1200.a.; and

   B. Radiation levels in unrestricted areas do not exceed the limits specified in RH-1208.a. and RH-1208.b.

2. In addition to the requirements of RH-10300.a.1., a radiation protection survey shall also be performed prior to any subsequent medical use and:

   A. After making any change in the treatment room shielding;

   B. After making any change in the location of the therapeutic radiation machine within the treatment room;

   C. After relocating the therapeutic radiation machine;

   D. Before using the therapeutic radiation machine in a manner that could result in increased radiation levels in areas outside the external beam radiation therapy treatment room;

   E. After making a change in the occupancy of areas adjacent to the treatment room; and

   F. At least annually to check for unknown changes and malfunctioning equipment.

~~RH-10300.a. (Cont'd)~~

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3. Initial radiation protection surveys of therapeutic radiation machine installations subject to RH-10302. shall be performed by, or under the ~~direction~~ direct supervision of, a Qualified Medical Physicist who did not consult in the design of the therapeutic radiation machine installation and is not employed by or within any corporation or partnership with the individual who consulted in the design of the installation.

4. A. The survey record shall indicate all instances where the facility, in the opinion of the Qualified Medical Physicist, is in violation of applicable rules. -Any deficiencies detected during the survey shall be corrected prior to using the therapeutic radiation machine.

B. The survey record shall include, but not be limited to, the following:

i. The date of the measurements;

ii. The reason the survey is required;

iii. A description of the therapeutic radiation machine including the manufacturer's name, model number and serial number, beam type, and beam energy;

iv. A diagram of the facility that details building structures; areas surrounding the treatment room that were surveyed; and the position of the therapeutic radiation machine, control panel, and associated equipment;

v. A description of the instrumentation used to determine radiation measurements, including the date of the most recent calibration and who performed the calibration for each instrument used;

vi. The conditions under which radiation measurements were taken;

vii. Survey data including:

(a). The measured dose rate at several points in each area expressed in millirems (microsieverts) per hour;

~~RH-10300.a.4.B.vii. (Cont'd)~~

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(b). The projected maximum "in-any-one-hour" dose equivalent in each unrestricted area adjacent to the therapeutic radiation machine;

(c). The projected maximum annual total effective dose equivalent (TEDE) in each restricted and unrestricted area adjacent to the therapeutic radiation machine; and

(d). A description of workload, use, and occupancy factors employed in determining the projected annual TEDE; and

viii. The signature of the ~~individual~~ Qualified Medical Physicist responsible for ~~conducting~~ the survey.

5. If the results of the surveys required by RH-10300.a.1. or RH-10300.a.2. indicate any radiation levels in excess of the respective limit specified in RH-10300.a.1., the licensee or registrant shall lock the control in the "OFF" position and not use the unit:

A. Except as may be necessary to repair, replace, or test the therapeutic radiation machine, the therapeutic radiation machine shielding, or the treatment room shielding; or

B. Until the licensee or registrant has received a specific exemption from the Department.

6. Initial radiation protection survey reports shall be maintained for the duration of the license or registration. ~~-~~Other radiation protection survey reports shall be maintained for five (5) years.

b. **Modification of radiation therapy unit or room before beginning a treatment program**.

If the survey required by RH-10300.a. indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by RH-1208.a. and RH-1208.b., before beginning the treatment program the licensee or registrant shall ensure the following:

1. The unit is equipped with beam direction interlocks or additional radiation shielding is added to ensure compliance with RH-1208.a. and RH-1208.b.;

~~RH-10300.b. (Cont'd)~~

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2. The survey required by RH-10300.a. is performed again; and

3. The survey report generated is in accordance with RH-10300.a.4.B. and includes the results of the initial survey, a description of the modification made in order to comply with this paragraph, and the results of the second survey; or

4. A license or registration amendment is requested and received under RH-1208.d.that authorizes radiation levels in unrestricted areas greater than those permitted by RH-1208.a. and RH-1208.b.

c. **Dosimetry equipment**.

1. The licensee or registrant shall have a calibrated dosimetry system available for use. -The system shall have been calibrated by the National Institute for Standards and Technology (NIST) or by an American Association of Physicists in Medicine (AAPM) Accredited Dosimetry Calibration Laboratory (ADCL). -The calibration shall have been performed within the previous twenty-four (24) months; after any servicing that may have affected the system's calibration; and after any constancy checks performed on the system indicated the need.

A. For beams with energies greater than 1 MV (1 MeV), the dosimetry system shall have been calibrated for cobalt-60;

B. For beams with energies equal to or less than 1 MV (1 MeV), the dosimetry system shall have been calibrated at an energy (energy range) appropriate for the radiation being measured;

2. The licensee or registrant shall have available for use a dosimetry system for quality assurance check measurements. -To meet this requirement, the system may be compared with a system that has been calibrated in accordance with RH-10300.c.1. -This comparison shall have been performed within the previous twelve (12) months and after each servicing that may have affected system calibration. -The quality assurance check system may be the same system used to meet the requirement in RH-10300.c.1.;

~~RH-10300.c. (Cont'd)~~

3. The licensee or registrant shall maintain a record of each dosimetry system calibration and comparison for five (5) years. For each calibration or comparison, the record shall include the following:

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the date of the calibration or comparison; the manufacturer's name, model numbers, and serial numbers of the instruments that were calibrated or compared as required by RH-10300.c.1. and RH-10300.c.2.; the correction factors that were determined; the names of the individuals who performed the calibration or comparison; and evidence that the comparison was performed by, or under the ~~direct~~ personal supervision ~~and in the physical presence~~ of, a Qualified Medical Physicist.

d. **Reports of external beam radiation therapy surveys and measurements**.

The licensee or registrant for any therapeutic radiation machine subject to RH-10301. or RH-10302. shall furnish a copy of the records required in RH-10300.a~~.~~. and RH-10300.b. to the Department within thirty (30) calendar days following completion of the action that initiated the record requirement. ~~-~~Annual radiation protection surveys shall not be submitted unless it is discovered that radiation levels in unrestricted ~~and/or~~or restricted areas exceed the dose limits specified in Section 3.

RH-10301. **Therapeutic Radiation Machines of Less Than 500 kV**.[1/]

a. **Leakage radiation**.

When the x-ray tube is operated at its maximum rated tube current for the maximum kV, the leakage air kerma rate shall not exceed the value specified at the distance specified for that classification of therapeutic radiation machine:

1. **5-50 kV systems**.

The leakage air kerma rate measured at any position 5 centimeters from the tube housing assembly shall not exceed 100 mrad (1 mGy) in any one hour.

~~RH-10301.a. (Cont'd)~~

2. **>50 and <500 kV systems**.

The leakage air kerma rate measured at a distance of 1 meter from the target in any direction shall not exceed 1 rad (1 cGy) in any 1 hour. ~~-~~This air kerma rate measurement may be averaged over areas no larger than one hundred square centimeters (100 cm^2).~~-~~ In addition, the air kerma rate at a distance of 5 centimeters from the

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surface of the tube housing assembly shall not exceed 30 rad (30 cGy) per hour.

3. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in RH-10301.a.1. and RH-10301.a.2. for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by the Department.

b. **Permanent beam limiting devices**.

Permanent diaphragms or cones used for limiting the useful beam shall provide at least the same degree of attenuation as required for the tube housing assembly.

c. **Adjustable or removable beam limiting devices**.

1. All adjustable or removable beam limiting devices, diaphragms, cones, or blocks shall not transmit more than five percent (5%) of the useful beam for the most penetrating beam used; and

2. When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light beam.

d. **Filter system**.

The filter system shall be so designed that:

1. Filters cannot be accidentally displaced at any possible tube orientation;

2. For equipment installed after an interlock system prevents irradiation if the proper filter is not in place;

~~RH-10301.d. (Cont'd)~~

3. The air kerma rate escaping from the filter slot shall not exceed 1 rad (1 cGy) per hour at one (1) meter under any operating conditions; and

4. Each filter shall be marked as to its material of construction and its thickness.

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e. **Tube immobilization**.

1. The x-ray tube shall be so mounted that it cannot accidentally turn or slide with respect to the housing aperture; and

2. The tube housing assembly shall be capable of being immobilized for stationary portal treatments.

f. **Source marking**.

The tube housing assembly shall be so marked that it is possible to determine the location of the source to within five (5) millimeters, and such marking shall be readily accessible for use during calibration procedures.

g. **Beam block**.

Contact therapy tube housing assemblies shall have a removable shield of material, equivalent in attenuation to 0.5 millimeters of lead at 100 kV, that can be positioned over the entire useful beam exit port during periods when the beam is not in use.

h. **Timer**.

A suitable irradiation control device shall be provided to terminate the irradiation after a pre-set time interval.

1. A timer with a display shall be provided at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time or time remaining indicator;

2. The timer shall be a cumulative timer that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

~~RH-10301.h. (Cont'd)~~

3. The timer shall terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system present has not previously terminated irradiation;

4. The timer shall permit accurate pre-setting and determination of exposure times as short as 1 second;

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5. The timer shall not permit an exposure if set at zero;

6. The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer error correction to compensate for mechanical lag; and

7. Timer shall be accurate to within one percent (1%) of the selected value or 1 second, whichever is greater.

i. **Control panel**.

In addition to other applicable requirements specified in Section 11, the control panel shall also:

1. Provide an indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;

2. Provide an indication of whether x-rays are being produced;

3. Provide a means for indicating x-ray tube potential and current;

4. Provide the means for terminating an exposure at any time;

5. Provide a positive display of specific filter(s) in the beam;

6. Include an access control (locking) device that will prevent unauthorized use of the therapeutic radiation machine; and

7. Include emergency buttons~~/~~ or switches that shall be clearly labeled as to their functions.

j. **Multiple tubes**.

When a control panel may energize more than one x-ray tube:

1. It shall be possible to activate only one x-ray tube at any time;

~~RH-10301.j. (Cont'd)~~

2. There shall be an indication at the control panel identifying which x-ray tube is activated; and

3. There shall be an indication at the tube housing assembly when that tube is energized.

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k. **Target-skin distance (TSD)**.

There shall be a means of determining the central axis TSD to within one (1) centimeter and of reproducing this measurement to within two (2) millimeters thereafter.

l. **Shutters**.

Unless it is possible to bring the x-ray output to the prescribed exposure parameters within 5 seconds after the x-ray "ON" switch is energized, the beam shall be attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly. In addition, after the unit is at operating parameters, the shutter shall be controlled by the operator from the control panel. An indication of shutter position shall appear at the control panel.

m. **Low filtration x-ray tubes**.

Each therapeutic radiation machine equipped with a beryllium or other low-filtration window shall be clearly labeled as such upon the tube housing assembly and shall be provided with a permanent warning device on the control panel that is activated when no additional filtration is present, to indicate that the dose rate is very high.

n. **Facility design requirements for therapeutic radiation machines capable of operating in the range 50 kV to 500 kV**.

In addition to shielding adequate to meet requirements of RH-10305., the treatment room shall meet the following design requirements:

1. **Aural communication**.

Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel. The therapeutic radiation machine shall not be used for irradiation of patients unless continuous two-way aural communication is possible.

~~RH-10301.n. (Cont'd)~~

2. **Viewing systems**.

Provision shall be made to permit continuous observation of the patient during irradiation, and the viewing system shall be so located that the operator can observe the patient from the control panel. The therapeutic radiation machine shall not be used for

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irradiation of patients unless at least one viewing system is operational.

o. **Additional requirements**.

Treatment rooms that contain a therapeutic radiation machine capable of operating above 150 kV shall meet the following additional requirements:

1. All protective barriers shall be fixed except for entrance doors or beam interceptors;

2. The control panel shall be located outside the treatment room or in a totally enclosed booth, which has a ceiling, inside the room;

3. Interlocks shall be provided such that all entrance doors, including doors to any interior booths, shall be closed before treatment can be initiated or continued. ~~-~~If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel; and

4. When any door referred to in RH-10301.o.3. is opened while the x-ray tube is activated, the air kerma rate at a distance of 1 meter from the source shall be reduced to less than 1 mGy (100 mrad) per hour.

p. **Full calibration measurements**.

1. Full calibration of a therapeutic radiation machine subject to RH-10301. shall be performed by, or under the direct supervision of, a Qualified Medical Physicist~~. who is physically present at the facility during the calibration:~~

A. Before the first medical use following installation or reinstallation of the therapeutic radiation machine;

B. At intervals not exceeding one (1) year; and

~~RH-10301.p.1. (Cont'd)~~

C. Before medical use under the following conditions:

i. Whenever quality assurance check measurements indicate that the radiation output differs by more than five percent (5%) from the value obtained at

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the last full calibration and the difference cannot be reconciled; and

ii. Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam.

D. Notwithstanding the requirements of RH-10301.p.1.C.:

i. Full calibration of therapeutic radiation machines with multi-energy capabilities is required only for those modes ~~and/or~~ or energies that are not within their acceptable range; and

ii. If the repair, replacement, or modification does not affect all energies, full calibration shall be performed on the affected energy that is in most frequent clinical use at the facility. ~~-~~The remaining energies may be validated with quality assurance check procedures against the criteria in RH-10301.p.1.C.i.

2. To satisfy the requirement of RH-10301.p.1., full calibration shall include all measurements recommended for annual calibration by NCRP Report No. 69, "Dosimetry of X-Ray and Gamma-Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV."

3. The registrant shall use a dosimetry system described in RH-10300.c.1. to measure the radiation output of a therapeutic radiation machine subject to RH-10301.

4. A copy of the most recent calibration performed pursuant to RH-10301.p.1. shall be available at a designated area within the therapy facility housing the therapeutic radiation machine.

~~RH-10301.p. (Cont'd)~~

5. The registrant shall maintain a record of each calibration for five (5) years.~~-~~ The record shall include the following:~~-~~ the date of the calibration; the manufacturer's name, model number, and serial number for both the therapeutic radiation machine and the x-ray

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tube; the manufacturer's name, model numbers, and serial numbers of the instruments used to calibrate the therapeutic radiation machine; the results and an assessment of the full calibration; and the signature of the Qualified Medical Physicist responsible for the calibration.

q. **Periodic quality assurance checks**.

1. Periodic quality assurance checks shall be performed on those therapeutic radiation machines subject to RH-10301. that are capable of operation at greater than or equal to 50 kV.

2. The registrant shall perform periodic quality assurance checks required by RH-10301.q.1. in accordance with written procedures established by the Qualified Medical Physicist. The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed and that the quality assurance check shall be performed during the calibration specified in RH-10301.p.1. The acceptable tolerance for each parameter measured in the quality assurance check, when compared to the value for that parameter determined in the calibration specified in RH-10301.p.1., shall be stated.

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3. The cause for a parameter exceeding a tolerance set by the Qualified Medical Physicist shall be investigated and corrected before the system is used for patient irradiation.

4. Whenever a quality assurance check indicates a significant change in the operating characteristics of a system, as specified in the Qualified Medical Physicist's quality assurance check procedures, the system shall be recalibrated as required in RH-10301.p.1.

5. The registrant shall use a dosimetry system described in RH-10300.c.2. to perform periodic quality assurance checks involving measurement of radiation output.

6. The registrant shall have the Qualified Medical Physicist review and sign the results of each quality assurance check within thirty (30) calendar days of the date that the check was performed.

~~RH-10301.q. (Cont'd)~~

7. The registrant shall ensure that safety quality assurance checks of therapeutic radiation machines subject to RH-10301. are performed at intervals not to exceed thirty (30) calendar days.

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8. Notwithstanding the requirements of RH-10301.q.6. and RH-10301.q.7., the registrant shall ensure that no therapeutic radiation machine is used to administer radiation to a human unless the quality assurance checks required by RH-10301.q.6. and RH-10301.q.7. have been performed within the thirty (30) calendar day period immediately prior to said administration.

9. To satisfy the requirement of RH-10301.q.7., safety quality assurance checks shall, at a minimum, ensure proper operation of:

   A. Electrical interlocks at each external beam radiation therapy room entrance, if applicable;

   B. The "BEAM-ON" and termination switches;

   C. Beam condition indicator lights on the access door(s) and in the radiation therapy room, if applicable, and on the control console;

   D. Viewing and intercom systems, if applicable;

   E. Radiation area monitors, if applicable; and

   F. Electrically operated treatment room doors from inside and outside the treatment room, if applicable.

10. A copy of the most recent quality assurance checks performed pursuant to RH-10301.q. shall be available at a designated area within the therapy facility housing the therapeutic radiation machine.

11. If the results of the safety quality assurance checks required in RH-10301.q.9. indicate the malfunction of any system, a registrant shall secure the control console in the OFF position and not use the therapeutic radiation machine except as may be necessary to repair, replace, or check the malfunctioning system.

~~RH-10301.q. (Cont'd)~~

12. The registrant shall maintain a record of each quality assurance check required by RH-10301.q. for five (5) years. The record shall include the results of the check plus the following: the date of the quality assurance check; the manufacturer's name, model number, and serial number of the therapeutic radiation machine; the manufacturer's name, model numbers, and serial numbers for the instruments used to measure the radiation output of the therapeutic

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radiation machine; the name of the individual who performed the periodic quality assurance check; and the signature of the Qualified Medical Physicist who reviewed the quality assurance check.

r. **Operating procedures**.

1. A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console.

2. Operating procedures shall include, but are not limited to, the following:

A. Therapeutic radiation machines shall not be used for irradiation of patients unless all applicable requirements of Section 11 have been met;

B. Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use;

C. When a patient must be held in position for radiation therapy, mechanical supporting or restraining devices shall be used;

D. The tube housing assembly shall not be held by an individual during operation unless the assembly is designed to require such holding and the peak tube potential of the system does not exceed 50 kV. In such cases, the holder shall wear protective gloves and apron of not less than 0.5 millimeters lead equivalency at 100 kV; and

E. No individual other than the patient shall be in the treatment room during exposures from therapeutic radiation machines operating above 150 kV. At energies less than or equal to 150 kV, any individual in the treatment room, other than the patient, shall be protected by a barrier sufficient to meet the dose limit requirements specified in Section 3.

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~~RH-10301. (Cont'd)~~

s. **Possession of survey instrument(s)**.

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Each facility location authorized to use a therapeutic radiation machine in accordance with RH-10301. shall possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 mrem (10 µSv) per hour to 1000 mrem (10

mSv) per hour. The survey instrument(s) shall be operable in accordance with RH-10303. and shall be calibrated in accordance with RH-10304.

RH-10302. **Therapeutic Radiation Machines - Photon Therapy Systems (500 kV and Above) and Electron Therapy Systems (500 keV and Above)**.

a. **Possession of survey instrument(s)**.

Each facility location authorized to use a therapeutic radiation machine in accordance with RH-10302. shall possess appropriately calibrated portable monitoring equipment. As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range of 1 mrem (10 µSv) per hour to 1000 mrem (10 mSv) per hour. The survey instrument(s) shall be operable in accordance with RH-10303. and shall be calibrated in accordance with RH-10304.

b. **Leakage radiation outside the maximum useful beam in photon and electron modes**.

1. The absorbed dose due to leakage radiation (excluding neutrons) at any point outside the maximum sized useful beam, but within a circular plane of radius two (2) meters which is perpendicular to and centered on the central axis of the useful beam at the nominal treatment distance (i.e., patient plane), shall not exceed a maximum of 0.2 percent and an average of 0.1 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding one hundred square centimeters (100 cm^2) at a minimum of sixteen (16) points uniformly distributed in the plane.

~~RH-10302.b. (Cont'd)~~

2. Except for the area defined in RH-10302.b.1., the absorbed dose due to leakage radiation (excluding neutrons) at 1 meter from the electron path between the electron source and the target or electron window shall not exceed 0.5 percent of the absorbed dose on the central axis of the beam at the nominal treatment distance. Measurements shall be averaged over an area not exceeding one hundred square centimeters (100 cm^2).

3. For equipment manufactured after November 30, 2014, the neutron absorbed dose outside the useful beam shall be in compliance with the most current revision of International Electrotechnical Commission (IEC) Document 60601-2-1 ~~(most current revision)~~.

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4. For each therapeutic radiation machine, the licensee shall determine, or obtain from the manufacturer, the leakage radiation existing at the positions specified in RH-10302.b.1. through RH-10302.b.3. for the specified operating conditions. Records on leakage radiation measurements shall be maintained at the installation for inspection by the Department.

c. **Leakage radiation through beam limiting devices**.

1. **Photon radiation**.

All adjustable or interchangeable beam limiting devices shall attenuate the useful beam such that at the nominal treatment distance, the maximum absorbed dose anywhere in the area shielded by the beam limiting device(s) shall not exceed two percent (2%) of the maximum absorbed dose on the central axis of the useful beam measured in a 100 cm^2 radiation field, or maximum available field size if less than 100 cm^2;

2. **Electron radiation**.

All adjustable or interchangeable electron applicators shall attenuate the radiation, including but not limited to photon radiation generated by electrons incident on the beam limiting device and electron applicator and other parts of the radiation head, such that the absorbed dose in a plane perpendicular to the central axis of the useful beam at the nominal treatment distance shall not exceed:

~~RH-10302.c. (Cont'd)~~

A. A maximum of two percent (2%) and average of 0.5 percent of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line seven (7) centimeters outside the periphery of the useful beam; and

B. A maximum of ten percent (10%) of the absorbed dose on the central axis of the useful beam at the nominal treatment distance. This limit shall apply beyond a line two (2) centimeters outside the periphery of the useful beam.

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3. **Measurement of leakage radiation**.

A. **Photon radiation**.

Measurements of leakage radiation through the beam limiting devices shall be made with the beam limiting devices closed and any residual aperture blocked by at least two (2) tenth value layers of suitable absorbing material. In the case of overlapping beam limiting devices, the leakage radiation through each set shall be measured independently at the depth of maximum dose. Measurements shall be made using a radiation detector of area not exceeding ten square centimeters (10 cm^2);

B. **Electron radiation**.

Measurements of leakage radiation through the electron applicators shall be made with the electron beam directed into the air and using a radiation detector of area up to but not exceeding one (1) square centimeter suitably protected against radiation which has been scattered from material beyond the radiation detector. Measurements shall be made using one (1) centimeter of water equivalent build up material.

~~RH-10302.c.3. (Cont'd)~~

d. **Filters~~/~~ or wedges**.

1. Each wedge filter that is removable from the system shall be clearly marked with an identification number. For removable wedge filters, the nominal wedge angle shall appear on the wedge or wedge tray (if permanently mounted to the tray). If the wedge or wedge tray is significantly damaged, the wedge transmission factor shall be redetermined.

2. If the absorbed dose rate information required by RH-10302.i. relates exclusively to operation with a field flattening filter or beam scattering foil in place, such foil or filter shall be removable only by the use of tools.

3. For equipment which utilizes wedge filters, interchangeable field flattening filters, or interchangeable beam scattering foils:

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A. Irradiation shall not be possible until a selection of a filter or a positive selection to use "no filter" has been made at the treatment control panel, either manually or automatically;

B. An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position;

C. A display shall be provided at the treatment control panel showing the wedge filter(s), interchangeable field flattening filter(s), ~~and/or~~ or interchangeable beam scattering foil(s) in use; and

D. An interlock shall be provided to prevent irradiation if any filter ~~and/or~~ or beam scattering foil selection operation carried out in the treatment room does not agree with the filter ~~and/or~~ or beam scattering foil selection operation carried out at the treatment control panel.

~~RH-10302. (Cont'd)~~

e. **Stray radiation in the useful beam**.

For equipment manufactured after November 30, 2014, the licensee shall determine during acceptance testing, or obtain from the manufacturer, data sufficient to ensure that x-ray stray radiation in the useful electron beam, absorbed dose at the surface during x-ray irradiation, and stray neutron radiation in the useful x-ray beam are in compliance with the most current revision of International Electrotechnical Commission (IEC) Document 60601-2-1.

f. **Beam monitors**.

All therapeutic radiation machines subject to RH-10302. shall be provided with redundant beam monitoring systems. The sensors for these systems shall be fixed in the useful beam during treatment to indicate the dose monitor unit rate.

1. A therapeutic radiation machine subject to RH-10302. shall be provided with at least two (2) independently powered integrating dose meters. Alternatively, common elements may be used if the production of radiation is terminated upon failure of any common element.

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2. The detector and the system into which that detector is incorporated shall meet the following requirements:

A. Each detector shall be removable only with tools and, if movable, shall be interlocked to prevent incorrect positioning;

B. Each detector shall form part of a beam monitoring system from whose readings in dose monitor units the absorbed dose at a reference point can be calculated;

C. Each beam monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation;

D. The design of the beam monitoring systems shall ensure that the:

i. Malfunctioning of one system shall not affect the correct functioning of the other system(s); and

~~RH-10302.f.2. (Cont'd)~~

ii. Failure of either system shall terminate irradiation or prevent the initiation of radiation; and

E. Each beam monitoring system shall have a legible display at the treatment control panel. ~~-~~Each display shall:

i. Maintain a reading until intentionally reset;

ii. Have only one scale and no electrical or mechanical scale multiplying factors;

iii. Utilize a design such that increasing dose is displayed by increasing numbers; and

iv. In the event of power failure, the beam monitoring information required in RH-10302.f.2.E.iii. displayed at the control panel at the time of failure shall be retrievable in at least one system for a twenty (20) minute period of time.

g. **Beam symmetry**.

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1. A bent-beam linear accelerator with beam flattening filter(s) subject to RH-10302. shall be provided with auxiliary device(s) to monitor beam symmetry;

2. The device(s) referenced in RH-10302.g.1. shall be able to detect field asymmetry greater than ten percent (10%); and

3. The device(s) referenced in RH-10302.g.1. shall be configured to terminate irradiation if the specifications in RH-10302.g.2. cannot be maintained.

h. **Selection and display of dose monitor units**.

1. Irradiation shall not be possible until a new selection of a number of dose monitor units has been made at the treatment control panel;

2. The pre-selected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation;

~~RH-10302.h. (Cont'd)~~

3. After termination of irradiation, it shall be necessary to reset the dosimeter display before subsequent treatment can be initiated; and

4. After termination of irradiation, it shall be necessary for the operator to reset the pre-selected dose monitor units before irradiation can be initiated.

i. **Air kerma rate~~/~~ or absorbed dose rate**.

A system shall be provided from whose readings the air kerma rate or absorbed dose rate at a reference point can be calculated. ~~-~~The radiation detectors specified in RH-10302.f. may form part of this system.~~-~~ In addition:

1. The dose monitor unit rate shall be displayed at the treatment control panel;

2. If the equipment can deliver under any conditions an air kerma rate or absorbed dose rate at the nominal treatment distance more than twice the maximum value specified by the manufacturer, a device shall be provided which terminates irradiation when the air kerma rate or absorbed dose rate exceeds a value twice the specified maximum. ~~-~~The dose rate at which the irradiation will be terminated shall be a record maintained by the licensee;

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3. If the equipment can deliver under any fault condition(s) an air kerma rate or absorbed dose rate at the nominal treatment distance more than ten (10) times the maximum value specified by the manufacturer, a device shall be provided to prevent the air kerma rate or absorbed dose rate anywhere in the radiation field from exceeding twice the specified maximum value and to terminate irradiation if the excess absorbed dose at the nominal treatment distance exceeds 4 Gy (400 rad); and

4. For each therapeutic radiation machine, the registrant shall determine, or obtain from the manufacturer, the maximum value(s) specified in RH-10302.i.2. and RH-10302.i.3. for the specified operating conditions.- Records of these maximum value(s) shall be maintained at the installation for inspection by the Department.

j. **Termination of irradiation by the beam monitoring system or systems during stationary beam radiation therapy**.

~~RH-10302. (Cont'd)~~

1. Each primary system shall terminate irradiation when the pre-selected number of dose monitor units has been detected by the system.

2. If the original design of the equipment included a secondary dose monitoring system, that system shall be capable of terminating irradiation when not more than fifteen percent (15%) or forty (40) dose monitor units above the pre-selected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system; and

3. An indicator on the control panel shall show which monitoring system has terminated irradiation.

k. **Termination of irradiation**.

It shall be possible to terminate irradiation and equipment movement or go from an interruption condition to termination condition at any time from the operator's position at the treatment control panel.

l. **Interruption of irradiation**.

If a therapeutic radiation machine has an interrupt mode, it shall be possible to interrupt irradiation and equipment movements at any time from the treatment control panel.- Following an interruption it shall be

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possible to restart irradiation by operator action without any reselection of operating conditions. If any change is made of a pre-selected value during an interruption, irradiation and equipment movements shall be automatically terminated.

m. **Timer**.

A suitable irradiation control device shall be provided to terminate the irradiation after a pre-set time interval.

1. A timer shall be provided which has a display at the treatment control panel. The timer shall have a pre-set time selector and an elapsed time indicator;

2. The timer shall be a cumulative timer that activates with an indication of **"BEAM-ON"** and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator; and

~~RH-10302.m. (Cont'd)~~

3. The timer shall terminate irradiation when a pre-selected time has elapsed, if the dose monitoring systems have not previously terminated irradiation.

n. **Selection of radiation type**.

Equipment capable of both x-ray therapy and electron therapy shall meet the following additional requirements:

1. Irradiation shall not be possible until a selection of radiation type (x-rays or electrons) has been made at the treatment control panel;

2. The radiation type selected shall be displayed at the treatment control panel before and during irradiation;

3. An interlock system shall be provided to ensure that the equipment can principally emit only the radiation type that has been selected;

4. An interlock system shall be provided to prevent irradiation with x-rays, except to obtain an image, when electron applicators are fitted;

5. An interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted; and

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6. An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

o. **Selection of energy**.

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Equipment capable of generating radiation beams of different energies shall meet the following requirements:

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1. Irradiation shall not be possible until a selection of energy has been made at the treatment control panel;

2. The nominal energy value selected shall be displayed at the treatment control panel until reset manually for the next irradiation. After termination of irradiation, it shall be necessary to reset the nominal energy value selected before subsequent treatment can be initiated;

~~RH-10302.o. (Cont'd)~~

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3. Irradiation shall not be possible until the appropriate flattening filter or scattering foil for the selected energy is in its proper location; and

4. For equipment manufactured after November 30, 2014, the selection of energy shall be in compliance with the most current revision of International Electrotechnical Commission (IEC) Document 60601-2-1.

p. **Selection of stationary beam radiation therapy or moving beam radiation therapy**.

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Therapeutic radiation machines capable of both stationary beam radiation therapy and moving beam radiation therapy shall meet the following requirements:

1. Irradiation shall not be possible until a selection of stationary beam radiation therapy or moving beam radiation therapy has been made at the treatment control panel;

2. The mode of operation shall be displayed at the treatment control panel;

3. An interlock system shall be provided to ensure that the equipment can operate only in the mode that has been selected;

4. An interlock system shall be provided to prevent irradiation if any selected parameter in the treatment room does not agree with the selected parameter at the treatment control panel;

5. Moving beam radiation therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental movement. For all equipment:

   A. An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any ten (10) degrees of rotation or one (1) cm of linear motion differs by more than twenty percent (20%) from the selected value;

   B. Where angle terminates the irradiation in moving beam radiation therapy, the dose monitor units delivered shall differ by less than five percent (5%) from the dose monitor unit value selected;

~~RH-10302.p. (Cont'd)~~

   C. An interlock shall be provided to prevent motion of more than five (5) degrees or one (1) cm beyond the selected limits during moving beam radiation therapy;

   D. An interlock shall be provided to require that a selection of direction be made at the treatment control panel in all units which are capable of both clockwise and counter-clockwise moving beam radiation therapy; and

   E. Moving beam radiation therapy shall be controlled with both primary position sensors and secondary position sensors to obtain the selected relationships between incremental dose monitor units and incremental movement;

6. Where the beam monitor system terminates the irradiation in moving beam radiation therapy, the termination of irradiation shall be as required by RH-10302.j.; and

7. An interlock system shall be provided to terminate irradiation if movement:

   A. Occurs during stationary beam radiation therapy; or

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B. Does not start or stops during moving beam radiation therapy unless such stoppage is a pre-planned function.

q. **Facility design requirements for therapeutic radiation machines operating above 500 kV**.

In addition to shielding adequate to meet requirements of RH-10305., the following design requirements shall apply:

1. **Protective barriers**.

All protective barriers shall be fixed, except for access doors to the treatment room or movable beam interceptors;

2. **Control panel**.

In addition to other applicable requirements specified in Section 11, the control panel shall also:

~~RH-10302. (Cont'd)~~

A. Be located outside the treatment room;

B. Provide an indication of whether electrical power is available at the control panel and if activation of the radiation is possible;

C. Provide an indication of whether radiation is being produced; and

D. Include an access control (locking) device that will prevent unauthorized use of the therapeutic radiation machine;

3. **Viewing systems**.

Windows, mirrors, closed-circuit television, or an equivalent viewing system shall be provided to permit continuous observation of the patient following positioning and during irradiation and shall be so located that the operator may observe the patient from the treatment control panel. The therapeutic radiation machine shall not be used for irradiation of patients unless at least one viewing system is operational;

4. **Aural communications**.

Provision shall be made for continuous two-way aural communication between the patient and the operator at the control

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panel. The therapeutic radiation machine shall not be used for irradiation of patients unless continuous two-way aural communication is possible;

5. **Room entrances**.

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Treatment room entrances shall be provided with warning lights in a readily observable position near the outside of all access doors. These warning lights shall indicate when the useful beam is "ON" and when it is "OFF";

~~RH-10302.q. (Cont'd)~~

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6. **Entrance interlocks**.

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Interlocks shall be provided such that all access controls are activated before treatment can be initiated or continued. If the radiation beam is interrupted by any access control, it shall not be possible to restore the machine to operation without resetting the access control and reinitiating irradiation by manual action at the control panel;

7. **Beam interceptor interlocks**.

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If the shielding material in any protective barrier requires the presence of a beam interceptor to ensure compliance with RH-1208.a. and RH-1208.b., interlocks shall be provided to prevent the production of radiation, unless the beam interceptor is in place, whenever the useful beam is directed at the designated barrier(s);

8. **Emergency cutoff switches**.

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At least 1 emergency power cutoff switch shall be located in the radiation therapy room and shall terminate all equipment electrical power including radiation and mechanical motion. This switch is in addition to the termination switch required by RH-10302.k. All emergency power cutoff switches shall include a manual reset so that the therapeutic radiation machine cannot be restarted from the unit's control console without resetting the emergency cutoff switch;

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9. **Safety interlocks**.

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All safety interlocks shall be designed so that any defect or component failure in the safety interlock system prevents or terminates operation of the therapeutic radiation machine; and

10. **Surveys for residual activity**.

Surveys for residual activity shall be conducted on all therapeutic radiation machines capable of generating energies above 10 MV (10 MeV) prior to machining, removing, or working on therapeutic radiation machine components which may have become activated due to photo-neutron production. Records of surveys pursuant to this subparagraph shall be maintained for five (5) years.

~~RH-10302.q. (Cont'd)~~

r. **Qualified Medical Physicist support**.

1. The services of a Qualified Medical Physicist shall be required in facilities having therapeutic radiation machines with energies of 500 kV and above. The Qualified Medical Physicist shall be responsible for:

   A. Full calibrations required by RH-10302.t.;

   B. Radiation protection surveys required by RH-10300.a.;

   C. Supervision and review of beam and clinical dosimetry;

   D. Beam data acquisition and transfer for computerized dosimetry, and supervision of its use;

   E. Establishment of quality assurance procedures and performance of quality assurance check review required by RH-10302.u.

   F. Consultation with the Authorized User in treatment planning, as needed; and

   G. Performing of calculations~~/~~ or assessments regarding patient treatments that may constitute misadministrations.

2. If the Qualified Medical Physicist is not a full-time employee of the licensee, the operating procedures required by RH-10302.s. shall also specifically address how the Qualified Medical Physicist is to be contacted for problems or emergencies, as well as the

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specific actions, if any, to be taken until the Qualified Medical Physicist can be reached for instruction.

s. **Operating procedures**.

1. A copy of the current operating and emergency procedures shall be maintained at the therapeutic radiation machine control console.

2. Operating procedures shall include, but are not limited to, the following:

~~RH-10302.s. (Cont'd)~~

A. No individual, other than the patient, shall be in the treatment room during treatment. ~~-~~No individual shall be in the treatment room during any irradiation for testing or calibration purposes;

B. Therapeutic radiation machines shall not be used for irradiation of patients unless all applicable requirements of Section 11 have been met;

C. Therapeutic radiation machines, when not in operation, shall be secured to prevent unauthorized use;

D. When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light field; and

E. If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used.

t. **Acceptance testing, commissioning, and full calibration measurements**.

1. Acceptance testing, commissioning, and full calibration of a therapeutic radiation machine subject to RH-10302. shall be performed by, or under the direct supervision of, a Qualified Medical Physicist who is physically present at the facility during the calibration.

2. Acceptance testing and commissioning shall be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators" – AAPM Report No. 47, prepared by Radiation Therapy Task Group No. 45, and the manufacturer's contractual specifications. ~~-~~Acceptance testing and commissioning shall be

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conducted before the first medical use following installation or reinstallation of the therapeutic radiation machine.

~~RH-10302.t. (Cont'd)~~

3. Full calibration shall include measurement of all applicable parameters recommended in "Task Group 142 Report: Quality Assurance of Medical Accelerators" – AAPM Report No. 142, prepared by the Quality Assurance and Outcome Improvement Subcommittee Task Group No. 142. Full calibration shall be performed in accordance with Report No. 142 and with "AAPM Code of Practice for Radiotherapy Accelerators" – AAPM Report No. 47, prepared by Radiation Therapy Task Group No. 45. Although it is not necessary to complete all elements of a full calibration at the same time, all applicable parameters (for all energies) shall be completed at intervals not exceeding twelve (12) months, unless a more frequent interval is referenced in Report No. 142.

4. The Qualified Medical Physicist shall perform or directly supervise, while being physically present at the facility, all elements of a full calibration necessary to determine that all parameters are within acceptable limits:

   A. Whenever quality assurance check measurements indicate that the radiation output differs by more than five percent (5%) from the value obtained at the last full calibration and the difference cannot be reconciled. Therapeutic radiation machines with multi-energy ~~and/or~~ or multi-mode capabilities shall only require measurements for those modes ~~and/or~~ or energies that are not within their acceptable range; and

   B. Following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the radiation beam. If the repair, replacement, or modification does not affect all modes ~~and/or~~ or energies, measurements shall be performed on the effected mode~~/~~ or energy that is in most frequent clinical use at the facility. The remaining energies~~/~~ or modes may be validated with quality assurance check procedures against the criteria in RH-10302.t.4.A.

5. The licensee shall use a dosimetry system described in RH-10300.c.1. to measure the radiation output of a therapeutic radiation machine subject to RH-10302.

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6. A copy of the most recent calibration performed pursuant to RH-10302.t. shall be available at a designated area within the therapy facility housing the therapeutic radiation machine.

7. The licensee shall maintain a record of each calibration for five (5) years. The record shall include the following: the date of the calibration; the manufacturer's name, model number, and serial number for the therapeutic radiation machine and for the instruments used to calibrate the therapeutic radiation machine; the results and an assessment of the full calibration; and the signature of the Qualified Medical Physicist responsible for the calibration.

u. **Periodic quality assurance checks**.

1. Periodic quality assurance checks shall be performed on all therapeutic radiation machines subject to RH-10302. These quality assurance checks shall be performed in accordance with "Task Group 142 Report: Quality Assurance of Medical Accelerators" – AAPM Report No. 142, prepared by the Quality Assurance and Outcome Improvement Subcommittee Task Group No. 142, at intervals not to exceed those specified in Report No. 142. All periodic quality assurance checks with an annual frequency do not have to be performed at the same time but shall be completed within an interval not to exceed twelve (12) months.

2. To satisfy the requirement of RH-10302.u.1., periodic quality assurance checks shall include determination of central axis radiation output and all other applicable quality assurance checks contained in "Task Group 142 Report: Quality Assurance of Medical Accelerators" – AAPM Report No. 142, prepared by the Quality Assurance and Outcome Improvement Subcommittee Task Group No. 142.

3. The licensee shall use a dosimetry system described in RH-10300.c.2. to perform periodic quality assurance checks involving measurement of radiation output.

4. The licensee shall perform periodic quality assurance checks required by RH-10302.u.1. in accordance with written procedures established by the Qualified Medical Physicist. The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed and the acceptable tolerance for each parameter measured in the quality assurance

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check when compared to the value for that parameter determined in the full calibration.

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5. The licensee shall review the results of each periodic quality assurance check according to the following procedures:

   A. The Authorized User and Qualified Medical Physicist shall be immediately notified if any parameter is not within its acceptable tolerance. The therapeutic radiation machine shall not be made available for subsequent medical use until the Qualified Medical Physicist has determined that all parameters are within their acceptable tolerances;

   B. If all quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either the Authorized User or Qualified Medical Physicist within three (3) treatment days; and

   C. The Qualified Medical Physicist shall review and sign the results of each quality assurance check at intervals not to exceed thirty (30) calendar days.

6. Applicable safety quality assurance checks shall be performed on all therapeutic radiation machines subject to RH-10302. at intervals not to exceed those specified in "Task Group 142 Report: Quality Assurance of Medical Accelerators" – AAPM Report No. 142, prepared by the Quality Assurance and Outcome Improvement Subcommittee Task Group No. 142. Safety quality assurance checks performed pursuant to RH-10302.u.7. shall be performed at intervals not to exceed three (3) months, unless a more frequent interval is referenced in Report No. 142.

7. To satisfy the requirement of RH-10302.u.6., safety quality assurance checks shall, at a minimum, ensure proper operation of:

   A. Electrical interlocks at each external beam radiation therapy room entrance;

   B. Proper operation of the "BEAM-ON," interrupt, and termination switches;

   C. Beam condition indicator lights on the access doors, control console, and in the radiation therapy room;

D. Viewing and intercom systems;

~~RH-10302.u.7. (Cont'd)~~

E. Radiation area monitors;

F. Electrically operated treatment room door(s) from inside and outside the treatment room; and

G. At least one emergency power cutoff switch. If more than one emergency power cutoff switch is installed and not all switches are tested at once, each switch shall be tested on a rotating basis. Safety quality assurance checks of the emergency power cutoff switches may be conducted at the end of the treatment day in order to minimize possible stability problems with the therapeutic radiation machine.

8. If the results of the safety quality assurance checks required in RH-10302.u.7. indicate the malfunction of any system, a licensee shall secure the control console in the OFF position and not use the therapeutic radiation machine except as may be necessary to repair, replace, or check the malfunctioning system.

9. A copy of the most recent quality assurance checks performed pursuant to RH-10302.u. shall be available at a designated area within the therapy facility housing the therapeutic radiation machine.

10. The licensee shall maintain a record of each quality assurance check required by RH-10302.u. for five (5) years. The record shall include the results of the check plus the following: the date of the quality assurance check; the manufacturer's name, model number, and serial number of the therapeutic radiation machine; the manufacturer's name, model numbers, and serial numbers for the instruments used to measure the radiation output of the therapeutic radiation machine; the name of the individual who performed the periodic quality assurance check; and the signature of the Qualified Medical Physicist who reviewed the quality assurance check.

v. **Quality assurance for Intensity-Modulated Radiation Therapy**.

Quality assurance for Intensity-Modulated Radiation Therapy (IMRT) shall:

~~RH-10302. (Cont'd)~~

1. Include commissioning and testing (if applicable) of the treatment planning and delivery systems, routine quality assurance of the

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delivery system, and patient-specific validation for each treatment plan utilizing IMRT; and

2. Be performed in accordance with:

A. Department rules;

B. The licensee's procedures;

C. "Guidance Document on Delivery, Treatment Planning, and Clinical Implementation of IMRT: -Report of the IMRT Subcommittee of the AAPM Radiation Therapy Committee" - AAPM Report No. 82, prepared by the IMRT Subcommittee of the Radiation Therapy Committee, or current published recommendations from a recognized national professional association with expertise in IMRT;[2/] and

D. Manufacturer's contractual specifications.

RH-10303. **Operability of Survey Instruments**.

a. Portable monitoring equipment shall be tested for proper operation by way of a reference check performed at the following frequencies:

1. At the time of calibration;

2. Before each use and also after each survey to ensure the equipment was operational during the survey;

3. After each maintenance ~~and/or~~ or battery change; and

4. At least quarterly.

b. If any reference check performed using a pre-defined geometry yields a reading that is not within +/- 20% of the reading measured immediately after calibration, the instrument shall be recalibrated.

c. Records of portable monitoring equipment operability shall be maintained for five (5) years.

RH-10304. **Calibration of Survey Instruments**.

a. The licensee or registrant shall ensure that the survey instruments used to show compliance with this Section have been calibrated before first use, at

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intervals not to exceed twelve (12) months, and following any repair that will affect the calibration.

b. To satisfy the requirements of RH-10304.a., the licensee or registrant shall ensure:

1. Calibration of all scales with readings up to 1000 mrem (10 mSv) per hour with an appropriate radiation source that is traceable to the National Institute of Standards and Technology (NIST);

2. Calibration of at least two (2) points located at approximately 1/3 and 2/3 of full scale on each scale of a linear scale instrument; calibration at midrange for each decade and at two (2) points of at least one decade on each scale of a logarithmic scale instrument; calibration at three (3) points between 2 and 1000 mrem (0.02 and 10 mSv) per hour for digital instruments.

c. To satisfy the requirements of RH-10304.b., the licensee or registrant shall:

1. Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 10 percent (10%); and

2. Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 20 percent (20%) if a correction factor or graph is conspicuously attached to the instrument and is used to interpret readings to within 10 percent (10%).

d. The licensee or registrant shall retain a record of each calibration required in RH-10304.a. for five (5) years. The record shall include:

1. A description of the calibration procedure; and

2. A description of the source used and the certified dose rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, the signature of the individual who performed the calibration, and the date of calibration.

~~RH-10304. (Cont'd)~~

e. The licensee or registrant may obtain the services of individuals licensed by the Department, the U.S. Nuclear Regulatory Commission, or an Agreement State to perform calibrations of survey instruments. Records

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of calibrations that contain information required by RH-10304.d. shall be maintained by the licensee or registrant.

f. The licensee or registrant shall conspicuously note on the instrument the date of calibration.

RH-10305. **Shielding and Safety Design Requirements**.

a. Each therapeutic radiation machine shall be provided with such primary ~~and/or~~ or secondary barriers as are necessary to ensure compliance with RH-1200. and RH-1208.

b. Facility design information for all new installations of a therapeutic radiation machine or installations of a therapeutic radiation machine of higher energy into a room not previously approved for that energy shall be submitted for Department approval prior to actual installation of the therapeutic radiation machine. -The minimum facility design information that must be submitted is contained in Appendix A to Section 11.

RH-10306. **Quality Assurance for Radiation Therapy Simulation Systems**.

Quality assurance for a conventional or virtual simulator shall:

a. Include acceptance testing and periodic verification of system performance; and

b. Be performed in accordance with current published recommendations from a recognized national professional association with expertise in simulation systems.[3/]

RH-10307. **Electronic Brachytherapy**.

a. An electronic brachytherapy device that does not meet the requirements of RH-10307. shall not be used for irradiation of patients; and

b. An electronic brachytherapy device shall only be utilized for human use applications specifically approved by the U.S. Food and Drug Administration (FDA) unless participating in a research study approved by the registrant's Institutional Review Board (IRB).

~~RH-10306. (Cont'd)~~

c. **Possession of survey instrument(s)**.

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Each facility location authorized to use an electronic brachytherapy device in accordance with RH-10307. shall possess appropriately calibrated portable monitoring equipment. ~~-~~As a minimum, such equipment shall include a portable radiation measurement survey instrument capable of measuring dose rates over the range of 1 mrem (10 µSv) per hour to 1000 mrem (10 mSv) per hour. ~~-~~The survey instrument(s) shall be operable in accordance with RH-10303. and shall be calibrated in accordance with RH-10304. for the applicable electronic brachytherapy source energy.

d. **Facility design requirements for electronic brachytherapy devices**.

In addition to shielding adequate to meet requirements of RH-10305., the treatment room shall meet the following design requirements:

1. If applicable, provision shall be made to prevent simultaneous operation of more than one therapeutic radiation machine in a treatment room;

2. Access to the treatment room shall be controlled by a door at each entrance;

3. Each treatment room shall have provisions to permit continuous two-way aural communication between the patient and the operator at the control panel.~~-~~ The electronic brachytherapy device shall not be used for irradiation of patients unless continuous two-way aural communication is possible;

4. Each treatment room shall have provisions to permit continuous visual observation of the patient from the treatment control panel during irradiation.~~-~~ The electronic brachytherapy device shall not be used for irradiation of patients unless the patient can be observed;

5. For electronic brachytherapy devices operating at or below 150 kV, radiation shielding for the staff in the treatment room shall be available, either as a portable shield ~~and/or~~ or as localized shielding material around the treatment site; and

6. For electronic brachytherapy devices capable of operating above 150 kV:

~~RH-10307.d. (Cont'd)~~

A. The control panel shall be located outside the treatment room; and

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B. Electrical interlocks shall be provided for all door(s) to the treatment room. These interlocks shall:

i. Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;

ii. Cause the source to be shielded when an entrance door is opened; and

iii. Prevent the source from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source on-off control is reset at the console.

e. **Control panel**.

In addition to other applicable requirements specified in Section 11, the control panel shall also:

1. Provide an indication of whether electrical power is available at the control panel and if activation of the electronic brachytherapy source is possible;

2. Provide an indication of whether x-rays are being produced;

3. Provide a means for indicating electronic brachytherapy source potential and current;

4. Provide the means for terminating an exposure at any time;

5. Include an access control (locking) device that will prevent unauthorized use of the electronic brachytherapy device; and

6. Include emergency buttons~~/~~ or switches that shall be clearly labeled as to their functions.

~~RH-10307.e. (Cont'd)~~

f. **Timer**.

A suitable irradiation control device (timer) shall be provided to terminate the irradiation after a pre-set time interval or integrated charge on a dosimeter-based monitor.

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1. A timer shall be provided at the treatment control panel. The timer shall indicate the planned setting and the time elapsed or remaining;

2. The timer shall not permit an exposure if set at zero;

3. The timer shall be a cumulative device that activates with an indication of "BEAM-ON" and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator;

4. The timer shall terminate irradiation when a pre-selected time has elapsed, if any dose monitoring system has not previously terminated irradiation.

5. The timer shall permit setting of exposure times as short as 0.1 second; and

6. The timer shall be accurate to within one percent (1%) of the selected value or 0.1 second, whichever is greater.

g. **Qualified Medical Physicist support.**

1. The services of a Qualified Medical Physicist shall be required in facilities having electronic brachytherapy devices. The Qualified Medical Physicist shall be responsible for:

   A. Evaluation of the output from the electronic brachytherapy source;

   B. Radiation protection surveys required by RH-10300.a.;

   C. Generation of the necessary dosimetric information;

   D. Supervision and review of treatment calculations prior to initial treatment of any treatment site;

~~RH-10307. (Cont'd)~~

   E. Establishment of quality assurance procedures and performance of quality assurance check review required by RH-10307.k.;

   F. Consultation with the Authorized User in treatment planning, as needed;

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G. Performing calculations~~,~~ or assessments regarding patient treatments that may constitute misadministrations; and

H. Implementation of shield locations and safe distances for individuals present in the treatment room during electronic brachytherapy treatments.

2. If the Qualified Medical Physicist is not a full-time employee of the registrant, the operating procedures required by RH-10307.h. shall also specifically address how the Qualified Medical Physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the Qualified Medical Physicist can be reached for instruction.

h. **Operating procedures**.

1. A copy of the current operating and emergency procedures shall be maintained at the electronic brachytherapy device control console.

2. Operating procedures shall include, but are not limited to, the following:

A. Only individuals approved by the Authorized User, Radiation Safety Officer, or Qualified Medical Physicist shall be present in the treatment room during treatment;

B. Electronic brachytherapy devices shall not be used for irradiation of patients unless all applicable requirements of Section 11 have been met;

C. The electronic brachytherapy device shall be inoperable, either by hardware or password, when unattended by qualified staff or service personnel;

~~RH-10307.h. (Cont'd)~~

D. During operation, the Qualified Medical Physicist shall ensure that all persons in the treatment room, and all persons entering the treatment room, are prevented from exceeding the dose limits specified in Section 3;

E. If a patient must be held in position during treatment, mechanical supporting or restraining devices shall be used;

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F. Written procedures shall be developed, implemented, and maintained for responding to an abnormal situation. These procedures shall include:

i. Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions; and

ii. The names and telephone numbers of the Authorized Users, the Qualified Medical Physicist, and the Radiation Safety Officer to be contacted if the device or console operates abnormally.

G. Instructions shall be posted at the electronic brachytherapy device control console to inform the operator of the names and telephone numbers of the Authorized Users, the Qualified Medical Physicist, and the Radiation Safety Officer to be contacted if the device or console operates abnormally; and

H. The Radiation Safety Officer, or ~~his/her~~ his or her designee, and an Authorized User shall be notified as soon as possible if the patient has a medical emergency, suffers injury, or dies. The Department shall be notified as soon as possible if the patient expires during a treatment.

i. **Safety precautions for electronic brachytherapy devices**.

1. In accordance with RH-1302., "Conditions Requiring Individual Monitoring of External and Internal Occupational Dose," each registrant shall monitor exposures to radiation at levels sufficient to demonstrate compliance with the occupational dose limits of Section 3, "Standards for Protection Against Radiation."

~~RH-10307.h.2. (Cont'd)~~

2. An Authorized User and a Qualified Medical Physicist shall be physically present during the initiation of all patient treatments involving the electronic brachytherapy device;

3. A Qualified Medical Physicist and either an Authorized User or a physician or electronic brachytherapy device operator shall be physically present during continuation of all patient treatments involving the electronic brachytherapy device, provided the physician or operator is under the supervision of an Authorized User. All individuals present pursuant to RH-10307.i.2. or i.3.

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shall be trained in the operation and emergency response for the electronic brachytherapy device;

4. A Qualified Medical Physicist shall designate shield locations or safe distances sufficient to meet the dose limit requirements of Section 3 for any individual, other than the patient, in the treatment room; and

5. All personnel in the treatment room are required to remain behind shielding or at a safe distance during treatment. A Qualified Medical Physicist shall approve any deviation from this requirement and shall designate alternative radiation safety protocols, compatible with patient safety, to provide an equivalent degree of protection.

j. **Electronic brachytherapy source calibration measurements**.

1. Calibration of the electronic brachytherapy source output for an electronic brachytherapy device shall be performed by, or under the direct supervision of, a Qualified Medical Physicist ~~who is physically present at the facility during the calibration~~.

2. Calibration of the electronic brachytherapy source output shall be made for each electronic brachytherapy source, after any repair affecting the x-ray beam generation, when indicated by the electronic brachytherapy source quality assurance checks, and in accordance with RH-10307.j.5.

3. Calibration of the electronic brachytherapy source output shall utilize a dosimetry system described in RH-10300.c.1.

4. Calibration of the electronic brachytherapy source output shall include, as applicable, determination of:

~~RH-10307. (Cont'd)~~

A. The output within two percent (2%) of the expected value, if applicable, or determination of the output if there is no expected value;

B. Timer accuracy and linearity over the typical range of use;

C. Proper operation of back-up exposure control devices;

D. Evaluation that the relative dose distribution about the source is within five percent (5%) of that expected; and

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E. Source positioning accuracy to within one (1) millimeter within the applicator.

5. Calibration of the x-ray source output, as described in RH-10307.j.1. through j.4., shall be in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy (when available). In the absence of a calibration protocol published by a national professional association, the manufacturer's calibration protocol shall be followed.

6. A copy of the most recent calibration performed pursuant to RH-10307.j. shall be available at a designated area within the therapy facility housing the therapeutic radiation machine.

7. The registrant shall maintain a record of each calibration for five (5) years. The record shall include the following: the date of the calibration; the manufacturer's name, model number, and serial number for the electronic brachytherapy device and a unique identifier for its electronic brachytherapy source; the manufacturer's name, model numbers, and serial numbers of the instruments used to calibrate the electronic brachytherapy device; the results and an assessment of the calibration; and the signature of the Qualified Medical Physicist responsible for the calibration.

k. **Periodic quality assurance checks for electronic brachytherapy devices**.

1. Quality assurance checks shall be performed on each electronic brachytherapy device:

A. At the beginning of each day of use;

~~RH-10307.k. (Cont'd)~~

B. Each time the device is moved to a new room within the same facility or to a different site (i.e., different address of use); and

C. After each x-ray tube installation.

2. The registrant shall perform periodic quality assurance checks required by RH-10307.k.1. in accordance with written procedures established by the Qualified Medical Physicist. The quality assurance check procedures shall specify the frequency at which tests or measurements are to be performed and the acceptable

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tolerance for each parameter measured in the quality assurance check.

3. To satisfy the requirements of RH-10307.k.1., periodic quality assurance checks shall include, at a minimum:

A. Verification that output of the electronic brachytherapy source falls within three percent (3%) of expected values, as appropriate for the device, as determined by:

i. Output as a function of time, or

ii. Output as a function of setting on a monitor chamber.

B. Verification of the consistency of the dose distribution to within three percent (3%) of that found during calibration required by RH-10307.j. -If within three percent (3%) is unachievable, manufacturer's specifications shall be followed ; and

C. Validation of the operation of positioning methods to ensure that the treatment dose exposes the intended location within two (2) mm.

4. The registrant shall use a dosimetry system described in RH-10300.c.2. to perform periodic quality assurance checks involving measurement of radiation output.

5. The registrant shall review the results of each quality assurance check according to the following procedures:

~~RH-10307.k.5. (Cont'd)~~

A. An Authorized User and Qualified Medical Physicist shall be immediately notified if any parameter is not within its acceptable tolerance.- The electronic brachytherapy device shall not be made available for subsequent medical use until the Qualified Medical Physicist has determined that all parameters are within their acceptable tolerances;

B. If all quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either the Authorized User

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or Qualified Medical Physicist within two (2) working days; and

C. The Qualified Medical Physicist shall review and sign the results of each quality assurance check at intervals not to exceed thirty (30) calendar days.

6. To satisfy the requirements of RH-10307.k.1., safety quality assurance checks shall, at a minimum, ensure:

A. Proper operation of radiation exposure indicator lights on the control console and, if applicable, on the electronic brachytherapy device;

B. Proper operation of viewing and intercom systems, if applicable, in each electronic brachytherapy facility;

C. Proper operation of radiation area monitors, if applicable;

D. Proper operation of electrical interlocks at each treatment room entrance, if applicable;

E. The integrity of all cables, catheters, or parts of the device that carry high voltages; and

F. Connecting guide tubes, transfer tubes, transfer-tube-applicator interfaces, and treatment spacers are free from any defects that interfere with proper operation.

7. If the results of the safety quality assurance checks required in RH-10307.k.6. indicate the malfunction of any system, a registrant shall secure the control console in the OFF position and not use the electronic brachytherapy device except as may be necessary to repair, replace, or check the malfunctioning system.

~~RH-10307.k.6. (Cont'd)~~

8. A copy of the most recent quality assurance checks performed pursuant to RH-10307.k. shall be available at a designated area within the therapy facility housing the therapeutic radiation machine.

9. The registrant shall maintain a record of each quality assurance check required by RH-10307.k. for five (5) years.

A. The record shall include the results of the check plus the following:- the date of the quality assurance check; the

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manufacturer's name, model number, and serial number for the electronic brachytherapy device; the name of the individual who performed the periodic quality assurance check; and the signature of the Qualified Medical Physicist who reviewed the quality assurance check.

B. For radiation output quality assurance checks required by RH-10307.k.3., the record shall also include the unique identifier for the electronic brachytherapy source; and the manufacturer's name, model numbers, and serial numbers for the instruments used to measure the radiation output of the electronic brachytherapy device.

l. **Therapy-related computer systems**.

The registrant shall perform acceptance testing on the treatment planning system of electronic brachytherapy-related computer systems in accordance with current published recommendations from a recognized national professional association with expertise in electronic brachytherapy ~~(when available).~~ In the absence of an acceptance testing protocol published by a national professional association, the manufacturer's acceptance testing protocol shall be followed.

1. Acceptance testing shall be performed by, or under the direct supervision of, a Qualified Medical Physicist (QMP), ~~who is physically present at the facility during the testing.~~ The testing shall be signed by the QMP responsible for the testing. At a minimum, the acceptance testing shall include, as applicable, verification of:

A. The source-specific input parameters required by the dose calculation algorithm;

B. The accuracy of dose, dwell time, and treatment time calculations at representative points;

~~RH-10307. (Cont'd)~~

C. The accuracy of isodose plots and graphic displays;

D. The accuracy of the software used to determine radiation source positions from radiographic images; and

E. If the treatment-planning system is different from the treatment-delivery system, the accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

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2. The position indicators in the applicator shall be compared to the actual position of the source or planned dwell positions, as appropriate, at the time of commissioning.

3. Prior to each patient treatment regimen, the parameters for the treatment shall be evaluated and approved by the Authorized User or the Qualified Medical Physicist for correctness through means independent of that used for the determination of the parameters.

m. **Training**.

The following training requirements are in addition to the training and experience requirements of RH-10200.c. for therapeutic radiation machine Authorized Users and RH-10200.d. for Qualified Medical Physicists:

1. A registrant shall provide instruction initially, at least annually, and upon significant procedural changes to all individuals who operate the electronic brachytherapy device, as appropriate to the individual's assigned duties. Instruction shall be provided in the operating procedures specified in RH-10307.h. and in the device's emergency procedures. If the interval between patients exceeds one (1) year, retraining of the individuals shall be provided.

2. Authorized Users, Qualified Medical Physicists, and electronic brachytherapy device operators shall receive device specific instruction initially from the manufacturer and annually from either the manufacturer or other qualified trainer. The training shall be of a duration recommended by the manufacturer's training protocol. The training shall include, but not be limited to:

   A. Device-specific radiation safety requirements;

   B. Device operation;

~~RH-10307. (Cont'd)~~

   C. Clinical use for the types of use approved by the FDA;

   D. Emergency procedures, including an emergency drill; and

   E. The registrant's quality assurance program.

3. A registrant shall retain a record of individuals receiving instruction required by this paragraph for five (5) years. The record shall include a list of the topics covered, the date of the

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instruction, the names of the attendees, and the names of the individuals who provided the instruction.

n. **Mobile electronic brachytherapy service**.

A registrant providing mobile electronic brachytherapy service shall, at a minimum:

1. Obtain a memorandum of understanding addressing radiation safety if the device is to be used at sites that are not under the control of the mobile service itself, prior to operation at those sites;

2. Check all radiation survey instruments for operability before medical use at each address of use or on each day of use, whichever is more frequent;

3. Account for the electronic brachytherapy source in the electronic brachytherapy device before departure from the client's address; and

4. Perform, at each location on each day of use, all of the required quality assurance checks specified in RH-10307.k. to ensure proper operation of the device.

RH-10308. **Other Use of Electronically-Produced Radiation to Deliver Therapeutic Radiation Dose**.

A person shall not utilize any device which is designed to electrically generate a source of ionizing radiation to deliver therapeutic radiation dose, and which is not appropriately regulated under any existing device category, until:

a. The applicant, licensee, or registrant has, at a minimum, provided the Department with:

~~RH-10308. (Cont'd)~~

1. A completed "Radiation Machine Facility Registration" form or "Application for Medical Particle Accelerator," as applicable;

2. A copy of the device manufacturer's U.S. Food and Drug Administration clearance or approval;

3. A detailed description of the device and its intended applications;

4. Facility design information, including shielding and access control;

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5. Documentation of appropriate training and experience for prospective Authorized User physicians and Qualified Medical Physicists;

6. Quality management program procedures;

7. Methodology for measurement of dose to be administered to patients or human research subjects;

8. Operating and safety procedures;

9. Documentation regarding calibration, maintenance, and repair of the device, as well as instruments and equipment necessary for radiation safety;

10. Quality assurance program procedures;

11. Acceptance testing protocol to be followed;

12. A copy of any memorandums of understanding addressing radiation safety; and

13. Other information requested by the Department in its review of the application; and

b. The applicant, licensee, or registrant has received written approval from the Department to utilize the device in accordance with the rules and specific conditions the Department considers necessary for the medical use of the device.

RH-10309.- RH-10399. _–Reserved.

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PART E.
[RESERVED]

RH-10400.- RH-10499. _–Reserved.

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PART F.
ENFORCEMENT

RH-10500. **Violations.**

a. An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any rule or order issued thereunder. Any person who willfully violates any provision of the Act or any rule or order issued thereunder may be guilty of a felony, misdemeanor, or crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law. Arkansas Code Annotated §20-21-204 describes criminal and civil penalties which may be assessed.

b. **Impounding**.

Sources of radiation shall be subject to impounding pursuant to Section 5 of these Rules.

RH-10501.- RH-10999. Reserved.

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APPENDIX A TO SECTION 11

~~INFORMATION ON~~ RADIATION SHIELDING INFORMATION REQUIRED FOR PLAN REVIEWS PURSUANT TO RH-10305.

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I. All Therapeutic Radiation Machines

A. Submit basic facility information including the following: name, telephone number, and Department vendor registration number of the individual responsible for preparation of the shielding plan; name and telephone number of the facility supervisor; the street address of the therapeutic radiation machine facility; and the room number of the therapeutic radiation machine. The plan should also indicate whether this is a new structure or a modification to an existing structure.

B. All wall, floor, and ceiling areas struck by the useful beam shall have primary barriers.

C. Secondary barriers shall be provided in all wall, floor, and ceiling areas not having primary barriers.

II. Therapeutic Radiation Machines up to 150 Kv (photons only)

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities which produce only photons with a maximum energy less than or equal to 150 kV shall submit shielding plans which contain, at a minimum, the following additional information:

A. Equipment specifications, including the manufacturer and model number of the therapeutic radiation machine, as well as the maximum technique factors;

B. The maximum design workload for the facility including total weekly radiation output (expressed in gray [rad] or air kerma at 1 meter), total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week;

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C. A facility blueprint~~/~~ or drawing indicating the following: scale (0.25 inch = 1 foot is typical); direction of North; normal location of the therapeutic radiation machine's radiation port(s); the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors; and the location of the therapeutic radiation machine control panel. If the control panel is located inside the therapeutic radiation machine treatment room, the location of the operator's booth shall be noted on the plan and the operator's station at the

control panel shall be behind a protective barrier sufficient to ensure compliance with RH-1200.;

~~**Appendix A to Section 11. (Cont'd)**~~

D. The structural composition and thickness or lead~~/~~concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned;

E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest areas where it is likely that individuals may be present; and

F. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition (i.e., primary and secondary ~~/~~ or leakage barriers, restricted and unrestricted areas, and entry doors) and shielding material in the facility:

1. If commercial software is used to generate shielding requirements, identify the software used and the version~~/~~ or revision date.

2. If the software used to generate shielding requirements is not in the open literature, also submit quality control sample calculations to verify the result obtained with the software.

III. **Therapeutic Radiation Machines Over 150 kV**

In addition to the requirements listed in Section I above, therapeutic radiation machine facilities that produce photons with a maximum energy in excess of 150 kV ~~and/or~~ or electrons shall submit shielding plans which contain, at a minimum, the following additional information:

A. Equipment specifications including the manufacturer and model number of the therapeutic radiation machine, and gray (rad) at the isocenter and the energy(s) and type(s) of radiation produced (i.e., photon, electron). The target to isocenter distance shall be specified;

B. The maximum design workload for the facility including total weekly radiation output (expressed in gray [rad] at 1 meter), total beam-on time per day or week, the average treatment time per patient, along with the anticipated number of patients to be treated per day or week;

C. A facility blueprint~~/~~ or drawing (including both floor plan and elevation views) indicating the following: relative orientation of the therapeutic radiation machine; scale (0.25 inch = 1 foot is typical); type(s), thickness, and minimum density of shielding materials; direction of North; the locations and size of all penetrations

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through each shielding barrier (ceiling, walls, and floor), as well as details of the doors and maze;

~~**Appendix A to Section 11. (Cont'd)**~~

D. The structural composition and thickness or concrete equivalent of all walls, doors, partitions, floor, and ceiling of the room(s) concerned;

E. The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest areas where it is likely that individuals may be present;

F. A description of all assumptions that were in shielding calculations, including, but not limited to, the following: design energy (i.e., room may be designed for 6 MV unit although only a 4 MV unit is currently proposed), workload, presence of integral beam-stop in unit, occupancy and uses of adjacent areas, fraction of time that useful beam will intercept each permanent barrier (walls, floor, and ceiling), and "allowed" radiation exposure in both restricted and unrestricted areas; and

G. At least one example calculation which shows the methodology used to determine the amount of shielding required for each physical condition (i.e., primary and secondary~~/~~ or leakage barriers, restricted and unrestricted areas, small angle scatter, entry doors, and maze] and shielding material in the facility:

1. If commercial software is used to generate shielding requirements, identify the software used and the version~~/~~ or revision date; and

2. If the software used to generate shielding requirements is not in the open literature, also submit quality control sample calculations to verify the result obtained with the software.

IV. **Neutron Shielding**

In addition to the requirements listed in Section III above, therapeutic radiation machine facilities that are capable of generating energies above 10 MV (10 MeV) shall submit shielding plans which contain, at a minimum, the following additional information:

A. The structural composition, thickness, minimum density, and location of all neutron shielding material;

B. A description of all assumptions that were used in neutron shielding calculations, including, but not limited to, the following: neutron spectra as a function of energy, neutron fluence rate, and absorbed dose and dose equivalent (due to neutrons) in both restricted and unrestricted areas;

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~~**Appendix A to Section 11.** (Cont'd)~~

C. At least one example calculation which shows the methodology used to determine the amount of neutron shielding required for each physical condition (i.e., restricted and unrestricted areas, entry doors, and maze) and neutron shielding material utilized in the facility:

1. If commercial software is used to generate shielding requirements, identify the software used and the version~~/~~ or revision date; and

2. If the software used to generate shielding requirements is not in the open literature, also submit quality control sample calculations to verify the result obtained with the software.

D. The method(s) and instrumentation that will be used to verify the adequacy of all neutron shielding installed in the facility.

V. **References**

A. NCRP Report No. 49, "Structural Shielding Design and Evaluation for Medical Use of X Rays and Gamma Rays of Energies Up to 10 MeV" (1976).

B. NCRP Report No. 79, "Neutron Contamination from Medical Electron Accelerators" (1984).

C. NCRP Report No. 144, "Radiation Protection for Particle Accelerator Facilities" (2003).

D. NCRP Report No. 151, "Structural Shielding Design and Evaluation for Megavoltage X- and Gamma-Ray Radiotherapy Facilities" (2005).

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FOOTNOTES TO SECTION 11

1/ Electronic brachytherapy devices are subject to the requirements of RH-10307. and are exempt from the requirements of RH-10301.

2/ "IMRT Commissioning:- Multiple Institution Planning and Dosimetry Comparisons, a Report from AAPM Task Group 119" – AAPM Report No. 119, prepared by the Work Group on IMRT Task Group No. 119, and "Dosimetry Tools and Techniques for IMRT" – AAPM Report No. 120, prepared by the Work Group on IMRT Task Group No. 120, provide further recommendations.

3/ "Comprehensive QA for Radiation Oncology," – AAPM Report No. 46, prepared by the Radiation Therapy Committee Task Group No. 40, provides recommendations regarding conventional simulators.- "Quality Assurance for Computed-Tomography Simulators and the Computed-Tomography-Simulation Process:- Report of the AAPM Radiation Therapy Committee Task Group No. 66," – AAPM Report No. 83, prepared by the Radiation Therapy Committee Task Group No. 66, provides recommendations regarding virtual simulators.

SECTION 12.
PHYSICAL PROTECTION OF CATEGORY 1 AND CATEGORY 2 QUANTITIES OF RADIOACTIVE MATERIAL

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PART A.
GENERAL

RH-11000. Reserved.

RH-11001. **Purpose**.

This Section has been established to provide the requirements for the physical protection program for any licensee that possesses an aggregated category 1 or category 2 quantity of radioactive material listed in Appendix A to this Section. These requirements provide reasonable assurance of the security of category 1 or category 2 quantities of radioactive material by protecting these materials from theft or diversion. Specific requirements for access to material, use of material, transfer of material, and transport of material are included. No provision of this Section authorizes possession of licensed material.

RH-11002. Reserved.

RH-11003. **Scope**.

a. Parts B and C of this Section apply to any person who, under these Rules, possesses or uses at any site, an aggregated category 1 or category 2 quantity of radioactive material.

b. Part D of this Section applies to any person who:

1. Transports or delivers to a carrier for transport in a single shipment, a category 1 or category 2 quantity of radioactive material, under these Rules; or

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2. Imports or exports a category 1 or category 2 quantity of radioactive material; the provisions only apply to the domestic portion of the transport.

RH-11004. Reserved.

RH-11005. **Definitions**.

Access control - A system for allowing only approved individuals to have unescorted access to the security zone and for ensuring that all other individuals are subject to escorted access.

Act - Act 8 of the Second Extraordinary Session of 1961, as amended.

Aggregated - Accessible by the breach of a single physical barrier that would allow access to radioactive material in any form, including any devices that contain the radioactive material, when the total activity equals or exceeds a category 2 quantity of radioactive material.

Agreement State - Any state with which the Atomic Energy Commission or the U.S. Nuclear Regulatory Commission has entered into an effective agreement under subsection 274 b. of the Atomic Energy Act of 1954 (68 Stat. 919), including any amendments thereto. Non-agreement State means any other State.

Approved individual - An individual whom the licensee has determined to be trustworthy and reliable for unescorted access in accordance with Part B of this Section and who has completed the training required by RH-11043.c.

Background investigation - The investigation conducted by a licensee or applicant to support the determination of trustworthiness and reliability.

Carrier - A person engaged in the transportation of passengers or property by land or water as a common, contract, or private carrier, or by civil aircraft.

Category 1 quantity of radioactive material - A quantity of radioactive material meeting or exceeding the category 1 threshold in Table 1 of Appendix A to this Section. This is determined by calculating the ratio of the total activity of each radionuclide to the category 1 threshold for that radionuclide and adding the ratios together. If the sum is equal to or exceeds 1, the quantity would be considered a category 1 quantity. Category 1 quantities of radioactive material do not include the radioactive material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

Category 2 quantity of radioactive material - A quantity of radioactive material meeting or exceeding the category 2 threshold but less than the category 1 threshold in Table 1 of Appendix A to this Section. This is determined by calculating the ratio of the total activity of each radionuclide to the category 2 threshold for that radionuclide and adding the ratios together. If the sum is equal to or exceeds 1, the quantity would be considered a category 2 quantity. Category 2 quantities of radioactive material do not include the radioactive material contained in any fuel assembly, subassembly, fuel rod, or fuel pellet.

~~RH-11005. (Cont'd)~~

Diversion - The unauthorized movement of radioactive material subject to this Section to a location different from the material's authorized destination inside or outside of the site at which the material is used or stored.

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Escorted access - Accompaniment while in a security zone by an approved individual who maintains continuous direct visual surveillance at all times over an individual who is not approved for unescorted access.

Fingerprint orders - The orders issued by the U.S. Nuclear Regulatory Commission or the legally binding requirements issued by Agreement States that require fingerprints and criminal history records checks for individuals with unescorted access to category 1 and category 2 quantities of radioactive material or safeguards information-modified handling.

Government agency - Any executive department, commission, independent establishment, corporation, wholly or partly owned by the United States of America which is an instrumentality of the United States, or any board, bureau, division, service, office, officer, authority, administration, or other establishment in the executive branch of the Government.

License issuing authority - The licensing agency that issued the license, i.e., the Department, the appropriate agency of an Agreement State, or the U.S. Nuclear Regulatory Commission.

Local law enforcement agency (LLEA) - A public or private organization that has been approved by a federal, state, or local government to carry firearms and make arrests, and is authorized and has the capability to provide an armed response in the jurisdiction where the licensed category 1 or category 2 quantity of radioactive material is used, stored, or transported.

Lost or missing licensed material - Licensed material whose location is unknown. It includes material that has been shipped but has not reached its destination and whose location cannot be readily traced in the transportation system.

Mobile device - A piece of equipment containing licensed radioactive material that is either mounted on wheels or casters, or otherwise equipped for moving without a need for disassembly or dismounting; or designed to be hand carried. Mobile devices do not include stationary equipment installed in a fixed location.

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Movement control center - An operations center that is remote from transport activity and that maintains position information on the movement of radioactive material, receives reports of attempted attacks or thefts, provides a means for reporting these and other problems to appropriate agencies and can request and coordinate appropriate aid.

No-later-than arrival time - The date and time that the shipping licensee and

receiving licensee have established as the time at which an investigation will be initiated if the shipment has not arrived at the receiving facility. The no-later-than arrival time may not be more than six (6) hours after the estimated arrival time for shipments of category 2 quantities of radioactive material.

Person -

1. Any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency of this state, political subdivision of this state, any other state or political subdivision or agency thereof; and

2. Any legal successor, representative, agent, or agency of the foregoing, but not including United States Government agencies.

Reviewing official - The individual who shall make the trustworthiness and reliability determination of an individual to determine whether the individual may have, or continue to have, unescorted access to the category 1 or category 2 quantities of radioactive materials that are possessed by the licensee.

Sabotage - Deliberate damage, with malevolent intent, to a category 1 or category 2 quantity of radioactive material, a device that contains a category 1 or category 2 quantity of radioactive material, or the components of the security system.

Safe haven - A readily recognizable and readily accessible site at which security is present or from which, in the event of an emergency, the transport crew can notify and wait for the local law enforcement authorities.

Security zone - Any temporary or permanent area determined and established by the licensee for the physical protection of category 1 or category 2 quantities of radioactive material during use or storage.

State - A State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

~~RH 11005. (Cont'd)~~

Telemetric position monitoring system - A data transfer system that captures information by instrumentation ~~and/or~~ or measuring devices about the location and status of a transport vehicle or package between the departure and destination locations.

Trustworthiness and reliability - Characteristics of an individual considered dependable in judgment, character, and performance, such that unescorted access

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to category 1 or category 2 quantities of radioactive material by that individual does not constitute an unreasonable risk to the public health and safety or security. A determination of trustworthiness and reliability for this purpose is based upon the results from a background investigation.

Unescorted access - Solitary access to an aggregated category 1 or category 2 quantity of radioactive material or the devices that contain the material.

United States – When used in a geographical sense, includes Puerto Rico and all territories and possessions of the United States.

RH-11006. Reserved.

RH-11007. **Communications**.

Except where otherwise specified, all communications concerning these Rules may be addressed to the Arkansas Department of Health, Radiation Control Section, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

RH-11008. Reserved.

RH-11009. **Interpretations**.

Except as specifically authorized by the Department in writing, no interpretations of the meaning of the rules in this Section by an officer or employee of the Department other than a written interpretation by the Department Director or designee will be recognized as binding upon the Department.

RH-11010. Reserved.

RH-11011. **Specific Exemptions**.

a. The Department may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the rules in this Section as it determines are authorized by law and will not result in undue hazard to public health and safety or property, and are otherwise in the public interest.

b. A licensee that possesses radioactive waste that contains category 1 or category 2 quantities of radioactive material is exempt from the requirements of Parts B, C, and D of this Section – except that any radioactive waste that contains discrete sources, ion-exchange resins, or activated material that weighs less than 2,000 kg (4,409 ~~lbs~~lbs.) is not exempt from the requirements of this Section.
-The licensee shall implement the following requirements to secure the radioactive waste:

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1. Use continuous physical barriers that allow access to the radioactive waste only through established access control points;

2. Use a locked door or gate with monitored alarm at the access control point;

3. Assess and respond to each actual or attempted unauthorized access to determine whether an actual or attempted theft, sabotage, or diversion occurred; and

4. Immediately notify the LLEA and request an armed response from the LLEA upon determination that there was an actual or attempted theft, sabotage, or diversion of the radioactive waste that contains category 1 or category 2 quantities of radioactive material.

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RH-11012.- RH-11019.– _Reserved.

PART B.
BACKGROUND INVESTIGATIONS AND ACCESS AUTHORIZATION PROGRAM

RH-11020. Reserved.

RH-11021. **Personnel Access Authorization Requirements for Category 1 or Category 2 Quantities of Radioactive Material**.

a. **General**.

1. Each licensee that possesses an aggregated quantity of radioactive material at or above the category 2 threshold shall establish, implement, and maintain its access authorization program in accordance with the requirements of this Part.

2. An applicant for a new license and each licensee that would become newly subject to the requirements of this Part upon application for modification of its license shall implement the requirements of this Part, as appropriate, before taking possession of an aggregated category 1 or category 2 quantity of radioactive material.

3. Any licensee that has not previously implemented the Security Orders or been subject to the provisions of this Part B shall implement the provisions of this Part B before aggregating radioactive material to a quantity that equals or exceeds the category 2 threshold.

b. **General performance objective**.

The licensee's access authorization program must ensure that the individuals specified in paragraph c.1. of this section are trustworthy and reliable.

c. **Applicability**.

1. Licensees shall subject the following individuals to an access authorization program:

A. Any individual whose assigned duties require unescorted access to category 1 or category 2 quantities of radioactive material or to any device that contains the radioactive material; and

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~~RH-11021.c.1. (Cont'd)~~

B. Reviewing officials.

2. Licensees need not subject the categories of individuals listed in RH-11029.a. to the investigation elements of the access authorization program.

3. Licensees shall approve for unescorted access to category 1 or category 2 quantities of radioactive material only those individuals with job duties that require unescorted access to category 1 or category 2 quantities of radioactive material.

4. Licensees may include individuals needing access to safeguards information-modified handling under 10 CFR Part 73 in the access authorization program under this Part B.

RH-11022. Reserved.

RH-11023. **Access Authorization Program Requirements**.

a. **Granting unescorted access authorization**.

1. Licensees shall implement the requirements of this Part for granting initial or reinstated unescorted access authorization.

2. Individuals who have been determined to be trustworthy and reliable shall also complete the security training required by RH-11043.c. before being allowed unescorted access to category 1 or category 2 quantities of radioactive material.

b. **Reviewing officials**.

1. Reviewing officials are the only individuals who may make trustworthiness and reliability determinations that allow individuals to have unescorted access to category 1 or category 2 quantities of radioactive materials possessed by the licensee.

~~RH-11023.b. (Cont'd)~~

2. Each licensee shall name one or more individuals to be reviewing officials. After completing the background investigation on the reviewing official, the licensee shall provide under oath or

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affirmation, a certification that the reviewing official is deemed trustworthy and reliable by the licensee. Provide oath or affirmation certifications to the Department by an appropriate method listed in RH-11007. The fingerprints of the named reviewing official must be taken by a law enforcement agency, Federal or State agencies that provide fingerprinting services to the public, or commercial fingerprinting services authorized by a State to take fingerprints. The licensee shall recertify that the reviewing official is deemed trustworthy and reliable every ten (10) years in accordance with RH-11025.c.

3. Reviewing officials must be permitted to have unescorted access to category 1 or category 2 quantities of radioactive material or access to safeguards information or safeguards information-modified handling, if the licensee possesses safeguards information or safeguards information-modified handling. Reviewing officials permitted unescorted access to category 1 or category 2 quantities of radioactive material shall receive appropriate radiation safety training, initially and at a frequency not to exceed twelve (12) months. The licensee shall maintain records of the initial and refresher training for three (3) years from the date of the training.

4. Reviewing officials cannot approve other individuals to act as reviewing officials.

5. A reviewing official does not need to undergo a new background investigation before being named by the licensee as the reviewing official if:

   A. The individual has undergone a background investigation that included fingerprinting and an FBI criminal history records check and has been determined to be trustworthy and reliable by the licensee; or

   B. The individual is subject to a category listed in RH-11029.a.

~~RH-11023. (Cont'd)~~

c. **Informed consent**.

1. Licensees may not initiate a background investigation without the informed and signed consent of the subject individual. This consent must include authorization to share personal information with other individuals or organizations as necessary to complete the background investigation. Before a final adverse determination, the licensee shall provide the individual with an

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opportunity to correct any inaccurate or incomplete information that is developed during the background investigation. Licensees do not need to obtain signed consent from those individuals that meet the requirements of RH-11025.b. A signed consent must be obtained prior to any reinvestigation.

2. The subject individual may withdraw his or her consent at any time. Licensees shall inform the individual that:

A. If an individual withdraws his or her consent, the licensee may not initiate any elements of the background investigation that were not in progress at the time the individual withdrew his or her consent; and

B. The withdrawal of consent for the background investigation is sufficient cause for denial or termination of unescorted access authorization.

d. **Personal history disclosure**.

Any individual who is applying for unescorted access authorization shall disclose the personal history information that is required by the licensee's access authorization program for the reviewing official to make a determination of the individual's trustworthiness and reliability. Refusal to provide, or the falsification of, any personal history information required by this Part is sufficient cause for denial or termination of unescorted access.

e. **Determination basis**.

1. The reviewing official shall determine whether to permit, deny, unfavorably terminate, maintain, or administratively withdraw an individual's unescorted access authorization based on an evaluation of all of the information collected to meet the requirements of this Part.

~~RH-11023.e. (Cont'd)~~

2. The reviewing official may not permit any individual to have unescorted access until the reviewing official has evaluated all of the information collected to meet the requirements of this Part and determined that the individual is trustworthy and reliable. The reviewing official may deny unescorted access to any individual based on information obtained at any time during the background investigation.

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3. The licensee shall document the basis for concluding whether or not there is reasonable assurance that an individual is trustworthy and reliable.

4. The reviewing official may terminate or administratively withdraw an individual's unescorted access authorization based on information obtained after the background investigation has been completed and the individual granted unescorted access authorization.

5. Licensees shall maintain a list of persons currently approved for unescorted access authorization. When a licensee determines that a person no longer requires unescorted access or meets the access authorization requirement, the licensee shall remove the person from the approved list as soon as possible, but no later than seven (7) working days, and take prompt measures to ensure that the individual is unable to have unescorted access to the material.

f. **Procedures**.

Licensees shall develop, implement, and maintain written procedures for implementing the access authorization program. The procedures must include provisions for the notification of individuals who are denied unescorted access. The procedures must include provisions for the review, at the request of the affected individual, of a denial or termination of unescorted access authorization. The procedures must contain a provision to ensure that the individual is informed of the grounds for the denial or termination of unescorted access authorization and allow the individual an opportunity to provide additional relevant information.

~~RH 11023. (Cont'd)~~

g. **Right to correct and complete information**.

1. Prior to any final adverse determination, licensees shall provide each individual subject to this Part with the right to complete, correct, and explain information obtained as a result of the licensee's background investigation. Confirmation of receipt by the individual of this notification must be maintained by the licensee for a period of one (1) year from the date of the notification.

2. If, after reviewing his or her criminal history record, an individual believes that it is incorrect or incomplete in any respect and wishes to change, correct, update, or explain anything in the record, the individual may initiate challenge procedures. These procedures

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include direct application by the individual challenging the record to the law enforcement agency that contributed the questioned information or a direct challenge as to the accuracy or completeness of any entry on the criminal history record to the Federal Bureau of Investigation, Criminal Justice Information Services (CJIS) Division, ATTN: SCU, Mod. D–2, 1000 Custer Hollow Road, Clarksburg, WV 26306 as set forth in 28 CFR 16.30 through 16.34. In the latter case, the Federal Bureau of Investigation (FBI) will forward the challenge to the agency that submitted the ~~data, and~~data and will request that the agency verify or correct the challenged entry. Upon receipt of an official communication directly from the agency that contributed the original information, the FBI Identification Division makes any changes necessary in accordance with the information supplied by that agency. Licensees must provide at least ten (10) days for an individual to initiate action to challenge the results of an FBI criminal history records check after the record being made available for his or her review. The licensee may make a final adverse determination based upon the criminal history records only after receipt of the FBI's confirmation or correction of the record.

h. **Records**.

1. The licensee shall retain documentation regarding the trustworthiness and reliability of individual employees for three (3) years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material.

~~RH-11023.h. (Cont'd)~~

2. The licensee shall retain a copy of the current access authorization program procedures as a record for three (3) years after the procedure is no longer needed. If any portion of the procedure is superseded, the licensee shall retain the superseded material for three (3) years after the record is superseded.

3. The licensee shall retain the list of persons approved for unescorted access authorization for three (3) years after the list is superseded or replaced.

RH-11024. Reserved.

RH-11025. **Background Investigations**.

a. **Initial investigation**.

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Before allowing an individual unescorted access to category 1 or category 2 quantities of radioactive material or to the devices that contain the material, licensees shall complete a background investigation of the individual seeking unescorted access authorization. -The scope of the investigation must encompass at least the seven (7) years preceding the date of the background investigation or since the individual's eighteenth birthday, whichever is shorter. -The background investigation must include at a minimum:

1. Fingerprinting and an FBI identification and criminal history records check in accordance with RH-11027.;

2. **Verification of true identity**.

   Licensees shall verify the true identity of the individual who is applying for unescorted access authorization to ensure that the applicant is who he or she claims to be. -A licensee shall review official identification documents (e.g., driver's license; passport; government identification; certificate of birth issued by the state, province, or country of birth) and compare the documents to personal information data provided by the individual to identify any discrepancy in the information.

   -Licensees shall document the type, expiration, and identification number of the identification document, or maintain a photocopy of identifying documents on file in accordance with RH-11031. Licensees shall certify in writing that the identification was properly reviewed, and shall

~~RH-11025.a. (Cont'd)~~

   maintain the certification and all related documents for review upon inspection;

3. **Employment history verification**.

   Licensees shall complete an employment history verification, including military history.- Licensees shall verify the individual's employment with each previous employer for the most recent seven (7) years before the date of application;

4. **Verification of education**.

   Licensees shall verify that the individual participated in the education process during the claimed period;

5. **Character and reputation determination**.

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Licensees shall complete reference checks to determine the character and reputation of the individual who has applied for unescorted access authorization. Unless other references are not available, reference checks may not be conducted with any person who is known to be a close member of the individual's family, including but not limited to the individual's spouse, parents, siblings, or children, or any individual who resides in the individual's permanent household. Reference checks under this Part must be limited to whether the individual has been and continues to be trustworthy and reliable;

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6. The licensee shall also, to the extent possible, obtain independent information to corroborate that provided by the individual (e.g., seek references not supplied by the individual); and

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7. If a previous employer, educational institution, or any other entity with which the individual claims to have been engaged fails to provide information or indicates an inability or unwillingness to provide information within a time frame deemed appropriate by the licensee but at least after ten (10) business days of the request or if the licensee is unable to reach the entity, the licensee shall document the refusal, unwillingness, or inability in the record of investigation; and attempt to obtain the information from an alternate source.

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b. **Grandfathering**.

1. Individuals who have been determined to be trustworthy and reliable for unescorted access to category 1 or category 2 quantities of radioactive material under the Fingerprint Orders may continue to have unescorted access to category 1 and category 2 quantities of radioactive material without further investigation. These individuals shall be subject to the reinvestigation requirement.

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2. Individuals who have been determined to be trustworthy and reliable under the provisions of 10 CFR Part 73 or the security orders for access to safeguards information, safeguards information-modified handling, or risk-significant material may have unescorted access to category 1 and category 2 quantities of radioactive material without further investigation. The licensee shall document that the individual was determined to be trustworthy and reliable under the provisions of 10 CFR Part 73 or a security order. Security order, in this context, refers to any order

that was issued by the NRC that required fingerprints and an FBI criminal history records check for access to safeguards information, safeguards information-modified handling, or risk significant material such as special nuclear material or large quantities of uranium hexafluoride. These individuals shall be subject to the reinvestigation requirement.

c. **Reinvestigations**.

Licensees shall conduct a reinvestigation every 10 years for any individual with unescorted access to category 1 or category 2 quantities of radioactive material. The reinvestigation shall consist of fingerprinting and an FBI identification and criminal history records check in accordance with RH-11027. The reinvestigations must be completed within ten (10) years of the date on which these elements were last completed.

RH-11026. Reserved.

RH-11027. **Requirements for Criminal History Records Checks of Individuals Granted Unescorted Access to Category 1 or Category 2 Quantities of Radioactive Material**.

a. **General performance objective and requirements**.

1. Except for those individuals listed in RH-11029. and those individuals grandfathered under RH-11025.b., each licensee subject to the provisions of this Part shall fingerprint each individual who is to be permitted unescorted access to category 1 or category 2 quantities of radioactive material. Licensees shall transmit all collected fingerprints to the U.S. Nuclear Regulatory Commission for transmission to the FBI. The licensee shall use the information received from the FBI as part of the required background investigation to determine whether to grant or deny further unescorted access to category 1 or category 2 quantities of radioactive materials for that individual.

2. The licensee shall notify each affected individual that his or her fingerprints will be used to secure a review of his or her criminal history record and shall inform him or her of the procedures for revising the record or adding explanations to the record.

3. Fingerprinting is not required if a licensee is reinstating an

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individual's unescorted access authorization to category 1 or category 2 quantities of radioactive materials if:

A. The individual returns to the same facility that granted unescorted access authorization within 365 days of the termination of his or her unescorted access authorization; and

B. The previous access was terminated under favorable conditions.

4. Fingerprints do not need to be taken if an individual who is an employee of a licensee, contractor, manufacturer, or supplier has been granted unescorted access to category 1 or category 2 quantities of radioactive material, access to safeguards information, or safeguards information-modified handling by another licensee, based upon a background investigation conducted under this Part, the Fingerprint Orders, or 10 CFR Part 73. An existing criminal history records check file may be transferred to the licensee asked to grant unescorted access in accordance with the provisions of RH-11031.c.

~~RH-11027.a. (Cont'd)~~

5. Licensees shall use the information obtained as part of a criminal history records check solely for the purpose of determining an individual's suitability for unescorted access authorization to category 1 or category 2 quantities of radioactive materials, access to safeguards information, or safeguards information-modified handling.

b. **Prohibitions**.

1. Licensees may not base a final determination to deny an individual unescorted access authorization to category 1 or category 2 quantities of radioactive material solely on the basis of information received from the FBI involving:

A. An arrest more than one (1) year old for which there is no information of the disposition of the case; or

B. An arrest that resulted in dismissal of the charge or an acquittal.

2. Licensees may not use information received from a criminal history records check obtained under this Part in a manner that

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would infringe upon the rights of any individual under the First Amendment to the Constitution of the United States, nor shall licensees use the information in any way that would discriminate among individuals on the basis of race, religion, national origin, gender, or age.

c. **Procedures for processing of fingerprint checks**.

1. For the purpose of complying with this Part, licensees shall submit to the U.S. Nuclear Regulatory Commission, Director, Division of Physical and Cyber Security Policy, 11545 Rockville Pike, ATTN: Criminal History Program/Mail Stop T-07D04M, Rockville, Maryland 20852, one completed, legible standard fingerprint card (Form FD–258, ORIMDNRCOOOZ), electronic fingerprint scan or, where practicable, other fingerprint record for each individual requiring unescorted access to category 1 or category 2 quantities of radioactive material. Copies of these forms may be obtained by emailing MAILSVS.Resource@nrc.gov. Guidance on submitting electronic fingerprints can be found at https://www.nrc.gov/security/chp.html.

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~~RH-11027.c. (Cont'd)~~

2. Fees for the processing of fingerprint checks are due upon application. Licensees shall submit payment with the application for the processing of fingerprints through corporate check, certified check, cashier's check, money order, or electronic payment, made payable to ''U.S. NRC.'' (For guidance on making electronic payments, contact the Division of Physical and Cyber Security Policy by emailing Crimhist.Resource@nrc.gov.) Combined payment for multiple applications is acceptable. The U.S. Nuclear Regulatory Commission publishes the amount of the fingerprint check application fee on the NRC's public Web site. (To find the current fee amount, go to the Licensee Criminal History Records Checks & Firearms Background Check Information page at https://www.nrc.gov/security/chp.html and see the link for "How do I determine how much to pay for the request?")

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3. The U.S. Nuclear Regulatory Commission will forward to the submitting licensee all data received from the FBI as a result of the licensee's application(s) for criminal history records checks.

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RH-11028. Reserved.

RH-11029. **Relief from Fingerprinting, Identification, and Criminal History Records Checks and Other Elements of Background Investigations for Designated Categories of Individuals Permitted Unescorted Access to Certain Radioactive Materials**.

a. Fingerprinting, and the identification and criminal history records checks required by section 149 of the Atomic Energy Act of 1954, as amended, and other elements of the background investigation are not required for the following individuals prior to granting unescorted access to category 1 or category 2 quantities of radioactive materials:

1. An employee of the U.S. Nuclear Regulatory Commission or of the Executive Branch of the U.S. Government who has undergone fingerprinting for a prior U.S. Government criminal history records check;

2. A Member of Congress;

3. An employee of a member of Congress or Congressional committee who has undergone fingerprinting for a prior U.S. Government criminal history records check;

~~RH-11029.a. (Cont'd)~~

4. The Governor of a State or his or her designated State employee representative;

5. Federal, State, or local law enforcement personnel;

6. State Radiation Control Program Directors and State Homeland Security Advisors or their designated State employee representatives;

7. Agreement State employees conducting security inspections on behalf of the NRC under an agreement executed under section 274.i. of the Atomic Energy Act;

8. Representatives of the International Atomic Energy Agency (IAEA) engaged in activities associated with the U.S./IAEA Safeguards Agreement who have been certified by the NRC;

9. Emergency response personnel who are responding to an emergency;

10. Commercial vehicle drivers for road shipments of category 1 and category 2 quantities of radioactive material;

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11. Package handlers at transportation facilities such as freight terminals and railroad yards;

12. Any individual who has an active Federal security clearance, provided that he or she makes available the appropriate documentation. Written confirmation from the agency/ or employer that granted the Federal security clearance or reviewed the criminal history records check must be provided to the licensee. The licensee shall retain this documentation for a period of three (3) years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material; and

~~RH 11029.a. (Cont'd)~~

13. Any individual employed by a service provider licensee for which the service provider licensee has conducted the background investigation for the individual and approved the individual for unescorted access to category 1 or category 2 quantities of radioactive material. Written verification from the service provider must be provided to the licensee. The licensee shall retain the documentation for a period of three (3) years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material.

b. Fingerprinting, and the identification and criminal history records checks required by section 149 of the Atomic Energy Act of 1954, as amended, are not required for an individual who has had a favorably adjudicated U.S. Government criminal history records check within the last five (5) years, under a comparable U.S. Government program involving fingerprinting and an FBI identification and criminal history records check provided that he or she makes available the appropriate documentation. Written confirmation from the agency/ or employer that reviewed the criminal history records check must be provided to the licensee. The licensee shall retain this documentation for a period of three (3) years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material. These programs include, but are not limited to:

1. National Agency Check;

2. Transportation Worker Identification Credentials (TWIC) under 49 CFR part 1572;

3. Bureau of Alcohol, Tobacco, Firearms, and Explosives background

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check and clearances under 27 CFR part 555;

4. Health and Human Services security risk assessments for possession and use of select agents and toxins under 42 CFR part 73;

5. Hazardous Material security threat assessment for hazardous material endorsement to commercial driver's license under 49 CFR part 1572; and

6. Customs and Border Protection's Free and Secure Trade (FAST) Program.

RH-11030. Reserved.

RH-11031. **Protection of Information**.

a. Each licensee who obtains background information on an individual under this Part shall establish and maintain a system of files and written procedures for protection of the record and the personal information from unauthorized disclosure.

b. The licensee may not disclose the record or personal information collected and maintained to persons other than the subject individual, his or her representative, or to those who have a need to have access to the information in performing assigned duties in the process of granting or denying unescorted access to category 1 or category 2 quantities of radioactive material, safeguards information, or safeguards information-modified handling. -No individual authorized to have access to the information may disseminate the information to any other individual who does not have a need to know.

c. The personal information obtained on an individual from a background investigation may be provided to another licensee:

1. Upon the individual's written request to the licensee holding the data to disseminate the information contained in his or her file; and

2. The recipient licensee verifies information such as name, date of birth, social security number, gender, and other applicable physical characteristics.

d. The licensee shall make background investigation records obtained under

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this Part available for examination by an authorized representative of the Department to determine compliance with the rules and laws.

e. The licensee shall retain all fingerprint and criminal history records (including data indicating no record) received from the FBI, or a copy of these records if the individual's file has been transferred, on an individual for three (3) years from the date the individual no longer requires unescorted access to category 1 or category 2 quantities of radioactive material.

RH-11032. Reserved.

RH-11033. **Access Authorization Program Review**.

a. Each licensee shall be responsible for the continuing effectiveness of the access authorization program. Each licensee shall ensure that access authorization programs are reviewed to confirm compliance with the requirements of this Part and that comprehensive actions are taken to correct any noncompliance that is identified. The review program shall evaluate all program performance objectives and requirements. Each licensee shall periodically (at least annually) review the access program content and implementation.

b. The results of the reviews, along with any recommendations, must be documented. Each review report must identify conditions that are adverse to the proper performance of the access authorization program, the cause of the condition(s), and, when appropriate, recommend corrective actions, and corrective actions taken. The licensee shall review the findings and take any additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.

c. Review records must be maintained for three (3) years.

RH-11034. RH-11039. Reserved.

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PART C.
PHYSICAL PROTECTION REQUIREMENTS DURING USE

RH-11040. Reserved.

RH-11041. **Security Program**.

a. **Applicability**.

1. Each licensee that possesses an aggregated category 1 or category 2 quantity of radioactive material shall establish, implement, and maintain a security program in accordance with the requirements of this Part.

2. An applicant for a new license and each licensee that would become newly subject to the requirements of this Part upon application for modification of its license shall implement the requirements of this Part, as appropriate, before taking possession of an aggregated category 1 or category 2 quantity of radioactive material.

3. Any licensee that has not previously implemented the security requirements or been subject to the provisions of Part C shall provide written notification to the Department as specified in RH-11007. at least ninety (90) days before aggregating radioactive material to a quantity that equals or exceeds the category 2 threshold.

b. **General performance objective**.

Each licensee shall establish, implement, and maintain a security program that is designed to monitor and, without delay, detect, assess, and respond to an actual or attempted unauthorized access to category 1 or category 2 quantities of radioactive material.

c. **Program features**.

Each licensee's security program must include the program features, as appropriate, described in RH-11043., RH-11045., RH-11047., RH-11049., RH-11051., RH-11053., and RH-11055.

RH-11042. Reserved.

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RH-11043. **General Security Program Requirements**.

a. **Security plan**.

1. Each licensee identified in RH-11041.a. shall develop a written security plan specific to its facilities and operations. The purpose of the security plan is to establish the licensee's overall security strategy to ensure the integrated and effective functioning of the security program required by this Part. The security plan must, at a minimum:

A. Describe the measures and strategies used to implement the requirements of this Part; and

B. Identify the security resources, equipment, and technology used to satisfy the requirements of this Part.

2. The security plan must be reviewed and approved by the individual with overall responsibility for the security program.

3. A licensee shall revise its security plan as necessary to ensure the effective implementation of Department requirements. The licensee shall ensure that:

A. The revision has been reviewed and approved by the individual with overall responsibility for the security program; and

B. The affected individuals are instructed on the revised plan before the changes are implemented.

4. The licensee shall retain a copy of the current security plan as a record for three (3) years after the security plan is no longer required. If any portion of the plan is superseded, the licensee shall retain the superseded material for three (3) years after the record is superseded.

b. **Implementing procedures**.

1. The licensee shall develop and maintain written procedures that document how the requirements of this Part and the security plan will be met.

2. The implementing procedures and revisions to these procedures must be approved in writing by the individual with overall

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responsibility for the security program.

~~RH-11043.b. (Cont'd)~~

3. The licensee shall retain a copy of the current procedure as a record for three (3) years after the procedure is no longer needed. Superseded portions of the procedure must be retained for three (3) years after the record is superseded.

c. **Training**.

1. Each licensee shall conduct training to ensure that those individuals implementing the security program possess and maintain the knowledge, skills, and abilities to carry out their assigned duties and responsibilities effectively. The training must include instruction in:

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A. The licensee's security program and procedures to secure category 1 or category 2 quantities of radioactive material, and in the purposes and functions of the security measures employed;

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B. The responsibility to report promptly to the licensee any condition that causes or may cause a violation of Department requirements;

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C. The responsibility of the licensee to report promptly to the local law enforcement agency and licensee any actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material; and

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D. The appropriate response to security alarms.

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2. In determining those individuals who shall be trained on the security program, the licensee shall consider each individual's assigned activities during authorized use and response to potential situations involving actual or attempted theft, diversion, or sabotage of category 1 or category 2 quantities of radioactive material. The extent of the training must be commensurate with the individual's potential involvement in the security of category 1 or category 2 quantities of radioactive material.

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~~RH-11043.c. (Cont'd)~~

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3. Refresher training must be provided at a frequency not to exceed twelve (12) months and when significant changes have been made to the security program. This training must include:

A. Review of the training requirements of paragraph c. of this section and any changes made to the security program since the last training;

B. Reports on any relevant security issues, problems, and lessons learned;

C. Relevant results of Department inspections; and

D. Relevant results of the licensee's program review and testing and maintenance.

4. The licensee shall maintain records of the initial and refresher training for three (3) years from the date of the training. The training records must include dates of the training, topics covered, a list of licensee personnel in attendance, and related information.

d. **Protection of information**.

1. Licensees authorized to possess category 1 or category 2 quantities of radioactive material shall limit access to and unauthorized disclosure of their security plan, implementing procedures, and the list of individuals that have been approved for unescorted access.

2. Efforts to limit access shall include the development, implementation, and maintenance of written policies and procedures for controlling access to, and for proper handling and protection against unauthorized disclosure of, the security plan, implementing procedures, and the list of individuals that have been approved for unescorted access.

3. Before granting an individual access to the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access, licensees shall:

A. Evaluate an individual's need to know the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access; and

~~RH-11043.d.3. (Cont'd)~~

B. If the individual has not been authorized for unescorted access to category 1 or category 2 quantities of radioactive material, safeguards information, or safeguards

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information-modified handling, the licensee must complete a background investigation to determine the individual's trustworthiness and reliability. A trustworthiness and reliability determination shall be conducted by the reviewing official and shall include the background investigation elements contained in RH-11025.a.2. through a.7.

4. Licensees need not subject the following individuals to the background investigation elements for protection of information:

   A. The categories of individuals listed in RH-11029.a.; or

   B. Security service provider employees, provided written verification that the employee has been determined to be trustworthy and reliable, by the required background investigation in RH-11025.a.2. through a.7., has been provided by the security service provider.

5. The licensee shall document the basis for concluding that an individual is trustworthy and reliable and should be granted access to the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access.

6. Licensees shall maintain a list of persons currently approved for access to the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access.

   When a licensee determines that a person no longer needs access to the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access, or no longer meets the access authorization requirements for access to the information, the licensee shall remove the person from the approved list as soon as possible, but no later than seven (7) working days, and take prompt measures to ensure that the individual is unable to obtain the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access.

~~RH-11043.d. (Cont'd)~~

7. When not in use, the licensee shall store its security plan, implementing procedures, and the list of individuals that have been approved for unescorted access in a manner to prevent unauthorized access. Information stored in nonremovable electronic form must be password protected.

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8. The licensee shall retain as a record for three (3) years after the document is no longer needed:

A. A copy of the information protection procedures; and

B. The list of individuals approved for access to the security plan, implementing procedures, or the list of individuals that have been approved for unescorted access.

RH-11044. Reserved.

RH-11045. **LLEA Coordination**.

a. A licensee subject to this Part shall coordinate, to the extent practicable, with an LLEA for responding to threats to the licensee's facility, including any necessary armed response. The information provided to the LLEA must include:

1. A description of the facilities and the category 1 and category 2 quantities of radioactive materials along with a description of the licensee's security measures that have been implemented to comply with this Part; and

2. A notification that the licensee will request a timely armed response by the LLEA to any actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of material.

b. The licensee shall notify the Department as specified in RH-11007. within three (3) business days if:

1. The LLEA has not responded to the request for coordination within sixty (60) days of the coordination request; or

2. The LLEA notifies the licensee that the LLEA does not plan to participate in coordination activities.

~~RH-11045. (Cont'd)~~

c. The licensee shall document its efforts to coordinate with the LLEA. The documentation must be kept for three (3) years.

d. The licensee shall coordinate with the LLEA at a frequency not to exceed twelve (12) months and when changes to the facility design or operation

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adversely affect the potential vulnerability of the licensee's material to theft, sabotage, or diversion.

RH-11046. Reserved.

RH-11047. **Security Zones**.

a. Licensees shall ensure that all aggregated category 1 and category 2 quantities of radioactive material are used or stored within licensee-established security zones. Security zones may be permanent or temporary.

b. Temporary security zones must be established as necessary to meet the licensee's transitory or intermittent business activities, such as periods of maintenance, source delivery, and source replacement.

c. Security zones must, at a minimum, allow unescorted access only to approved individuals through:

1. Isolation of category 1 and category 2 quantities of radioactive materials by the use of continuous physical barriers that allow access to the security zone only through established access control points. A physical barrier is a natural or man-made structure or formation sufficient for the isolation of the category 1 or category 2 quantities of radioactive material within a security zone; or

2. Direct control of the security zone by approved individuals at all times; or

3. A combination of continuous physical barriers and direct control.

~~RH-11047. (Cont'd)~~

d. For category 1 quantities of radioactive material during periods of maintenance, source receipt, preparation for shipment, installation, or source removal or exchange, the licensee shall, at a minimum, provide sufficient individuals approved for unescorted access to maintain continuous surveillance of sources in temporary security zones and in any security zone in which physical barriers or intrusion detection systems have been disabled to allow such activities.

e. Individuals not approved for unescorted access to category 1 or category 2 quantities of radioactive material must be escorted by an approved individual when in a security zone.

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RH-11048. Reserved.

RH-11049. **Monitoring, Detection, and Assessment**.

a. **Monitoring and detection**.

1. Licensees shall establish and maintain the capability to continuously monitor and detect without delay all unauthorized entries into its security zones. Licensees shall provide the means to maintain continuous monitoring and detection capability in the event of a loss of the primary power source, or provide for an alarm and response in the event of a loss of this capability to continuously monitor and detect unauthorized entries.

2. Monitoring and detection must be performed by:

A. A monitored intrusion detection system that is linked to an onsite or offsite central monitoring facility; or

B. Electronic devices for intrusion detection alarms that will alert nearby facility personnel; or

C. A monitored video surveillance system; or

D. Direct visual surveillance by approved individuals located within the security zone; or

E. Direct visual surveillance by a licensee designated individual located outside the security zone.

~~RH-11049.a. (Cont'd)~~

3. A licensee subject to this Part shall also have a means to detect unauthorized removal of the radioactive material from the security zone. This detection capability must provide:

A. For category 1 quantities of radioactive material, immediate detection of any attempted unauthorized removal of the radioactive material from the security zone. Such immediate detection capability must be provided by:

i. Electronic sensors linked to an alarm; or

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ii. Continuous monitored video surveillance; or

iii. Direct visual surveillance.

B. For category 2 quantities of radioactive material, weekly verification through physical checks, tamper indicating devices, use, or other means to ensure that the radioactive material is present.

b. **Assessment**.

Licensees shall immediately assess each actual or attempted unauthorized entry into the security zone to determine whether the unauthorized access was an actual or attempted theft, sabotage, or diversion.

c. **Personnel communications and data transmission**.

For personnel and automated or electronic systems supporting the licensee's monitoring, detection, and assessment systems, licensees shall:

1. Maintain continuous capability for personnel communication and electronic data transmission and processing among site security systems; and

2. Provide an alternative communication capability for personnel, and an alternative data transmission and processing capability, in the event of a loss of the primary means of communication or data transmission and processing. Alternative communications and data transmission systems may not be subject to the same failure modes as the primary systems.

~~RH-11049. (Cont'd)~~

d. **Response**.

Licensees shall immediately respond to any actual or attempted unauthorized access to the security zones, or actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material at licensee facilities or temporary job sites. For any unauthorized access involving an actual or attempted theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material, the licensee's response shall include requesting, without delay, an armed response from the LLEA.

RH-11050. Reserved.

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RH-11051. **Maintenance and Testing**.

a. Each licensee subject to this Part shall implement a maintenance and testing program to ensure that intrusion alarms, associated communication systems, and other physical components of the systems used to secure or detect unauthorized access to radioactive material are maintained in operable condition and are capable of performing their intended function when needed. The equipment relied on to meet the security requirements of this Part must be inspected and tested for operability and performance in accordance with manufacturer's specifications and at the manufacturer's suggested frequency. The licensee shall maintain documentation providing the manufacturer's specifications regarding inspections and testing as well as the recommended inspection and testing frequencies. If the manufacturer's specifications are unobtainable, documentation of the effort to obtain the specifications shall be maintained. If there is no manufacturer's suggested frequency, inspections and testing must be performed at a frequency not to exceed twelve (12) months.

b. The licensee shall maintain a record of each maintenance, inspection, or testing activity for three (3) years. The record must include the date of the activity; what type of activity was performed; the equipment involved; the results of the activity; the name of the individual who conducted the activity; and what repair ~~and/or~~ or maintenance, if any, was performed.

RH-11052. Reserved.

RH-11053. **Requirements for Mobile Devices**.

Each licensee that possesses mobile devices containing category 1 or category 2 quantities of radioactive material must:

a. Have two independent physical controls that form tangible barriers to secure the material from unauthorized removal when the device is not under direct control and constant surveillance by the licensee; and

b. For devices in or on a vehicle or trailer, unless the health and safety requirements for a site prohibit the disabling of the vehicle, the licensee shall utilize a method to disable the vehicle or trailer when not under direct control and constant surveillance by the licensee. Licensees shall not rely on the removal of an ignition key to meet this requirement.

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RH-11054. Reserved.

RH-11055. **Security Program Review**.

a. Each licensee shall be responsible for the continuing effectiveness of the security program. Each licensee shall ensure that the security program is reviewed to confirm compliance with the requirements of this Part and that comprehensive actions are taken to correct any noncompliance that is identified. The review must include the radioactive material security program content and implementation. Each licensee shall periodically (at least annually) review the security program content and implementation.

b. The results of the review, along with any recommendations, must be documented. Each review report must identify conditions that are adverse to the proper performance of the security program, the cause of the condition(s), and, when appropriate, recommend corrective actions, and corrective actions taken. The licensee shall review the findings and take any additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.

c. The licensee shall maintain the review documentation for three (3) years.

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RH-11056. Reserved.

RH-11057. **Reporting of Events**.

a. The licensee shall immediately notify the LLEA after determining that an unauthorized entry resulted in an actual or attempted theft, sabotage, or diversion of a category 1 or category 2 quantity of radioactive material. As soon as possible after initiating a response, but not at the expense of causing delay or interfering with the LLEA response to the event, the licensee shall notify the Department by telephone at 1-800-633-1735. In no case shall the notification to the Department be later than four (4) hours after the discovery of any attempted or actual theft, sabotage, or diversion.

b. The licensee shall assess any suspicious activity related to possible theft, sabotage, or diversion of category 1 or category 2 quantities of radioactive material and notify the LLEA as appropriate. As soon as possible but not later than four (4) hours after notifying the LLEA, the licensee shall notify the Department by telephone at 1-800-633-1735.

c. The initial telephone notification required by paragraph a. of this section must be followed within a period of thirty (30) days by a written report submitted to the Department by an appropriate method listed in RH-

11007. -The report must include sufficient information for Department analysis and evaluation, including identification of any necessary corrective actions to prevent future instances.

RH-11058.- RH-11069.– _Reserved.

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PART D.
PHYSICAL PROTECTION IN TRANSIT

RH-11070. Reserved.

RH-11071. **Additional Requirements for Transfer of Category 1 and Category 2 Quantities of Radioactive Material**.

A licensee transferring a category 1 or category 2 quantity of radioactive material to a licensee of the Department, U.S. Nuclear Regulatory Commission, or an Agreement State shall meet the license verification provisions listed below instead of those listed in RH-501.c.:

a. Any licensee transferring category 1 quantities of radioactive material to a licensee of the Department, U.S. Nuclear Regulatory Commission, or an Agreement State, prior to conducting such transfer, shall verify with the NRC's license verification system or the license issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred and that the licensee is authorized to receive radioactive material at the location requested for delivery.

If the verification is conducted by contacting the license issuing authority, the transferor shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

b. Any licensee transferring category 2 quantities of radioactive material to a licensee of the Department, U.S. Nuclear Regulatory Commission, or an Agreement State, prior to conducting such transfer, shall verify with the NRC's license verification system or the license issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred. If the verification is conducted by contacting the license issuing authority, the transferor shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

~~RH-11071. (Cont'd)~~

c. In an emergency where the licensee cannot reach the license issuing authority and the license verification system is nonfunctional, the licensee may accept a written certification by the transferee that it is authorized by license to receive the type, form, and quantity of radioactive material to be transferred. The certification must include the license number, current revision number, issuing agency, expiration date, and for a category 1

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shipment the authorized address. -The licensee shall keep a copy of the certification. -The certification must be confirmed by use of the NRC's license verification system or by contacting the license issuing authority by the end of the next business day.

d. The transferor shall keep a copy of the verification documentation as a record for three (3) years.

RH-11072. Reserved.

RH-11073. **Applicability of Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material During Transit**.

a. For shipments of category 1 quantities of radioactive material, each shipping licensee shall comply with the requirements for physical protection contained in RH-11075.a. and e.; RH-11077.; RH-11079.a.1., b.1., and c.; and RH-11081.a., c., e., g., and h.

b. For shipments of category 2 quantities of radioactive material, each shipping licensee shall comply with the requirements for physical protection contained in RH-11075.b. through e.; RH-11079.a.2., a.3., b.2., and c.; and RH-11081.b., d., f., g., and h. -For those shipments of category 2 quantities of radioactive material that meet the criteria of RH-3509.b., the shipping licensee shall also comply with the advance notification provisions of RH-3509.

c. The shipping licensee shall be responsible for meeting the requirements of this Part unless the receiving licensee has agreed in writing to arrange for the in-transit physical protection required under this Part.

d. Each licensee that imports or exports category 1 quantities of radioactive material shall comply with the requirements for physical protection during transit contained in RH-11075.a.2. and e.; RH-11077.; RH-11079.a.1., b.1., and c.; and RH-11081.a., c., e., g., and h. for the domestic portion of the shipment.

~~RH-11073. (Cont'd)~~

e. Each licensee that imports or exports category 2 quantities of radioactive material shall comply with the requirements for physical protection during transit contained in RH-11079.a.2., a.3., and b.2.; and RH-11081.b., d., f., g., and h. for the domestic portion of the shipment.

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RH-11074. Reserved.

RH-11075. **Preplanning and Coordination of Shipment of Category 1 or Category 2 Quantities of Radioactive Material**.

a. Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a category 1 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall:

1. Preplan and coordinate shipment arrival and departure times with the receiving licensee;

2. Preplan and coordinate shipment information with the Department and with the governor or the governor's designee of any State through which the shipment will pass to:

A. Discuss the State's intention to provide law enforcement escorts; and

B. Identify safe havens; and

3. Document the preplanning and coordination activities.

b. Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a category 2 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall coordinate the shipment no-later-than arrival time and the expected shipment arrival with the receiving licensee. -The licensee shall document the coordination activities.

c. Each licensee who receives a shipment of a category 2 quantity of radioactive material shall confirm receipt of the shipment with the originator. -If the shipment has not arrived by the no-later-than arrival time, the receiving licensee shall notify the originator.

~~RH-11075. (Cont'd)~~

d. Each licensee, who transports or plans to transport a shipment of a category 2 quantity of radioactive material, and determines that the shipment will arrive after the no-later-than arrival time provided pursuant to paragraph b. of this section, shall promptly notify the receiving licensee of the new no-later-than arrival time.

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e. The licensee shall retain a copy of the documentation for preplanning and coordination and any revision thereof, as a record for three (3) years.

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RH-11076. Reserved.

RH-11077. **Advance Notification of Shipment of Category 1 Quantities of Radioactive Material**.

As specified in paragraphs a. and b. of this section, each licensee shall provide advance notification to the Department and to the governor of a State, or the governor's designee, of the shipment of licensed material in a category 1 quantity, through or across the boundary of the State, before the transport, or delivery to a carrier for transport, of the licensed material outside the confines of the licensee's facility or other place of use or storage.

a. **Procedures for submitting advance notification**.

1. The notification must be made to the Department and to the office of each appropriate governor or governor's designee. The contact information, including telephone and mailing addresses, of the Department and of governors and governors' designees, is available on the U.S. Nuclear Regulatory Commission website at https://scp.nrc.gov/special/designee.pdf. A list of the contact information is also available upon request from the Department. The notification to the Department may be made by email to Communication.Center@arkansas.gov.

2. A notification delivered by mail must be postmarked at least seven (7) days before transport of the shipment commences at the shipping facility.

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3. A notification delivered by any means other than mail must reach the Department at least four (4) days before the transport of the shipment commences and must reach the office of the governor or the governor's designee at least four (4) days before transport of a shipment within or through the State.

~~RH-11077. (Cont'd)~~

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b. **Information to be furnished in advance notification of shipment**.

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Each advance notification of shipment of category 1 quantities of radioactive material must contain the following information, if available at the time of notification:

1. The name, address, and telephone number of the shipper, carrier, and receiver of the category 1 radioactive material;

2. The license numbers of the shipper and receiver;

3. A description of the radioactive material contained in the shipment, including the radionuclides and quantity;

4. The point of origin of the shipment and the estimated time and date that shipment will commence;

5. The estimated time and date that the shipment is expected to enter each State along the route;

6. The estimated time and date of arrival of the shipment at the destination; and

7. A point of contact, with a telephone number, for current shipment information.

c. **Revision notice**.

1. The licensee shall provide any information not previously available at the time of the initial notification, as soon as the information becomes available but not later than commencement of the shipment, to the governor of the State or the governor's designee and to the Department.

2. A licensee shall promptly notify the governor of the State or the governor's designee of any changes to the information provided in accordance with paragraphs b. and c.1. of this section. The licensee shall also immediately notify the Department of any such changes.

~~RH 11077. (Cont'd)~~

d. **Cancellation notice**.

Each licensee who cancels a shipment for which advance notification has been sent shall send a cancellation notice to the governor of each State or to the governor's designee previously notified and to the Department. The licensee shall send the cancellation notice before the shipment would have commenced or as soon thereafter as possible. The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being cancelled.

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e. **Records**.

The licensee shall retain a copy of the advance notification and any revision and cancellation notices as a record for three (3) years.

f. **Protection of information.**

State officials, State employees, and other individuals, whether or not licensees of the Department, the NRC, or of an Agreement State, who receive schedule information of the kind specified in RH-11077.b. shall protect that information against unauthorized disclosure as specified in RH-11043.d.

RH-11078. Reserved.

RH-11079. **Requirements for Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material During Shipment**.

a. **Shipments by road**.

1. Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 1 quantity of radioactive material shall:

A. Ensure that movement control centers are established that maintain position information from a remote location. These control centers must monitor shipments 24 hours a day, 7 days a week, and have the ability to communicate immediately, in an emergency, with the appropriate law enforcement agencies.

~~RH-11079.a.1. (Cont'd)~~

B. Ensure that redundant communications are established that allow the transport to contact the escort vehicle (when used) and movement control center at all times. Redundant communications may not be subject to the same interference factors as the primary communication.

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C. Ensure that shipments are continuously and actively monitored by a telemetric position monitoring system or an alternative tracking system reporting to a movement control center. A movement control center must provide positive confirmation of the location, status, and control over the shipment. The movement control center must be prepared to promptly implement preplanned procedures in response to deviations from the authorized route or a notification of actual, attempted, or suspicious activities related to the theft, loss, or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route.

D. Provide an individual to accompany the driver for those highway shipments with a driving time period greater than the maximum number of allowable hours of service in a 24-hour duty day as established by the Department of Transportation Federal Motor Carrier Safety Administration. The accompanying individual may be another driver.

E. Develop written normal and contingency procedures to address:

i. Notifications to the communication center and law enforcement agencies;

ii. Communication protocols. Communication protocols must include a strategy for the use of authentication codes and duress codes and provisions for refueling or other stops, detours, and locations where communication is expected to be temporarily lost;

iii. Loss of communications; and

iv. Responses to an actual or attempted theft or diversion of a shipment.

~~RH 11079.a.1. (Cont'd)~~

F. Each licensee who makes arrangements for the shipment of category 1 quantities of radioactive material shall ensure that drivers, accompanying personnel, and movement control center personnel have access to the normal and contingency procedures.

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2. Each licensee that transports category 2 quantities of radioactive material shall maintain constant control ~~and/or~~ or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance.

3. Each licensee who delivers to a carrier for transport, in a single shipment, a category 2 quantity of radioactive material shall:

A. Use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control ~~and/or~~ or surveillance, the package tracking system must allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control.

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B. Use carriers that maintain constant control ~~and/or~~ or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and

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C. Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

b. **Shipments by rail**.

1. Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 1 quantity of radioactive material shall:

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A. Ensure that rail shipments are monitored by a telemetric position monitoring system or an alternative tracking system reporting to the licensee, third-party, or railroad communications center. The communications center shall provide positive confirmation of the location of the shipment and its status. The communications center shall

~~RH-11079.b.1.A. (Cont'd)~~

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implement preplanned procedures in response to deviations from the authorized route or to a notification of actual, attempted, or suspicious activities related to the theft or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact

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information for the appropriate LLEA along the shipment route.

B. Ensure that periodic reports to the communications center are made at preset intervals.

2. Each licensee who transports, or delivers to a carrier for transport, in a single shipment, a category 2 quantity of radioactive material shall:

A. Use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control ~~and/or~~ or surveillance, the package tracking system must allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control.

B. Use carriers that maintain constant control ~~and/or~~ or surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and

C. Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

c. **Investigations**.

Each licensee who makes arrangements for the shipment of category 1 quantities of radioactive material shall immediately conduct an investigation upon the discovery that a category 1 shipment is lost or missing. Each licensee who makes arrangements for the shipment of category 2 quantities of radioactive material shall immediately conduct an investigation, in coordination with the receiving licensee, of any shipment that has not arrived by the designated no-later-than arrival time.

RH-11080. Reserved.

RH-11081. **Reporting of Events**.

a. The shipping licensee shall notify the appropriate LLEA and the Department (1-800-633-1735) within one (1) hour of its determination that

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a shipment of category 1 quantities of radioactive material is lost or missing. The appropriate LLEA would be the law enforcement agency in the area of the shipment's last confirmed location. During the investigation required by RH-11079.c., the shipping licensee will provide agreed upon updates to the Department on the status of the investigation.

b. The shipping licensee shall notify the Department (1-800-633-1735) within four (4) hours of its determination that a shipment of category 2 quantities of radioactive material is lost or missing. If, after 24 hours of its determination that the shipment is lost or missing, the radioactive material has not been located and secured, the licensee shall immediately notify the Department.

c. The shipping licensee shall notify the designated LLEA along the shipment route as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment or suspicious activities related to the theft or diversion of a shipment of a category 1 quantity of radioactive material. As soon as possible after notifying the LLEA, the licensee shall notify the Department (1-800-633-1735) upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment of category 1 radioactive material.

d. The shipping licensee shall notify the Department (1-800-633-1735) as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment, of a category 2 quantity of radioactive material.

e. The shipping licensee shall notify the Department (1-800-633-1735) and the LLEA as soon as possible upon recovery of any lost or missing category 1 quantities of radioactive material.

f. The shipping licensee shall notify the Department (1-800-633-1735) as soon as possible upon recovery of any lost or missing category 2 quantities of radioactive material.

g. The initial telephone notification required by paragraphs a. through d. of this section must be followed within a period of thirty (30) days by a written report submitted to the Department by an appropriate method listed in RH-11007. A written report is not required for notifications on

~~RH-11081.g. (Cont'd)~~

suspicious activities required by paragraphs c. and d. of this section. The report must set forth the following information, as appropriate:

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1. A description of the licensed material involved, including kind, quantity, and chemical and physical form;

2. A description of the circumstances under which the loss, theft, etc. occurred;

3. A statement of disposition, or probable disposition, of the licensed material involved;

4. Actions that have been taken, or will be taken, to recover the material; and

5. Procedures or measures that have been, or will be, adopted to ensure against a recurrence of this type of event.

h. Subsequent to filing the written report, the licensee shall also report, by an appropriate method listed in RH-11007., any additional substantive information on the event within thirty (30) days after the licensee learns of such information.

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RH-11082.- RH-11099. _–Reserved.

PART E.
[RESERVED]

RH-11100.- RH-11199.– _Reserved.

PART F.
RECORDS

RH-11200. **Form of Records**.

Each record required by this Section must be legible throughout the retention period specified by each Department rule. The record may be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

RH-11201. Reserved.

RH-11202. **Record Retention**.

Licensees shall maintain the records that are required by the rules in this Section for the period specified by the appropriate rule. If a retention period is not otherwise specified, these records must be retained until the Department terminates the facility's license. All records related to this Section may be destroyed upon Department termination of the facility license.

RH-11203. - RH-11299. Reserved.

PART G.
ENFORCEMENT

RH-11300. **Inspections**.

a. Each licensee shall afford to the Department at all reasonable times opportunity to inspect category 1 or category 2 quantities of radioactive material and the premises and facilities wherein such radioactive material is used, produced, or stored.

b. Each licensee shall make available to the Department for inspection, upon reasonable notice, records kept by the licensee pursuant to these Rules.

RH-11301. **Violations**.

An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any rule or order issued thereunder. Any person who willfully violates any provision of the Act or any rule or order issued thereunder may be guilty of a felony, misdemeanor, or crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law. Arkansas Code Annotated §20-21-204 describes criminal and civil penalties which may be assessed.

RH-11302.- RH-11999. Reserved.

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APPENDIX A TO SECTION 12

CATEGORY 1 AND CATEGORY 2 RADIOACTIVE MATERIALS

TABLE 1—CATEGORY 1 AND CATEGORY 2 THRESHOLDS

The terabecquerel (TBq) values are the regulatory standard. The curie (Ci) values specified are obtained by converting from the TBq value. The curie values are provided for practical usefulness only.

Radioactive material	Category 1 (TBq)	Category 1 (Ci)	Category 2 (TBq)	Category 2 (Ci)
Americium-241	60	1,620	0.6	16.2
Americium-241/Be	60	1,620	0.6	16.2
Californium-252	20	540	0.2	5.40
Cobalt-60	30	810	0.3	8.10
Curium-244	50	1,350	0.5	13.5
Cesium-137	100	2,700	1	27.0
Gadolinium-153	1,000	27,000	10	270
Iridium-192	80	2,160	0.8	21.6
Plutonium-238	60	1,620	0.6	16.2
Plutonium-239/Be	60	1,620	0.6	16.2
Promethium-147	40,000	1,080,000	400	10,800
Radium-226	40	1,080	0.4	10.8
Selenium-75	200	5,400	2	54.0
Strontium-90	1,000	27,000	10	270
Thulium-170	20,000	540,000	200	5,400
Ytterbium-169	300	8,100	3	81.0

Note: Calculations Concerning Multiple Sources or Multiple Radionuclides

The "sum of fractions" methodology for evaluating combinations of multiple sources or multiple radionuclides is to be used in determining whether a location meets or exceeds the threshold and is thus subject to the requirements of this Section.

I. If multiple sources of the same radionuclide ~~and/or~~ or multiple radionuclides are aggregated at a location, the sum of the ratios of the total activity of each of the radionuclides must be determined to verify whether the activity at the location is less than the category 1 or category 2 thresholds of Table 1, as appropriate. If the calculated sum of the ratios, using the equation below, is greater than or equal to 1.0, then the applicable requirements of this Section apply.

II. First, determine the total activity for each radionuclide from Table 1. This is done by adding the activity of each individual source, material in any device, and any loose or bulk material that contains the radionuclide. Then use the equation below to calculate the sum of the ratios by inserting the total activity of the applicable radionuclides from Table 1 in the numerator of the equation and the corresponding threshold activity from Table 1 in the denominator of the equation. Calculations must be performed in metric values (i.e., TBq) and the numerator and denominator values must be in the same units.

R_1 = total activity for radionuclide 1
R_2 = total activity for radionuclide 2
R_N = total activity for radionuclide n

AR_1 = activity threshold for radionuclide 1
AR_2 = activity threshold for radionuclide 2
AR_N = activity threshold for radionuclide n

$$\frac{R_1}{AR_1} + \frac{R_2}{AR_2} + \cdots + \frac{R_n}{AR_n} \geq 1.0$$

SECTION 13.

NON-HEALING ARTS USE OF MACHINE-PRODUCED RADIATION – RADIATION GENERATING DEVICES

PART A. GENERAL

RH-12000. **Purpose**.

This Section provides special requirements for non-healing arts radiation generating devices (RGDs) operating between 5 kiloelectron volts (5 keV) and 1 million electron volts (1 MeV). Machines operating at energies usually in excess of 1 MeV are subject to Section 6, "Licenses and Radiation Safety Requirements for Particle Accelerators."

RH-12001. **Scope**.

a. In addition to the requirements of this Section, all registrants are subject to the requirements of Section 1, "Registration of Radiation Machine Facilities and Vendor Services"; Section 3, "Standards for Protection Against Radiation"; and Part N of Section 3, "Notices, Instructions, and Reports to Workers; Inspections." This Section does not contain radiation safety requirements for those sources of radiation that are explicitly covered in other sections of these Rules (e.g., Part I of Section 3, "Licenses and Registrations for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations"; Section 6, "Licenses and Radiation Safety Requirements for Particle Accelerators"; and Section 10, "Non-Therapeutic Use of Machine-Produced Radiation in the Healing Arts and Veterinary Medicine; Morgue, Educational, and Forensic Medicine Use").

b. RGDs are a broad class of equipment for non-healing arts purposes, generating x-rays or particle radiation with energies between 5 keV and 1 MeV. All RGDs shall comply with applicable U.S. Food and Drug Administration performance standards present in Title 21 of the Code of Federal Regulations, Subchapter J Examples of RGDs include, but are not limited to, open and closed analytical x-ray equipment (table top and hand-held), x-ray gauges, cabinet radiographic units, cabinet x-ray systems, security screening units, quality control application devices, flash x-ray systems, ion implantation devices, electron beam welders, cathodoluminescence systems, non-healing arts x-ray fluoroscopic units, x-ray bomb detection equipment, and x-ray irradiators.

This Section does not prescribe safety parameters by what type of work the radiation machine performs (analytical, gauging, etc.) but classifies by

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hazard (open-beam versus closed-beam) or dose rate. Industrial radiography that is open-beam, and not in a shielded room as defined in RH-12100., and not otherwise described in this Section, shall be regulated under Part I of Section 3.

RH-12002. **Communications**.

Except where otherwise specified, all communications concerning these Rules may be addressed to the Arkansas Department of Health, Radiation Control Section, 4815 West Markham Street, Slot 30, Little Rock, Arkansas, 72205-3867.

RH-12003. **Interpretations**.

Except as specifically authorized by the Department in writing, no interpretations of the meaning of the rules in this Section by an officer or employee of the Department other than a written interpretation by the Department Director or designee will be recognized as binding upon the Department.

RH-12004.- 12099. Reserved.

PART B.
DEFINITIONS

RH-12100. **Definitions**.

Accessible surface - The external or outside surface of the enclosure or housing provided by the manufacturer. This includes the high-voltage generator, doors, access panels, latches, control knobs, and other permanently mounted hardware and including the plane across the exterior edge of any opening.

Analytical x-ray equipment - Equipment that generates (by electronic means) and uses ionizing radiation for the purpose of examining the microstructure of materials, i.e., diffraction and spectroscopy (including fluorescence).

Baggage unit - See "security screening unit."

Beam-port - An opening on the x-ray apparatus designed to emit a primary beam. This does not include openings on baggage units.

Bomb detection radiographic equipment - X-ray generating equipment used solely for the purpose of remotely detecting explosive devices. This definition does not include hand-held x-ray bomb detection equipment for the purposes of this Section.

Cabinet radiography - Industrial radiography using radiation machines not subject to U.S. Food and Drug Administration performance standards for cabinet

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x-ray systems, conducted in an enclosed, interlocked cabinet in which the portion of a material being irradiated is contained, and in which:

1. The radiation machine will not operate unless all openings are closed with interlocks activated;

2. The cabinet is shielded such that every location on the exterior meets the conditions for an unrestricted area specified in Section 3; and

3. The cabinet is constructed or arranged as to exclude the entrance of any part of the body of an individual during irradiation.

Cabinet x-ray system - An x-ray system with the x-ray tube installed in an enclosure which, independently of existing architectural structures except the floor on which it may be placed, is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of x-radiation. An x-ray tube used within a shielded part of a building, or x-ray equipment which may temporarily or occasionally incorporate portable shielding, is not a cabinet x-ray system.

Certified cabinet x-ray system - An RGD certified by the manufacturer in accordance with 21 CFR 1010.2 as being manufactured and assembled pursuant to the provisions of applicable federal radiation safety performance standards 21 CFR 1010 and 1020.40.

Certifiable cabinet x-ray system - An existing uncertified RGD that has been modified to meet the certification requirements specified in 21 CFR 1020.40.

Closed-beam x-ray equipment - A system in which the beam path cannot be entered by any part of the body during normal operation.

Collimator - A device for restricting the useful radiation in one or more directions.

Control panel - A device containing means for regulation and activation of an RGD or for the preselection and indications of operating factors.

Emergency procedure - The written pre-planned steps to be taken in the event of actual or suspected exposure of an individual in excess of administrative or regulatory limits. This procedure shall include the names and telephone numbers of individuals to be contacted as well as directives for processing the film badge or other personnel monitoring devices.

Fail-safe design - A design in which all realistically anticipated failures of indicators or safety components result in a condition in which individuals are safe from exposure to radiation. For example, if a light indicating "**X-RAY ON**" fails,

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the production of x-rays shall be prevented, or if a shutter status indicator fails, the shutter shall close.

General-use system - A personnel screening system that delivers an effective dose equal to or less than 25 µrem (0.25 µSv) per screening. Given proper justification and certain restrictions, general-use systems may be operated without specific controls that would limit the number of individuals scanned or the number of scans per individual in a year.

Hand-held x-ray system - A portable instrument that is designed to operate when held in the hand, e.g., hand-held XRF analytical devices.

Industrial radiography - An examination of the structure of materials by nondestructive methods utilizing ionizing radiation to make radiographic images.

Interlock - A device or engineered system that precludes access to an area of radiation hazard either by preventing entry or by automatically removing the hazard.

Leakage radiation - All radiation coming from within the source housing, except the useful beam.

Limited-use system - A personnel screening system that is capable of delivering an effective dose greater than 25 µrem (0.25 µSv) per screening but cannot exceed an effective dose of 1 mrem (10 µSv) per screening. Limited-use systems require additional controls and documentation to ensure the annual individual dose limit given in RH-12212.d. is not exceeded.

Local components - Part of an RGD x-ray system that includes those components that are struck by x-rays such as radiation source housings, beam-port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors, and shielding, but does not include power supplies, transformers, amplifiers, readout devices, and control panels.

Mobile equipment - See "radiation generating device."

Mode of operation – For RGDs under RH-12212., a selectable set of technique factors or machine settings that is pre-determined by the manufacturer for a specific purpose.

Normal operating procedures - Step-by-step instructions necessary to accomplish the task. These procedures are written in relation to radiation safety and may include sample insertion and manipulation, equipment alignment, routine maintenance by the registrant, and data recording procedures.

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Open-beam x-ray equipment - An open-beam x-ray system in which the beam path could be entered by any part of the body at any time.

Personnel security screening system - Any x-ray equipment used on humans for security evaluation.

Portable equipment - See "radiation generating device."

Primary beam - The ionizing radiation coming directly from the radiation source through a beam-port into the volume defined by the collimation system.

Qualified Expert - An individual specifically approved by the Department as having the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection matters. Individuals shall be certified in an appropriate field, commensurate with his or her duties, either by the American Board of Radiology, the American Board of Health Physics, the American Board of Medical Physics, or the Canadian College of Physicists in Medicine, or individuals may have equivalent qualifications. An individual that meets the qualifications in RH-10200.d. for a Qualified Medical Physicist also meets the qualifications of a Qualified Expert.

Radiation generating device (RGD) - Any system, device, subsystem, or component thereof that may generate x-rays or particle radiation between 5 keV and 1 MeV and that is not intended for healing arts use. RGD equipment may be described as:

1. Mobile - mounted on a permanent base with wheels or casters for moving while completely assembled;

2. Portable - designed to be hand-carried;

3. Stationary - installed or placed in a fixed location; or

4. Transportable - installed in a vehicle or readily disassembled for transport or use in a vehicle.

Radiation Safety Officer (RSO) - An individual who has the knowledge and responsibility to apply appropriate radiation protection rules and has been assigned such responsibility by the registrant. Qualifications of the individual shall be submitted for Department approval with the application in accordance with RH-21.c. Notification of a change in the designation of the RSO shall be submitted in accordance with RH-26.

Radiation source (or x-ray tube) housing - That portion of an x-ray system which contains the x-ray tube or x-ray emitting target. Often the housing contains radiation shielding material or inherently provides shielding.

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Radiograph - A permanent film or digital image produced on a sensitive surface by a form of radiation other than direct visible light.

Radiography - The process of creating radiographic images.

Safety device - A device, interlock, or system that prevents the entry of any portion of an individual's body into the primary x-ray beam or that causes the beam to shut off upon entry into its path.

Scan – For RGDs under RH-12212., the operation necessary to produce one image (e.g., front view) from one radiation source. One radiation source simultaneously producing multiple images also constitutes one scan. Two sources simultaneously producing two images constitute two scans. In some cases, several scans may be required for a single screening of the subject.

Scattered radiation - Radiation that has been deviated in direction or energy by passing through matter.

Screening – For RGDs under RH-12212., the sum of radiation exposures or scans necessary to image objects concealed on all sides of the body as intended by the system design under normal conditions:

1. For backscatter systems, a screening typically consists of four scans, one from each side.

2. For transmission systems, a screening typically consists of one scan.

3. For portal systems, a screening consists of a complete pass through the inspection zone.

Security screening unit - A non-human use open-beam or cabinet x-ray system with accessible openings designed for the detection of weapons, bombs, or contraband concealed in baggage, mail, packages, or other commodities or structure.

Shielded room - A room housing an RGD where, with the RGD at maximum techniques, areas adjacent to the room meet the RH-1208. limits of 2 mrem (0.02 mSv) in any one hour and 100 mrem (1 mSv) in a year at thirty (30) cm from the barrier. A shielded room does not include an RGD which meets the definition of cabinet x-ray system.

Shutter - A moveable device used to block the useful (or primary) beam emitted from an x-ray tube assembly.

Source - The point of origin of the radiation, e.g., the focal spot of an x-ray tube.

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Stationary equipment - See "radiation generating device."

Stray radiation - The sum of leakage and scattered radiation.

Technique factors – For RGDs under RH-12212., the x-ray settings including:

1. The peak kilovoltage applied to the x-ray tube;

2. The electric current passing through the x-ray tube; and

3. The scan time.

Warning device - A visible or audible signal that warns individuals of a potential radiation hazard.

X-ray generator - That portion of an x-ray system which produces the x-rays. Typically, this is the accelerating (high) voltage and current for the x-ray tube; however, it may also be a laser and a target.

X-ray gauge - An x-ray producing device designed and manufactured for the purpose of detecting, measuring, gauging, or controlling thickness, density, level, or interface location.

RH-12101.- RH-12199. Reserved.

PART C.
RADIATION SAFETY REQUIREMENTS FOR THE USE OF RGD'S

RH-12200. **General Regulatory Provisions**.

Unless otherwise provided in this Section 13, this section applies to all radiation generating devices (RGDs). Certified and certifiable cabinet x-ray systems as defined in this Section shall also meet the requirements of 21 CFR 1020.40.

a. **Warning devices**.

1. Warning devices shall be labeled so that their purpose is easily identified.

2. An easily visible warning device light labeled with the words "**X-RAY ON**," or words having a similar intent, shall be located near any switch that energizes an x-ray tube and shall be illuminated only when the tube is energized. This warning light shall be of a fail-safe design.

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b. **Labeling**.

1. All RGD equipment shall be labeled with a readily visible and discernible sign or signs bearing the radiation symbol (prescribed in RH-1303.) and the words, or words having a similar intent, near any switch that energizes an x-ray tube.

"CAUTION RADIATION – THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED"

2. For RGDs with designed openings, for object entries (such as baggage units), the following shall be posted at or near each opening: or words having a similar intent.

"CAUTION – X-RAY HAZARD: DO NOT INSERT ANY PART OF THE BODY WHEN SYSTEM IS ENERGIZED"

c. **Radiation source housing**.

Each x-ray tube housing shall be subject to the following requirements:

1. **Interlock**.
When the x-ray tube housing is the primary shielding for the x-ray tube, and is intended to be opened for normal use or maintenance, the housing shall be equipped with an interlock that shuts off the high voltage to the x-ray tube if the housing is opened; and

2. **Radiation emission limit**.

Each x-ray tube housing shall be so constructed that, with all shutters closed, the leakage radiation measured at a distance of five (5) centimeters from the x-ray tube housing surface does not exceed 2.5 mrem (25 µSv) per hour. This limit shall be met at the maximum tube rating.

For closed-beam systems, this requirement is met by complying with the radiation emission limit in RH-12205.d. For an RGD in a shielded room, compliance with the limit shall be determined by measurements made at accessible surfaces outside the room housing the RGD. For hand-held, open-beam RGDs, this requirement is met by complying with the limits in RH-12207.b.

d. **Generator cabinet or high-voltage source radiation emission limits**.

Each x-ray generator or high-voltage source shall be supplied with a protective cabinet which limits leakage radiation to 0.25 mrem (2.5 µSv)

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per hour at a distance of five (5) centimeters measured at the nearest accessible surface. For closed-beam systems, this requirement is met by complying with the radiation emission limit in RH-12205.d. For an RGD in a shielded room with the high-voltage generator also inside the shielded room, compliance with the limit shall be determined by measurements made at accessible surfaces outside the room housing the RGD. For hand-held, open-beam RGDs, this requirement is met by complying with the limits in RH-12207.b.

e. **Surveys**.

1. Radiation surveys of all RGDs shall be sufficient to show compliance with radiation emission requirements of this Section, and as required by RH-1200., "Occupational Dose Limits for Adults," and RH-1208., "Dose Limits for Individual Members of the Public." Radiation surveys shall be sufficient to evaluate the magnitude and extent of radiation emissions and the potential radiological hazards that could be present. In addition to survey requirements prescribed in other sections, surveys shall be performed:

A. Upon installation of the equipment, and at least once every twelve (12) months thereafter;

B. Following any change in the initial arrangement, number, or type of local components in the system;

C. Following any maintenance requiring the disassembly, removal, or repair of a local component in the system;

D. During the performance of maintenance, calibration, and other procedures if the procedures require the presence of a primary x-ray beam while any local component in the system is disassembled or removed;

E. Post bypass of a safety device or interlock as required by RH-12200.j.2.;

F. Any time a visual inspection of the local components in the system reveals an abnormal condition; and

G. Whenever a personnel monitoring device shows a significant increase over a previous monitoring period or readings are approaching the limits specified in RH-1200.

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2. The registrant shall have access to sufficiently calibrated, appropriate, and operable radiation survey instruments to make physical radiation surveys as required by Section 13. The instruments shall be calibrated before first use, at intervals not to exceed twelve (12) months, and after instrument servicing, except for battery changes, for the types and levels of radiation involved (including primary, scattered, and leakage radiation). Records of calibrations shall be maintained for three (3) years.

3. Radiation survey measurements shall not be required if the Department approves alternate methods submitted by the registrant for demonstrating compliance with requirements in paragraph e. of this section.

f. **Personnel monitoring**.

1. In accordance with RH-1302., "Conditions Requiring Individual Monitoring of External and Internal Occupational Dose," each registrant shall monitor exposures to radiation at levels sufficient to demonstrate compliance with the occupational dose limits of Section 3, "Standards for Protection Against Radiation."

2. Documentation demonstrating compliance with RH-1302. shall be maintained for Department inspection.

3. Each registrant shall maintain records of doses received by all individuals for whom personnel monitoring is required under RH-1302. Such records shall be maintained in accordance with the provisions of RH-1500.

g. **Dose to individual members of the public**.

In accordance with RH-1500.g., each registrant shall maintain records sufficient to demonstrate compliance with the dose limits for individual members of the public. RH-1209. describes methods to demonstrate compliance.

h. **Posting**.

Each area or room containing an Radiation Generating Device (RGD) shall be conspicuously posted with a sign or signs bearing the radiation symbol (as described in RH-1303.a.) and the words or words having a similar intent.

"**CAUTION – X-RAY EQUIPMENT**" or "**CAUTION – RADIATION GENERATING DEVICE**"

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i. **Security and control.**

1. The registrant shall secure RGDs from unauthorized removal.

2. The registrant shall use devices or administrative procedures to prevent unauthorized use of RGDs.

i. **Operating requirements.**

1. **Procedures.**

A. Normal operating procedures shall be written and available to all RGD workers. No individual shall be permitted to operate an RGD in any manner other than that specified in the procedures unless such individual has obtained written approval of the Radiation Safety Officer (RSO).

B. Alignment procedures recommended by the manufacturer of the RGD shall be used when available.

2. **Bypassing.**

A. No individual shall bypass a safety device, interlock, or remove shielding unless such individual has obtained the approval of the RSO. Such approval shall be for a specified period of time.

B. When a safety device or interlock has been bypassed, a readily discernible sign bearing the words or words having a similar intent, shall be placed on the radiation source housing and at the control switch.

"SAFETY DEVICE NOT WORKING"

C. A record of any bypass of a safety device or interlock shall be maintained for five (5) years after the record is made. The record shall contain such information as the date the alteration was made, type of alteration, length of time the unit remained in the altered condition, post bypass survey and signature of the RSO, individual who made the alteration, and the individual who restored the unit to its original condition.

3. **Control panel.**

A. The RGD shall only be activated from a control panel.

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B. All indicators and controls that control the primary beam shall be identifiable and discernible through the use of labels, symbols, software displays, or the equivalent.

4. **Interlocks**.

A. An interlock shall not be used to de-activate the x-ray tube or RGD, except in an emergency or during testing of the interlock system.

B. After triggering any interlock, it shall be possible to reset the RGD to full operation only from a control panel.

C. All interlocks shall be of a fail-safe design.

5. **Multiple sources**.

If more than one x-ray tube assembly(s) or focal spot can be operated sequentially or simultaneously from a control panel, visual indicators shall identify which tube assembly(s) or focal spot has been selected. The selectors shall be identified as to their function. If a letter or number is used, a reference card or table explaining the code shall be affixed to the control panel.

k. **Repair or modification of x-ray tube or RGD systems**.

Only trained personnel or registered vendor service provider shall be permitted to install, repair, or make modifications to the RGD. No operation involving removal of covers, shielding materials or tube housings or modifications to shutters, collimators or beam stops shall be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored.

The main power switch with a lock-out or tag-out, rather than interlocks, shall be used for routine shutdown in preparation for repairs. It is the responsibility of the registrant to ensure that qualified personnel install, repair, or make modifications to the RGD.

l. **Testing of safety devices**.

1. Tests of all safety devices, such as interlocks, shutters, warning lights, and required emergency shut-off switches shall be conducted at intervals not to exceed six (6) months, as well as after significant changes or maintenance, on all operable RGDs.

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2. If any safety device fails during testing, the RGD shall be removed from service until the safety device failure is corrected or proper temporary administrative controls are established and approved in writing by the Radiation Safety Officer (RSO).

3. Records of testing shall include the date of the tests, the safety devices tested, survey instrument used, survey instrument calibration date, the results of the tests, the name of the person who performed the tests, and corrective actions taken for safety devices that failed the required test.

4. Records of testing shall be maintained for inspection by the Department for five (5) years after the record is made.

5. Testing of safety devices may be deferred if the unit or installation is clearly marked and kept out of service. Units or installations brought back into service after exceeding the six (6) month interval shall be tested prior to use.

6. If testing of a safety device cannot be performed due to manufacturer design, the registrant shall document that the safety device will not be tested and specifically why the safety device cannot be tested.

m. **Instruction and Training.**

1. The registrant shall document the scope of training required for the RGD they possess, in accordance with this paragraph. No individual shall be permitted to operate or maintain an RGD, or enter a shielded room, without appropriate instruction and training. Records of all required instruction and training shall be maintained for at least five (5) years beyond the last date the individual was subject to this paragraph. Each individual shall receive instruction in and demonstrate competence as to:

A. Types of radiation and identification of radiation hazards associated with the use of the RGD and associated equipment and precautions or measures to take to minimize radiation exposure;

B. Significance of the various radiation warning, safety devices, and interlocks incorporated into the equipment, or the reasons they have not been installed on certain pieces of equipment and the extra precautions required in such cases;

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C. Recognition of symptoms of an acute localized exposure, biological effects of radiation, and radiation risks, commensurate with potential hazards of use;

D. Normal operating procedures for each type of RGD and associated equipment, including receiving hands-on training, and procedures to prevent unauthorized use;

E. Procedures for reporting an actual or suspected accidental exposure or other radiation safety concerns, such as any unusual occurrence or malfunction that may involve exposure to radiation; and

F. Performing of surveys, where applicable.

2. In addition to the training requirements in paragraph m.1. of this section, the registrant shall provide refresher instruction and training at intervals not to exceed twelve (12) months and when a significant change occurs in duties, rules, or terms of the registration.

n. **Radiation protection responsibility**.

1. The registrant's senior management shall make the ultimate decision to use any RGD and be ultimately responsible for radiation safety.

2. The registrant's senior management shall designate a Radiation Safety Officer (RSO), who is responsible for implementing the radiation protection program required by RH-1004. This individual shall have direct access to senior management for radiation safety issues. The RSO shall have training and experience commensurate with the scope of the radiation protection program to carry out the following responsibilities:

A. Ensuring that all RGDs are operated within the limitations of the established radiation protection program and operating procedures;

B. Instructing personnel with regard to safe working practices and ensuring all personnel are trained in radiation safety commensurate with the hazards of the job;

C. Investigating any incident of abnormal operation or exposure or suspected overexposure of personnel to

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determine the cause, take remedial action, and report the incident to the proper authority;

D. Ensuring that safety devices, interlocks, warning signals, labels, postings, and signs are functioning and located where required; and

E. Maintaining all radiation safety records.

RH-12201.- RH-12204. Reserved.

RH-12205. **Additional Requirements for Closed-Beam RGDs.**

In addition to the requirements in RH-12200., the following requirements apply to all closed-beam RGDs:

a. **System enclosure.**

The radiation source, sample or object, detector, and analyzing crystal (if used) shall be enclosed in a chamber or coupled chambers that cannot be entered by any part of the body during normal operation.

b. **Interlocks.**

All doors and panels accessing the RGDs shall be interlocked. The interlocks required by this paragraph shall be of a fail-safe design.

c. **Interlock functions.**

The system enclosure, sample chamber, etc. closure shall be interlocked with the x–ray source power supply or a shutter in the primary beam so that no x-ray beam can enter the sample or object chamber while it is open unless the interlock has been conspicuously and deliberately defeated. The interlock required by this paragraph shall be of fail-safe design or adequate administrative controls shall be exercised to ensure operations will not continue without a proper functioning interlock.

d. **Radiation emission limit.**

The radiation emission for all closed-beam RGDs shall not exceed 0.5 mrem (5 µSv) in one hour at five (5) centimeters outside any accessible surface.

e. **Security screening units.**

Security screening units shall be provided with means to ensure operator presence at the control area in a position which permits surveillance of the

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openings and doors during generation of x-radiation. The means shall be in compliance, as applicable, with the following:

1. During an exposure or preset succession of exposures of one-half second or greater duration, the means provided shall enable the operator to terminate the exposure or preset succession of exposures at any time.

2. During an exposure or preset succession of exposures of less than one-half second duration, the means provided may allow completion of the exposure in progress but shall enable the operator to prevent additional exposures.

RH-12206. **Additional Requirements for Open-Beam RGDs**.

In addition to the requirements in RH-12200., the following requirements apply to all open-beam RGDs not otherwise addressed in this Section:

a. **Safety device**.

1. The registrant shall document their justification of the use of open-beam instead of closed-beam systems.

2. If the registrant needs to use an open-beam system, the registrant shall consider a safety device which prevents the entry of any portion of the operator's body into the path of the primary beam or which causes the primary beam to be shut off upon entry into its path.

3. If the registrant's use of the open-beam system does not permit the use of a safety device to prevent direct body exposure, the registrant shall maintain a written record of a description of the various safety devices that have been evaluated and reasons for why these devices cannot be used. These records shall be maintained for Department inspection.

4. In lieu of the safety device described in paragraph a.2. of this section, the registrant shall employ alternative methods (such as policies and procedures) to minimize the possibility of unnecessary exposure. These alternative methods shall be documented. The documentation shall include information about the absence of safety devices and shall be maintained for Department inspection for five (5) years after these methods are no longer employed.

5. For portable open-beam systems that are manufactured to be used hand-held, or potentially used as a hand-held, without such safety

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devices, compliance with the requirements in paragraphs a.2. through a.4. of this section may be demonstrated by following all requirements in RH-12207. prior to use.

b. **X-ray on status**.

1. For open-beam equipment, RGDs shall be provided with a readily discernible and active indication of:

A. X-ray tube "on-off" status located near the radiation source housing. The warning lights as required by RH-12200.a.2. can meet this requirement if the warning lights are readily discernible and viewable by anyone near the primary beam; and

B. Shutter "open-closed" status located at the control panel and near each beam-port on the radiation source housing, if the primary beam is controlled with a shutter. The shutter status device shall be clearly labeled as to the meaning of the status device (i.e., whether the shutter is open or closed). The status light at the control panel can meet the requirement for the status light at the beam-port if the status light at the control panel is readily discernible and viewable by anyone near the primary beam.

2. The x-ray tube "on-off" status indicator and the shutter "open-closed" status indicators shall be of a fail-safe design.

c. **Labeling**.

Each unit will be labeled at or near the x-ray exit beam-port to identify the location of the beam with the words or words having a similar intent.

"**CAUTION – X-RAY BEAM**" or "**CAUTION – HIGH INTENSITY X-RAY BEAM**"

d. **Beam-ports**.

Unused beam-ports on radiation source housings shall be secured in the closed position in a manner which will prevent inadvertent opening.

e. **Shutters**.

On open-beam RGD configurations that are designed to accommodate interchangeable components, each beam-port on the radiation source

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housing shall be equipped with a shutter that cannot be opened unless a collimator or a component coupling has been connected to the beam-port.

f. **Radiation emission limits**.

The local components of an open-beam RGD shall be located and arranged and shall include sufficient shielding or access control such that no radiation emissions exist (exclusive of the primary beam) in any area surrounding the local component group which could result in a dose to an individual present therein in excess of the dose limits delineated in RH-1208., "Dose Limits for Individual Members of the Public." These emissions shall be met at any specified tube rating.

g. **Primary beam attenuation**.

In cases where the primary x-ray beam is not intercepted by the detector device under all conditions of operation, protective measures shall be provided, such as auxiliary shielding or administrative procedures, to avoid exposure to any individual from the transmitted primary x-ray beam.

h. **Operator attendance**.

The operator shall be in immediate attendance at all times when the equipment is in operation except when the area is locked or the equipment is secured to protect against unauthorized or accidental entry.

i. **Control of access**.

If the RGD is not in a restricted area, as defined in RH-1100., the operator shall be able to control access to the RGD at all times during operation. If the RGD is not in a restricted area and the RGD is capable of creating a radiation area, as defined in RH-1100., or a high radiation area, as defined in RH-1100., the operator shall be able to control access to the RGD at all times during operation, and:

1. Radiation areas shall be conspicuously identified. The source of radiation shall be within a conspicuous perimeter (e.g., rope, tape, or other barrier) that identifies the area in which the dose rate exceeds 5 mrem (0.05 mSv) per hour. The area described by the temporary barricade shall be suitably posted with signs. The

   operator shall ensure that no one is inside or enters the radiation area during operation of the RGD;

   "CAUTION – RADIATION AREA"

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2. High radiation areas shall be conspicuously identified. The source of radiation shall be within a conspicuous perimeter (e.g., rope, tape, or other barrier) that identifies the area in which the dose rate exceeds 100 mrem (1 mSv) per hour. The area described by the temporary barricade shall be suitably posted with signs. The operator shall ensure that no one is inside or enters the high radiation area during operation of the RGD;

"CAUTION – HIGH RADIATION AREA"

3. The operator shall perform a visual check of the controlled area to ensure it is free of all unauthorized personnel immediately prior to energizing the x-ray tube;

4. Surveillance of the exposure area shall be maintained during operation, either by visual or by other reliable means to ensure that no person enters the area;

5. With the exception of hand-held x-ray systems, when approaching the source of radiation, following the conclusion of an exposure, the operator shall use a calibrated, appropriate, and operable radiation survey instrument to verify that the x-ray tube has been de-energized;

6. Notwithstanding RH-12206.i.5., a personal alarming ratemeter may be worn to approach the work area if the device is appropriately designed and appropriately calibrated for the type of x-ray emitted (i.e., pulse or continuous), set at an appropriate level to detect the presence of the source (e.g., 2 mrem [0.02 mSv] per hour), and has been checked to ensure operability in accordance with manufacturer's instructions prior to each day of use.

The radiation in the work area must be reasonably uniform so that the device responds to radiation exposure to any part of the body. The alarming ratemeter shall not be used to measure radiation levels nor to indicate the presence of the source of radiation for potential non-uniform exposure, such as may occur during machine maintenance or work in an RGD target area;

7. Measurement of radiation levels for a radiation survey shall be performed using a calibrated, appropriate, and operable radiation survey instrument (See RH-12200.e.). A radiation survey instrument shall also be used when there is potential for non-uniform exposure to personnel, such as may occur during machine maintenance or work in an RGD target area;

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8. During the initial exposure, the radiation levels shall be measured around the perimeter of the controlled area. The perimeter shall be adjusted accordingly to meet the access control requirement for radiation areas or high radiation areas; and

9. The survey around the perimeter shall be made for each new operating condition and the perimeter adjusted accordingly. The area of operation shall be monitored periodically if radiation levels are variable.

j. **Personnel monitoring.**

In addition to the requirements in RH-12200.f., extremity monitoring devices shall be provided to and used by:

1. Personnel working with or routinely working near and having potential for exposure to the primary beam of an open-beam RGD; and

2. Personnel maintaining RGDs if the maintenance procedures require the presence of a primary radiation beam when any local component in the RGD is disassembled or removed.

k. **Instruction and Training.**

1. In addition to the requirements in RH-12200.m., no individual shall be permitted to operate or maintain an open-beam RGD unless such individual has received additional detailed instruction in and demonstrated competence as to:

A. Sources and magnitude of common radiation exposure;

B. Units of radiation measurement;

C. Radiation protection concepts of time, distance, shielding, and ALARA;

D. Procedures and rights of a declared pregnancy;

E. Regulatory requirements and area postings;

F. Worker, embryo, or fetus, and public dose limits;

G. Proper use of survey instruments and personnel monitoring devices; and

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H. Policies and procedures required by RH-12206.a.

2. Records of training shall be maintained for at least five (5) years beyond the last date the individual operated or maintained the RGD.

RH-12207. **Additional Requirements for Open-Beam, Hand-Held RGDs**.

In addition to the requirements in RH-12200. and RH-12206., the following requirements apply to open-beam, hand-held RGDs:

a. **Procedures**.

All registrants possessing open-beam, hand-held RGDs shall have available for Department review operating policies and procedures that contain measures to ensure that:

1. Radiation protection is provided in compliance with RH-1208., "Dose Limits for Individual Members of the Public";

2. Radiation protection is provided equivalent to that afforded in RH-12206.g. pertaining to primary beam attenuation;

3. The operator will not hold the sample during operation of the RGD and that the operator's hands will not approach the primary beam;

4. The operator will not aim the primary beam at himself or herself or at any individual during operation of the RGD; and

5. Operator radiation exposure is as low as reasonably achievable (ALARA), e.g., by use of ancillary equipment that will reduce exposure.

b. **Radiation emission limit**.

For hand-held RGDs, the limits of RH-12200.c.2. pertaining to the radiation source housing radiation emission limit and RH-12200.d. pertaining to the generator cabinet or high-voltage source radiation emission limit, excluding the primary beam, shall be met if the radiation emission at any accessible surface of the RGD does not exceed 2.5 mrem (0.025 mSv) per hour at 5 cm.

c. **Extremity monitoring**.

For purposes of the requirements in RH-12206.j. pertaining to extremity monitoring, operators of open-beam, hand-held RGDs shall be considered as working near the primary beam.

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d. **Training**.

1. In addition to the requirements in RH-12200.m. and RH-12206.k., no individual shall be permitted to operate or maintain an open-beam, hand-held RGD unless such individual has received detailed training in and demonstrated competence concerning the subjects detailed in paragraph a. of this section.

2. Records of training shall be maintained for at least five (5) years beyond the last date the individual operated or maintained the RGD.

RH-12208.- RH-12209. Reserved.

RH-12210. **Shielded Room RGDs**.

For an RGD that does not meet the limits of RH-1208., "Dose Limits for Individual Members of the Public," the RGD can be maintained inside a shielded room such that areas adjacent to the room meet the limits of RH-1208. when the RGD is activated. An RGD in a shielded room shall be required to meet only the requirements of RH-12200. and the following:

a. **Posting**.

The door to the room containing the RGD shall be posted as required by Section 3.

"**CAUTION – RADIATION AREA**," or "**CAUTION – HIGH RADIATION AREA**," or "**DANGER – HIGH RADIATION AREA**," or "**GRAVE DANGER – VERY HIGH RADIATION AREA**"

b. **Entrance interlocks**.

All entrances into the shielded room shall be provided with interlocks. After an interlock has been interrupted, broken, or tripped, it shall be possible to cause x-rays to be produced again only from the control panel. Interlocks shall not be used to shut off the RGD except in an emergency or during testing.

c. **Entrance warning devices**.

All entrances into the shielded room shall be provided with a conspicuously visible warning device, which need not be flashing or rotating but which operates only when radiation is being produced. The warning device shall be labeled in accordance with RH-12200.a.

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d. **Room warning lights**.

The interior of the shielded room shall be provided with flashing or rotating warning lights that operate when, and only when, radiation is being produced. These lights shall be positioned so that they can be observed from any position or orientation within the room. The lights shall be posted indicating the meaning of the warning signal and instructions on what to do. This posting shall be legible, conspicuous, and accessible to view.

e. **Audible room warning device**.

An audible warning signal within the room shall be actuated for at least ten (10) seconds immediately prior to the first initiation of radiation after the closing of any opening that can admit personnel. The audible warning signal shall be clearly discernible. The registrant shall post the meaning of the warning signal and instructions on what to do. This posting shall be legible, conspicuous, and accessible to view.

f. **Emergency shut-off**.

Emergency shut-off switches shall be located within all high and very high radiation areas so as to be accessible to individuals therein within 10 seconds. These switches and their mode of operation shall be identified by a conspicuously posted sign adjacent to the switch. The emergency shut-off switches shall include a manual reset that must be reset at the switch before x-rays can again be produced from the control panel. After an emergency shut-off switch has been activated, it shall be possible to produce x-rays again only from the control panel.

g. **Separate electrical systems**.

The interlock system and the emergency shut-off system shall be separate electrical or mechanical systems.

h. **Egress from the shielded room**.

A person within the room housing the RGD shall be able to egress at all times.

i. **Entry into the shielded room**.

1. After each exposure and before entry of any personnel, a survey shall be performed upon entry to the shielded room to determine that the RGD is no longer producing radiation.

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2. Personnel monitoring devices providing an audible signal when activated by radiation shall be acceptable for the survey requirement in paragraph i.1. of this section, provided:

A. Proper operation of the audible personnel device is checked in accordance with manufacturer's instructions, each day of use, and a record is maintained of this check for five (5) years after the record is made;

B. The audible device is designed so as to clearly indicate entry into a 2 mrem (0.02 mSv) per hour or greater radiation field; and

C. All personnel working with the RGD are provided with such a device.

3. Stationary area monitors providing an audible signal when activated by radiation shall be acceptable for the survey requirement in paragraph i.1. of this section, provided:

A. Proper operation of the audible area device is checked in accordance with manufacturer's instructions, each day of use, and a record is maintained of this check for five (5) years after the record is made;

B. The audible device is designed so as to clearly indicate entry into a 2 mrem (0.02 mSv) per hour or greater radiation field; and

C. Stationary area monitors are calibrated annually to determine that the audible signal operates at a 2 mrem (0.02 mSv) per hour radiation field.

j. **Personnel monitoring**.

In addition to the requirements in RH-12200.f., all personnel associated with the RGD shall be provided with personnel monitoring devices appropriate for the x-ray energies being utilized.

k. **Training**.

In addition to the requirements in RH-12200.m., no registrant shall permit any individual to operate an RGD in a shielded room until such individual has received a copy of, and instruction in, and has demonstrated an understanding of, operating and emergency procedures for the unit, and

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has demonstrated competence in its use. Records shall be maintained of all operator training for at least five (5) years beyond the last date the individual operated the RGD.

l. **Control of use**.

The equipment control panel shall be provided with a locking device to prevent unauthorized use. Such locking device shall, when locked, prevent the production of radiation by the equipment.

m. **Malfunctions**.

If a safety or warning device malfunctions, the control panel shall be locked in the "off" position. The control panel shall not be used, except as may be necessary for repair or replacement of the malfunctioning safety or warning device, until the safety or warning device is functioning properly.

RH-12211. **Bomb Detection RGDs**.

In addition to the requirements in RH-12200. (unless otherwise exempted under Part E of this Section), the following requirements apply to bomb detection radiographic equipment:

a. **Control of use**.

When not in use, each bomb detection radiographic unit shall be locked to prevent unauthorized use.

b. **Utilization log**.

The registrant shall maintain for each bomb detection radiographic unit a utilization log. This log shall record the description of the unit, the date removed from storage, the date returned to storage, the identity and signature of the person to whom the device is assigned, the dates of use, and the site(s) of use. The registrant shall maintain the records for five (5) years from the date of use.

c. **Control of access**.

The registrant shall prevent entry into the restricted area by individuals when the unit is energized during training.

RH-12212. **RGDs Used in Personnel Security Screening for Public Protection**.

In addition to the requirements in RH-12200., the following requirements apply to RGDs used in personnel security screening for public protection:

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a. **Efficacy evaluation**.

An evaluation must be performed of all known alternate methods that could achieve the goals of the security screening program, detailing why these methods will not be used in preference to the proposed approach utilizing ionizing radiation.

b. **Administrative controls**.

1. No individual shall be exposed to the useful beam unless authorized by a law enforcement agency for security benefit and approved by the Department in writing;

2. No individual shall be exposed to the useful beam for demonstration or frivolous purpose;

3. An RGD used for personnel security screening that does not meet the provisions of these Rules shall not be used to irradiate individuals unless the Department determines that the continued use will not pose a radiation risk and arrangements have been made to promptly correct the deficiency;

4. The manufacturer's recommended maintenance schedule shall be followed, and a service log shall be maintained for the life of the system; and

5. All position locking, holding, or centering devices shall function as designed by the manufacturer.

c. **Equipment requirements**.

1. RGDs used for personnel security screening of humans shall be evaluated for optimization of image quality and radiation dose by a Qualified Expert prior to use, every twelve (12) months, and after any maintenance or change that may affect the reference effective dose;

2. Indicators that light only when a scan is in process shall be provided and clearly visible to all personnel security screening operators and anyone approaching the restricted area;

3. Power to the system shall be controlled by a key switch;

4. A device to terminate x-ray exposure at any time during a scan shall be provided;

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5. A means shall be provided to terminate the exposure at a preset time interval or exposure;

6. Access panels to the x-ray source and detector shall be provided with at least one safety interlock;

7. Operational safety interlocks must terminate the x-ray exposure in the event of any system problem that could result in abnormal or unintended radiation emission;

8. Following any premature termination, the personnel security screening system must prohibit resumption of x-ray generation until the normal control sequence is reset for a new scan;

9. A personnel security screening system designed to control the exposure output using multiple modes of operation shall indicate clearly to the operator the selected mode prior to each scan;

10. Technique factors for each mode of operation shall not be alterable by the operator and shall be preset by the manufacturer;

11. When the x-ray tube is operated at its maximum rated tube current for the maximum kilovoltage, the leakage radiation shall not exceed 0.25 mrem (2.5 µSv) in any one hour at any point thirty (30) cm from any external surface of the system; and

12. The primary x-ray beam shall be attenuated by at least one (1) millimeter of aluminum equivalent total filtration.

d. **Dose limits.**

The registrant shall maintain records demonstrating that the following criteria are being met:

1. **Dose limits for general-use, full-body systems.**

For general-use screening systems, where the system is used without regard to the number of individuals scanned or number of scans per individual in a year, an effective dose for a single complete screening shall be limited to 25 µrem (0.25µSv).

2. **Dose limits for limited-use, full-body systems.**

For limited-use screening systems, where the system is capable of operation at greater than 25 µrem (0.25µSv) per screening, and is

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used with discretion, the effective dose per screening shall be less than or equal to 1 mrem (0.01 mSv).

3. **Dose limits for repeat security screenings**.

Individuals subject to repeat security screening at a single venue shall not receive an effective dose greater than 25 mrem (0.25 mSv) in any one year at the registrant's facility.

4. **ALARA**.

The radiation dose delivered to a scanned individual shall be as low as reasonably achievable (ALARA) while meeting the required detection performance.

e. **Facility design requirements**.

1. A clearly marked restricted area shall be established. The dose outside of the restricted area shall not exceed 2 mrem (0.02 mSv) in any one hour;

2. A means shall be provided for the operator responsible for initiating the scan to maintain full visual surveillance of the scanning and restricted areas; and

3. Engineering or administrative controls shall be provided to ensure that individuals do not reenter the scanning area from the exit while x-rays are being produced.

f. **Training**.

In addition to the requirements in RH-12200.m., no registrant shall permit any individual to operate a personnel security screening system until such individual has received a copy of, and instruction in, and has demonstrated an understanding of, operating procedures for the unit, and has demonstrated competence in its use. Training topics covered shall be in accordance with the most current revision of ANSI/HPS N43.17, "Radiation Safety for Personnel Security Screening Systems Using X-Ray or Gamma Radiation." Records shall be maintained of all operator training for at least five (5) years beyond the last date the individual operated the RGD.

RH-12213.- RH-12299. Reserved.

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PART D.
[RESERVED]

RH-12300.- RH-12399. Reserved.

PART E.
EXEMPTIONS

RH-12400. **Exemptions**.

a. The Department may, upon application of any interested person, or upon its own initiative, grant such exemptions from the requirements of the rules in this Section as it determines are authorized by law and will not result in undue hazard to public health and safety or property, and are otherwise in the public interest.

b. Bomb detection radiographic equipment, as defined in RH-12100., is exempt from the requirements of RH-12200.h. pertaining to posting.

c. Unless utilized in a dedicated location, hand-held RGDs are exempt from the requirements of RH-12200.h. pertaining to posting.

RH-12401.- RH-12499. Reserved.

PART F.
[RESERVED]

RH-12500.- RH-12599. Reserved.

PART G.
ENFORCEMENT

RH-12600. **Violations**.

a. An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any rule or order issued thereunder. Any person who willfully violates any provision of the Act or any rule or order issued thereunder may be guilty of a felony, misdemeanor, or crime and, upon conviction, may be punished by fine or imprisonment or both, as provided by law. Arkansas Code Annotated §20-21-204 describes criminal and civil penalties which may be assessed.

b. **Impounding**.

Sources of radiation shall be subject to impounding pursuant to Section 5 of these Rules.

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RH-12601.- RH-12999. Reserved.

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SEVERABILITY

If any provision of these Rules or the application thereof to any person or circumstance is held invalid, such invalidity shall not affect other provisions or applications of these Rules which can give effect without the invalid provisions or applications, and to this end the provisions hereto are declared severable.

REPEAL

All rules and parts of rules in conflict herewith are hereby repealed.

CERTIFICATION

This will certify that the foregoing Rules for Control of Sources of Ionizing Radiation were adopted by the Arkansas Board of Health at a regular session of the Board held in Little Rock, Arkansas, on the ~~27th~~ _____ day of ~~July~~ _____, ~~2023~~ _____

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Jennifer Dillaha, MD
Secretary of the Board of Health
Director of the Department of Health

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