

Title 20. Public Health and Welfare

Chapter I. Generally, Department of Health

Subchapter B. Health Facilities

**Part 53. Rules Pertaining to the Management of Medical Waste from
Generators and Health Care Related Facilities**

Codification Notes. This part as promulgated prior to codification into the Code of Arkansas Rules provided as follows:

"Section I – AUTHORITY. The Rules pertaining to the definition, segregation, treatment, packaging, labeling, storage, transport and disposal of medical waste from generators and health care related facilities are hereby promulgated pursuant to the authority conferred by Act 96 of 1913, as amended, the same being Ark. Code Ann. § 20-7-109, Ark. Code Ann. §§ 20-32-101 through 112, These Rules are in consonance with the Occupational Safety and Health Administration 29 CFR Part 1910.1030; "Occupational Exposure to Bloodborne Pathogens" standard."

"CERTIFICATION

This is to certify that the foregoing Rules Pertaining to the Management of Medical Waste from Generators and Health Care Related Facilities were adopted by the Arkansas State Board of Health at a regular session of said Board in Little Rock, Arkansas on the 20th day of October, 2016.

Nathaniel Smith, MD, MPH

Director and State Health Officer Arkansas Department of Health"

Subpart 1. Generally

20 CAR § 53-101. Purpose.

(a) The purpose of this part is to:

- (1) Provide a definition of medical waste from generators and healthcare-related facilities;
- (2) Identify entities that are subject to provisions of this part; and
- (3) Establish criteria for the proper management of such waste materials in order to protect the public health.

(b) The management, transportation, treatment, and disposal of chemical, pharmaceutical, and radioactive wastes are not included since proper disposal of these items is governed by other rules.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-102. Definitions.

As used in this part:

- (1) "ADEQ" means the Division of Environmental Quality;
- (2) "Commercial medical waste" means any medical waste transported from a generator to an off-site facility for treatment/disposal where such off-site treatment/disposal facility is engaged in medical waste treatment/disposal for profit and/or medical waste treated/disposed on-site by a commercial treatment/disposal mobile unit operated as a business for profit;
- (3) "Commercial medical waste incineration facility" means any facility:
 - (A) Accepting medical waste materials for treatment and disposal by incineration from an off-site source; and
 - (B) Operating the treatment and disposal facility as a business for profit;
- (4)(A) "Commercial nonincinerator treatment, storage, and/or disposal (TSD) facility" means all contiguous land and structures, other appurtenances, and improvements on the land used for treating and/or destroying and/or storing and/or disposing of commercial medical waste as a business for profit.

(B) A treatment, storage, and/or disposal (TSD) facility may consist of several treatment, destruction, storage, or disposal operational units under the same facility management;

(5) "Commercial treater/disposer" means an entity that receives medical waste from various sources for treatment and disposal as a business for profit;

(6) "Contaminated" means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface;

(7) "Department" means the Department of Health;

(8) "DOT" means the United States Department of Transportation;

(9) "Destruction" means the process of changing the original characteristics of medical waste where it:

(A) Is unrecognizable; and

(B) May no longer be able to transmit an infectious disease when handled or disposed;

(10) "Disposal" means the deposit, discharge, dumping, spilling, leaking, or placing of any medical waste into or on any land or waters so that such waste or any constituent thereof may enter the environment;

(11) "EPA" means the United States Environmental Protection Agency;

(12)(A) "Facility" means all contiguous land and structures, other appurtenances, and improvements on the land, used for treating, destroying, storing, or disposing of medical waste, provided that all land and structures are under control of a single person or legal entity.

(B) A facility may consist of several treatment, destruction, storage, or disposal operational units or transfer facilities;

(13) "Generator" means any person or source institution whose action or process produces medical waste as defined in this part;

(14) "Labeling" means to write on or affix a color-coded label to a medical waste package that is:

(A) Water resistant;

(B) Legible; and

(C) Readily visible;

(15) "Medical waste" means a waste from a generator or a healthcare-related facility as outlined in 20 CAR § 53-103, which:

(A) If improperly treated, handled, or disposed of may serve to transmit an infectious disease as established by the Department of Health; and

(B) Includes the following:

(i)(a) "Pathological waste" means all human unfixated tissues, organs, and anatomical parts, other than intact skin, which emanate from surgeries, obstetrical procedures, dental procedures, autopsies and laboratories, including embalming waste.

(b) Such waste shall be exclusive of bulk formaldehyde and other preservative agents;

(ii)(a) Liquid or semiliquid blood such as human blood, human blood components, and/or products made from human blood (e.g., serum, plasma) and other potentially infectious materials, to include regulated human body fluids such as semen, vaginal secretions, cerebrospinal fluid, pleural fluid, pericardial fluid, synovial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids where it is difficult or impossible to differentiate between body fluids, can be discharged into the collection system of a publicly owned treatment works (POTW) within the generating facility.

(b) Breast milk, urine, and feces are not considered medical waste and can also be discharged into the POTW;

(iii)(a) Contaminated items to include dressings, bandages, packing, gauze, sponges, wipes, personal protective equipment, cotton rolls and balls, etc., which cannot be laundered or disinfected and from which blood, blood components, or regulated body fluids drip freely, or that would release blood or regulated body fluids in a liquid or semiliquid state if compressed or are caked with dried blood or regulated body fluids and all capable of releasing these materials during handling, not to include:

(1) Feminine products;

(2) Enema bags;

(3) Used condoms; or

(4) Diapers.

(b) Contaminated disposable, single-use gloves such as surgical or examination gloves shall not be washed or decontaminated for reuse and are to be handled as a contaminated item.

(c) Protective coverings such as plastic wrap and aluminum foil used to cover equipment and environmental surfaces when removed following their contamination are considered a contaminated item.

(d) All patient care items from hospital isolation rooms and end-stage renal dialysis units, or from patients with communicable diseases, which cannot be laundered and which are contaminated with regulated body fluids or blood or potential infectious material, must be considered a contaminated item.

(e) Biological waste and discarded materials contaminated with blood, excretion, exudates, or secretions from isolated animals known, or suspected, to be infected with communicable diseases;

(iv) Microbiological waste which includes, but is not limited to:

(a) Cells and tissue cultures;

(b) Culture medium or other solutions and stocks of infectious agents;

(c) Organ cultures;

(d) Culture dishes;

(e) Devices used to transfer, inoculate, and mix cultures;

(f) Paper and cloth that has come in contact with specimens or cultures; and

(g) Discarded live or attenuated vaccines;

(v)(a) Contaminated sharps which include, but are not limited to, any contaminated object that can penetrate the skin, e.g., hypodermic needles, intravenous tubing with needles attached, syringes with attached needles, razor blades used in surgery, scalpel blades, Pasteur pipettes, capillary tubes, broken glass from laboratories, and dental wires.

(b) Potentially breakable container or containers of blood, regulated body fluid, microbiological waste, or infectious material must be treated as contaminated sharps when disposed of.

(c) Sharps that have been used in human or animal patient care, treatment, or for other medical procedures are included.

(d) Any waste produced in the course of physically altering a human being or animal including tattooing, ear piercing, or any other process where a foreign object is used to cut or pierce the skin.

(e) All waste generated in this manner meeting the definition of sharps must be handled accordingly;

(vi)(a) Veterinary waste to include any and all animal-related waste (carcasses, body parts, bulk blood and blood products, bedding of animals, etc.) which meets the definition of any of the five (5) categories delineated above and has been or is suspected to have been exposed to a zoonotic disease or pathogens known to cause human disease, or which has been exposed to human pathogens in research or the production of biological, must be handled as medical waste.

(b) All contaminated sharps and microbiological waste must be handled as medical waste;

(vii)(a) Trace contaminated chemotherapy waste that can be treated as medical/infectious waste includes:

- (1)* Masks;
- (2)* Empty drug vials;
- (3)* Gloves;
- (4)* Gowns;
- (5)* IV tubing;
- (6)* Empty IV bags/bottles; and
- (7)* Spill clean-up materials.

(b) Bulk chemotherapy wastes to include full expired vials of chemotherapy drugs are not considered to be medical/infectious wastes.

(c) They are considered hazardous wastes and must be handled accordingly;

(viii) Spill/clean-up material collected during or resulting from the clean-up of a spill of regulated medical waste; and

(ix) Crime scene/accident/trauma clean-up waste generated by individuals or commercial entities hired to clean crime scenes or accidents that are saturated with human blood, sharps, or sharp objects contaminated with human blood;

(16) "Mobile treatment/disposal system" means a portable system used for the treatment/destruction of medical waste;

(17) "Off-site" means any facility that is not on-site;

(18) "On-site" means a facility on the same or adjacent property with adjacent meaning real property within four hundred (400) yards from the property boundary of the existing facility;

(19) "OSHA" means the United States Occupational Safety and Health Administration;

(20) "Packaging" means containment of medical waste in disposable or reusable containers in such a manner as to prevent exposure to the waste material;

(21) "Person" means any individual, partnership, company, corporation, association, firm, organization, federal and state government, or any other group of individuals, or any officer or employee thereof;

(22) "POTW" means publicly owned treatment works owned by a state or municipality as defined by section 502(a) of the Clean Water Act;

(23) "Processing" means the handling of medical waste at the generating facility after its segregation by the procedures of:

(A) Treatment;

(B) Packaging;

(C) Labeling;

(D) Storing;

(E) Transporting; and

F) Disposal;

(24) "Satellite facilities" means additional hospitals, affiliated off-site services and physician offices, or other affiliated services owned and managed by the primary generator/treater;

(25) "Segregation" means the separation of medical waste from other routine solid waste at the time waste is generated within the generating facility;

(26) "Storage" means the containment of medical waste in such a manner as not to constitute disposal;

(27) "Transfer facility" means a transporters facility permitted by the Department of Health that may be utilized for transferring medical waste from one (1) vehicle to another;

(28) "Transport" means the movement of medical waste from the point of generation to any intermediate points toward the point of ultimate disposal;

(29) "Treatment" means any method, technique, or process designed to alter the character or composition of any medical waste as to neutralize or render it potentially noninfectious; and

(30) "Unrecognizable" means physically altered to a state where the item is no longer usable for its original intended purpose nor identifiable as to its use or source.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

Codification Notes. "IV" means intravenous.

20 CAR § 53-103. Application.

All requirements of this part shall apply, without regard to quantity of medical waste produced per month, to any person generating medical waste, except as exempted in 20 CAR § 53-104, and to include but not be limited to, the following healthcare-related facilities:

- (1) Ambulatory surgical centers;
- (2) Abortion clinics;
- (3) Birthing centers;

- (4) Blood banks and blood drawing centers;
- (5) Clinics, including but not limited to, medical, dental, and veterinary;
- (6) Educational institution health centers, (school nurse offices) and research facilities;
- (7) Emergency medical services and minor emergency centers;
- (8) Employee health clinics;
- (9) Funeral establishments;
- (10) Health maintenance organizations;
- (11) Home health agencies;
- (12) Hospices;
- (13) Hospitals;
- (14) Laboratories, including but not limited to clinical, diagnostic, pathological, veterinary, and biomedical research;
- (15) Long-term care facilities;
- (16) Mental health facilities and facilities serving individuals with intellectual disabilities;
- (17) Pharmacies;
- (18) Pharmaceutical manufacturing plants and research facilities;
- (19) Professional offices, including but not limited to, the offices of physicians, dentists, and veterinarians;
- (20) Public health units;
- (21) Renal dialysis centers;
- (22) Special residential care and assisted living facilities;
- (23) Tattoo parlors; and
- (24) Trauma scene clean-up entities.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

Subpart 2. Exemptions and Home Disposal

20 CAR § 53-201. Residential areas.

(a) This part does not apply to medical waste generated by the operation of single or multifamily dwellings.

(b) This part does not apply to medical waste generated by the operation of:

(1) Hotels;

(2) Motels; or

(3) Other accommodations providing lodging for the public and not serving as a commercial or professional office where individuals, who are not family members, are receiving medical care by a healthcare professional.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-202. Healthcare providers.

(a)(1) Home health personnel, physicians, and dentists treating patients in the home often generate infectious medical waste during their visit or waste is generated as a result of their prescribed treatment and medication.

(2) It is the responsibility of the healthcare provider to instruct the patient and family members in the proper disposal of any subsequently generated medical waste.

(b)(1) Particular attention should be given to infectious wastes from patients with highly infectious conditions and/or with multiple resistant organisms, to include but not limited to methicillin resistant Staphylococcus infections, hepatitis B, hepatitis C, HIV, etc.

(2) Visiting healthcare providers:

(A) Should disinfect such wastes when they are in the home; and

(B) Shall properly instruct household members in the proper treatment and disposal of infectious waste items from all types of patient treatment during their absence.

(c)(1) Rigid leak-proof containers, marked as treated, should be used for the disposal of sharps which should be chemically disinfected using one (1) part freshly

prepared solution of free available chlorine (hypochlorite bleach) concentration to no more than ten (10) parts water (1:10 dilution) for at least ten (10) minutes.

(2) Drain solution off into the sink or commode before disposal as regular solid waste.

(3) It is not permissible to put a red biohazard bag or container in a solid waste landfill.

(4) Solid waste landfills are prohibited from accepting liquid and/or infectious waste as outlined in the Division of Environmental Quality's Solid Waste Management Code, 8 CAR pt. 60.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

Codification Notes. "HIV" means human immunodeficiency virus.

Subpart 3. Identification, Segregation, Packaging, Labeling, Storage, Transport, Treatment, and Disposal of Medical Waste

20 CAR § 53-301. Applicability.

This subpart is applicable as requirements for all generators in Arkansas, except those exempted in 20 CAR § 53-104.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-302. Identification of medical waste.

(a)(1) A person who generates a medical waste shall determine if that waste is a medical waste as defined in 20 CAR § 53-102(15).

(2) Any wastes that contain medical waste mixed with general solid waste shall be managed as medical waste if the solid waste has been contaminated by:

- (A) Pathological waste;
- (B) Blood or body fluids;

- (C) Contaminated items; and/or
- (D) Microbiological waste.

(b) Any medical wastes which meet the definition of "hazardous waste", or which are mixed with hazardous wastes shall be managed as hazardous waste in accordance with the Division of Environmental Quality's Hazardous Waste Management Code, 8 CAR pt. 81.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-303. Segregation of medical waste.

(a) Medical waste must be segregated from other regular waste at the point of its generation in the producing facility.

(b)(1) Segregation of medical waste must be made into containers in compliance with the United States Occupational Safety and Health Administration Bloodborne Pathogen Standard, 29 C.F.R. § 1910.1030.

(2) Containers (paper or plastic bags, metal or plastic rigid containers) meeting this standard must be closable and constructed to contain all contents and prevent leakage of fluids during:

- (A) Handling;
- (B) Storage;
- (C) Transport; or
- (D) Shipment.

(c) A nonsharps container (e.g., a step can) of medical waste shall be closed at all times except when actively receiving medical waste.

(d) A sharps container with openings large enough to allow entry of any human hand shall be subject to any additional physical and/or administration controls necessary to prevent access by the public during normal conditions of use.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-304. Packaging and labeling of medical waste.

(a)(1) Medical waste, except for sharps capable of cutting or puncturing, shall be contained for reprocessing at the site of generation in collection containers impervious to moisture, which are leak resistant and have a sufficient strength to preclude ripping, tearing, or bursting under normal conditions of usage.

(2) Full containers shall be securely closed (fastened, taped, or tied) to prevent leakage or loss of solid or liquid wastes.

(b)(1) Contaminated sharps shall be packaged for reprocessing at the site of generation in containers that are:

- (A) Leak resistant on the bottom and sides;
- (B) Rigid;
- (C) Closable; and
- (D) Puncture resistant.

(2) Sharps containers shall be assembled and utilized at all times as intended by the manufacturer.

(3) Sharps that have been treated and are still capable of cutting or puncturing must also meet this packaging requirement unless they:

- (A) Have been rendered unrecognizable; and
- (B) Are no longer capable of cutting or puncturing.

(c)(1)(A) Warning labels shall be affixed to all bags and containers used for medical waste or affixed as close as feasible to the container by:

- (i) String;
- (ii) Wire;
- (iii) Adhesive; or
- (iv) Other method that prevents their loss or unintentional removal.

(B) Labels must:

- (i) Be water resistant and legible;
- (ii) Be colored fluorescent orange or orange-red (or predominantly so), with lettering or symbols in a contrasting color; and
- (iii) Include the universal biohazard legend.

(2) Red bags or red containers shall be labeled as listed in subdivision (c)(1) of this section, above.

(3)(A) Rigid containers for contaminated sharps and treated sharps as outlined in subsection (b) of this section shall be colored or labeled as listed subdivision (c)(1) of this section.

(B) Treated sharps must also be labeled as in subdivision (c)(1) of this section.

(4)(A) Individual containers of medical waste that are placed in a labeled container as required in 20 CAR § 53-306 during storage, transport, shipment, or disposal are required to be labeled as listed in subdivision (c)(1) of this section.

(B) Subsection (f) of this section allows for the substitution of the 49 C.F.R. Hazardous Materials Regulation's labeling and packaging requirements during handling and transport of medical waste.

(d)(1) When medical waste leaves the facility where it was generated, the name and address of the generator must clearly be marked on the outside of the container.

(2) If the waste has been treated using an approved method as outlined in 20 CAR § 53-307(b) – (g), then it must also be labeled on the container with the words "TREATED" and "BIOHAZARDOUS WASTE" or "INFECTIOUS SUBSTANCE" or "MEDICAL WASTE" or the universal biohazard symbol.

(3) Medical waste that has been treated by an approved method and determined by the Department of Health as rendered unrecognizable, is not required to have special packaging or labeling when transported or disposed as outlined in 20 CAR § 53-314.

(4) The handling and disposal of incinerator ash is regulated by the Division of Environmental Quality.

(e)(1) Treated medical waste cannot be disposed of if it is in a red or orange-red bag or container as outlined in subdivisions (c)(2) and (3) of this section.

(2) It must be further over-packed in a different color container (e.g., brown, green, black paper or plastic) and then labeled as required in subsection (d) of this section.

(f) If medical waste requires labeling, packaging, or management under 49 C.F.R. pt. 171, 172, 173, 177, and/or 178 of the Hazardous Material regulations, 29 C.F.R. § 1910.1030 of the Bloodborne Pathogen standard, or other federal regulations, as applicable, then the generator shall comply with the labeling and other applicable requirements specified in those regulations instead of as outlined in subdivisions (c)(1) – (3) of this section.

(g) Mechanical compaction of medical waste shall not be conducted prior to treatment and/or disposal, unless the mechanical compaction and treatment are part of a single, self-contained process that does not place employees or the public at risk of exposure to untreated medical waste.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-305. Storage.

(a)(1) Medical waste packaged in disposable containers as described in 20 CAR § 53-304(a) and (b) shall be placed in:

(A) Disposable or reusable:

- (i) Pails;
- (ii) Cartons;
- (iii) Drums; or
- (iv) Dumpsters; or

(B) Portable bins.

(2) Disposable and reusable systems shall be kept:

(A) Clean and rigid, be designed to prevent leakage of fluids, remain impervious to moisture, and be of sufficient strength to prevent tearing or bursting under normal conditions of use and handling; and

(B) Sealed or closed to prevent leakage.

(3) The containers may be of any color and shall be conspicuously labeled as required in 20 CAR § 53-304.

(b)(1) Storage of medical waste shall be in a manner and location which:

(A) Affords protection from:

(i) Unauthorized entry;

(ii) Animals; and

(iii) Adverse weather conditions such as:

(a) Rain;

(b) Snow;

(c) Ice;

(d) Sleet;

(e) Hail; and

(f) Wind;

(B) Does not provide a breeding place or a food source for insects and rodents; and

(C) Minimizes exposure of employees and the public.

(2) When waste is not being actively placed in storage, the area must be secured.

(c) The location of the medical waste in storage shall be conspicuously marked with signs which shall include the universal biohazard legend outlined in 20 CAR § 53-304(c)(1).

(d)(1)(A) Storage time within the generating facility shall not exceed thirty (30) days once the container has been filled and closed.

(B) Storage of medical waste for longer than thirty (30) days must be approved by the Department of Health.

(2) Filled containers of medical waste must be held at room temperature (seventy-two degrees Fahrenheit (72°F), twenty-two degrees Celsius (22°C)) or below in a secure location with limited access (unauthorized entry) as specified in subsection (b) of this section.

(3) If the generating facility is unable to control odor from its stored waste, the department may require more frequent removal and further limit the storage time.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-306. Transport.

(a)(1) Generators of medical waste may transport their own waste to an off-site permitted treatment or disposal facility, or satellite facility in a fully enclosed container designed to prevent leakage of fluids as outlined in 20 CAR § 53-305(a), without having to obtain a transportation permit.

(2)(A) Generators that transport their medical waste shall keep a log of all medical waste transported.

(B) The log shall include the:

- (i) Quantity;
- (ii) Date of transport; and
- (iii) Name of the receiving facility.

(C) Logs shall be maintained on file at the generator's facility for three (3) years from the date of shipment.

(3) Commercial medical waste transportation must comply with 20 CAR § 53-401 et seq., requirements for transporters of commercial medical waste.

(b) Medical waste transported off site must be labeled as required in 20 CAR § 53-304.

(c)(1) For transport purposes, the generator shall transfer custody of untreated medical waste only to a transporter who has obtained a valid commercial regulated medical waste permit from the Department of Health as required in 20 CAR § 53-401.

(2) The department shall maintain a list of all permitted transporters.

(3) The list shall be made available by the department's Medical Waste Program.

(d)(1) The generator of medical waste shall maintain a log of all untreated medical waste transferred to a transporter that is permitted by the department or a department-permitted treatment, storage, and/or disposal facility.

(2) The log must include the:

- (A) Quantity;
- (B) Method used to determine the amount;

(C) Date the shipment was made; and

(D) Name and permit number of the transporter or treatment/disposal facility.

(3) The logs shall be maintained on file at the generator's facility for three (3) years from the date of shipment or transfer.

(4) If the information is listed on the manifest/tracking paper, then the manifest/tracking paper may be substituted for the log.

(e)(1) The generator shall obtain from the permitted transporter a signed receipt (manifest or tracking paper) for each shipment of medical waste.

(2) The requirements of the manifest/tracking paper or papers are listed in 20 CAR § 53-411.

(3) These manifests/tracking papers shall be maintained on file at the generators facility for three (3) years from the date of shipment.

(f)(1) Medical waste cannot be transported in open vehicles or trailers.

(2) Tarped loads are not permissible.

(g) Medical waste must be physically separated from other materials being transported.

(h)(1) Generators that transport large quantities of medical waste (not including commercial medical waste) must sign a letter of agreement provided by the department ensuring procedures are in place that will ensure the medical waste is managed during transport to protect the:

(A) Environment;

(B) Waste handlers; and

(C) Public health.

(2) Large quantity is defined as fifty (50) pounds or more of medical waste transported in a calendar month.

(i)(1) The United States Postal Service may be used to transport used and unused sharps for disposal.

(2) The generator must retain the original receipt and the returned registered or certified mail receipt.

(3) The generator shall retain the manifest/tracking paper for each shipment and they shall be maintained on file at the generator's facility for three (3) years from the date of shipment.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-307. Medical waste treatment.

(a) Treatment of medical waste shall be by one (1) of the following.

(b) **Incineration.**

(1) Burning of medical waste in conformance with the standards prescribed by the Division of Environmental Quality or the United States Environmental Protection Agency.

(2) A permit must be obtained from the division before an incinerator can be installed or operated.

(3) Inspection of incinerators shall be conducted by the division in compliance with the federal Clean Air Act, 42 U.S.C. § 7401 et seq., and/or the Arkansas Water and Air Pollution Control Act, Arkansas Code § 8-4-101 et seq., or other applicable air regulations.

(c) **Sterilization technology.**

(1) Sterilization is the complete elimination of microbial viability.

(2) Procedures utilized must be performed properly and according to the manufacturer's operating instructions (with regard to time, temperature, pressure, waste exposure, and capacity), provided the results:

(A) Change the biological character or composition of the medical waste completely and reliably inactivating *Bacillus stearothermophilus* spores or other appropriate organisms at a 4 Log 10 reduction (99.99%) or greater; and

(B) Meet or exceed the parameters listed below.

(3) If a primary container is used, the primary container shall be placed in the sterilization chamber with sufficient space provided between the chamber walls and the

container to allow the steam, heat, or chemical to surround the container and penetrate all of the medical waste.

(4) The primary container shall be sealed loosely enough to allow the steam to penetrate the entire contents of the container, unless a self-venting bag is used.

(5) All of the medical waste must be exposed to the temperatures and pressures listed below.

(6) Approved procedures are:

(A)(i) **Steam under pressure (autoclaving).** Steam at two hundred forty-eight degrees Fahrenheit (248°F) (one hundred twenty degrees Celsius (120°C)) at fifteen pounds per square inch (15 psi) for thirty (30) minutes.

(ii) **Steam auger.** Steam at two hundred five degrees Fahrenheit (205°F) (ninety-six degrees Celsius (96°C)) at fifteen pounds per square inch (15 psi) for sixty (60) minutes;

(B) **Dry heat.** Heat at three hundred twenty degrees Fahrenheit (320°F) (one hundred sixty degrees Celsius (160°C)) at atmospheric pressure for two (2) hours;

(C) **Chemical vapor.** Approved United States Environmental Protection Agency chemical mixture at two hundred sixty degrees Fahrenheit (260°F) (one hundred twenty-seven degrees Celsius (127°C)) at twenty pounds per square inch (20 psi) for thirty (30) minutes; and

(D) **Ethylene oxide.**

(i) Four-hour to five-hour cycle using eleven percent (11%) to twelve percent (12%) percent ethylene oxide.

(ii)(a) Chemical vapor and ethylene oxide sterilization may require an air permit from the division.

(b) Persons interested in applying this technology should contact the division before installing or operating such equipment.

(iii) Quality control of the sterilization process shall be performed at least once a month or after every forty (40) hours of operation, whichever comes later, using physical, chemical, and biological monitors (thermochemical indicators and integrators such as autoclave tape, spore strips, ampoules, thermocouples, etc.) placed

in or on the outside of the waste containers and distributed throughout the load, chamber, or vessel during treatment as listed in 20 CAR § 53-308 to evaluate the effectiveness of the treatment process.

(iv) Unless the sterilization unit is equipped to continuously monitor and record temperatures during the entire length of each sterilization cycle, except for treatment using ethylene oxide, the operator of such sterilization equipment shall affix to the medical waste a temperature-sensitive tape which will indicate that the required temperature was reached.

(d) **Disinfection.**

(1) A potentially less lethal process compared to sterilization that eliminates or inactivates many or all pathogenic microorganisms including viruses, fungi, and bacteria (but not necessarily all their endospores) on inanimate surfaces.

(2) Approved procedures are:

(A) **Thermal inactivation.**

(i) Procedure must be performed properly as indicated by the equipment manufacturer's operating instructions and the adequacy of disinfection verified by physical, chemical, and biological monitoring (thermochemical indicators and integrators such as autoclave tape, spore strips, ampoules, thermocouples, etc.) as listed in 20 CAR § 53-308.

(ii) Unless the thermal inactivation equipment is equipped to continuously monitor and record temperatures during the entire length of each disinfection cycle, the operator shall affix to the medical waste a temperature-sensitive tape (i.e. autoclave tape) which will indicate that the required temperature was reached.

(iii) Approved procedures are:

(a) Autoclave;

(b) Microwave; and

(c) Dielectric energy.

(iv) Thermal inactivation must allow for sufficient heat to access and penetrate the waste.

(v) The waste must be packaged according to the recommendations of the manufacturer and loaded into the chamber as to not exceed the capacity limits set by the manufacturer; and

(B) Chemical.

(i) The use of United States Environmental Protection Agency-approved chemical agents to significantly reduce microbial activity for waste treatment, e.g., one (1) part freshly prepared solution of free available chlorine (hypochlorite bleach) concentration to no more than ten (10) parts water (1:10 dilution) for at least ten (10) minutes.

(ii) The chemical agent shall be used according to the manufacturer's instructions.

(iii) The chemical agent must penetrate all the waste material.

(iv) If liquid chemical disinfectants or sterilants are used, excess liquid must be drained prior to disposal.

(v) Certain chemical disinfectants or sterilants may not be allowed to be discharged to a POTW.

(vi) Solid waste landfills are prohibited from accepting liquids or wastes containing free liquids and/or infectious waste as outlined in the division's Solid Waste Management Code, 8 CAR pt. 60.

(e) Discharge of liquid or semiliquid waste into the collection system of a publicly owned treatment works (POTW). Grinding and/or flushing of waste into a POTW within the generating facility, except as prohibited by the Department of Health, the division, or the superintendent/manager of the POTW.

(f) Encapsulation. Complete encapsulation of medical waste in a solid matrix (e.g., plaster of paris) which will significantly reduce the possibility of exposure.

(g) Other available technology (alternate technology).

(1) Technology other than listed above in subsections (b) – (f) of this section shall be evaluated and approved by the department.

(2) Alternate technologies are usually approved at the manufacturer level.

(3) Applications for approval of an alternate technology must be made on forms provided by the department's Medical Waste Program criteria used to evaluate alternate technologies will include, but not be limited to:

(A) Approval by states other than Arkansas that utilize a performance standards approach to review alternate treatment technologies;

(B) Environmental impact;

(C) Environmental permit requirements;

(D) Potential worker health effects;

(E) Manufacturer operating requirements and instructions; and

(F) Levels of microbial inactivation which includes:

(i) Inactivation of representative samples of mycobacteria, at a level of 6 log 10 (99.9999%) reduction or more, as determined by the department; and

(ii) Inactivation of *Geobacillus stearothermophilus* endospores or *Bacillus atrophaeus* endospores at a level of 4 log 10 (99.99%) reduction or more, as determined by the department.

(4) One (1) or more representative surrogate microorganisms from each microbial group shall be used in treatment efficacy evaluations.

(5) The department shall determine the appropriate microorganisms to serve as representative surrogate microorganisms.

(6) Protocols developed for efficacy testing shall incorporate, as applicable, recognized standard procedures.

(7) Guidelines for testing and approval of alternate medical waste technologies may be obtained from the department's Medical Waste Program.

(8) The department shall maintain a list of those approved alternate technologies, including:

(A) Manufacturer;

(B) Product name;

(C) Model number; or

(D) Other appropriate identifying information.

(10) The list shall be made available by the department's Medical Waste Program.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-308. Quality control.

(a)(1) Quality control of the treatment process must be performed at least once a month or after every forty (40) hours of operation, whichever comes later, using the appropriate physical, chemical, and biological monitors (thermochemical indicators and integrators such as autoclave tape, spore strips, ampoules, thermocouples etc.) to evaluate the effectiveness of the treatment process, except for discharge into a POTW or encapsulation.

(2) The types of biological monitors that shall be used, unless approved by the Department of Health for use of other organisms, are as follows:

Wet heat	<i>Geobacillus stearothermophilus</i>
Dry heat	<i>Bacillus atrophaeus</i>
Gas (ethylene oxide)	<i>Bacillus atrophaeus</i>
(formaldehyde)	<i>Geobacillus stearothermophilus</i>
Radiation	<i>Bacillus pumilus</i> or <i>Bacillus atrophaeus</i> or <u><i>Geobacillus stearothermophilus</i></u>
Liquids	<i>Bacillus atrophaeus</i> or <i>Clostridium sporogenes</i>

(3) The department must approve of biological monitors not listed above used for efficacy (quality control) testing.

(b) Total destruction technologies must receive approval from the department for the type, use, or waiver of efficacy testing.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-309. Log.

(a) For each medical waste treatment unit listed in 20 CAR § 53-307, a log shall be maintained which contains, at a minimum, the following information for each use:

- (1) Date;
- (2) Time;
- (3) Operator;
- (4) Type and approximate amount (by weight in pounds) of medical waste;
- (5) Sterilization pressure reading, as applicable;
- (6) Maximum temperature obtained during the process or the results of the temperature-sensitive tape, as applicable; and
- (7) The treatment process time.

(b) The log shall be completed during and after all treatment of medical waste in the treatment unit.

(c) The log shall also record the required quality control process using biological monitors including the type of organism used as listed in 20 CAR § 53-308 and the results when achieved.

(d) The treatment log shall be maintained for three (3) years from the date of last treatment.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-310. Filter requirement for equipment.

(a) Equipment such as shredders, choppers, etc., that have the potential to produce aerosols must be fully contained under negative air pressure and exhausted through a HEPA filter.

(b) Small medical waste treatment devices may be exempt from this requirement.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

Codification Notes. "HEPA" means high-efficiency particulate air.

20 CAR § 53-311. Disposal of medical waste.

Disposal of untreated medical waste shall be by one (1) of the following:

- (1) Discharged from the healthcare-related facility into a POTW;
- (2) **Interment.** The disposition of pathological waste by burial or cremation according to standards and practices of the mortuary industry;
- (3) **Other available technology.** If approved by the Department of Health and meeting the intent of this part;

(4)(A) Table 1 describes which methods are approved for treatment and disposal of each specific category of medical waste.

(B) Alternate technologies are approved individually for treatment and disposal for each specific category of medical waste.

(C) **Note.**

(i) Not all methods of treatment and disposal are approved for all categories of medical waste.

(ii) Medical waste which may no longer serve to transmit an infectious disease and is not recognizable may be disposed of in the regular solid waste stream and/or in a permitted landfill as outlined in the Division of Environmental Quality's Solid Waste Management Code, 8 CAR pt. 60, without any labeling requirements.

(iii) 20 CAR § 53-312 outlines the requirements for treated medical waste that is still recognizable; or

(5)(A) Untreated medical waste cannot be disposed of in a landfill.

(B) Treated medical waste may be disposed of in a permitted sanitary landfill in accordance with the division's Solid Waste Management Code, 8 CAR pt. 60.

(C) Solid waste landfills cannot accept liquid wastes.

(D) Treated medical waste, where applicable, must be packaged and labeled as in 20 CAR § 53-304 prior to land filling.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-312. Inclusion of medical waste with normal, solid waste.

If the generator of medical waste has treated the waste by an approved method and it is packaged and labeled as specified in 20 CAR § 53-304, then the waste may be included in the facility's normal solid waste stream in accordance with rules established by the Division of Environmental Quality or other appropriate regulatory bodies.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-313. Incineration of medical waste.

(a) A healthcare-related facility with a Division of Environmental Quality-permitted incinerator or use of an approved technology as outlined in 20 CAR § 53-304 may accept medical waste for treatment/disposal from physicians and surgeons on staff of the healthcare facility without obtaining a commercial incinerator or nonincinerator technology permit or operating license as outlined in 20 CAR § 53-501 et seq.

(b) Satellite facilities including additional hospitals, affiliated off-site services, and physician offices or other affiliated services owned and managed by the primary generator/treater may accept and treat such medical waste without a nonincineration technology permit or operating license unless the facility is engaged in medical waste disposal for profit.

(c) If the division determines that a facility's incinerator is operating as a commercial medical waste incinerator, then the facility shall obtain an operating license as outlined in 20 CAR § 53-501 et seq.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-314. Treated medical waste rendered unrecognizable.

Medical waste that has been treated by an approved method and determined by the Department of Health as rendered unrecognizable is not required to have special packaging or labeling when transported or disposed.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-315. Release of medical waste.

(a) All incidents involving the release of medical waste to the environment or other incidents that threaten the public health involving medical waste shall be reported verbally as soon as possible but within twelve (12) hours to the Department of Health with a follow-up written report on forms provided by the department in five (5) working days from the incident.

(b) The department shall be notified at (501) 661-2621 or (501) 661-2000 during working hours and (501) 661-2136 after normal working hours.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

Subpart 4. Requirements for Transporters of Commercial Medical Waste

20 CAR § 53-401. Permit.

(a) No person in Arkansas may transport commercial medical waste for a generator, other than the generator themselves, without first obtaining a commercial medical waste transportation permit from the Department of Health.

(b) The permit is required for all commercial transporters transporting commercial medical waste into the state, waste generated in the state and transported out of the state, and/or for waste transported within the state.

(c) United States Postal Service vehicles and vehicles transporting commercial medical waste through Arkansas to another jurisdiction outside the state without receiving or transferring commercial medical waste in Arkansas are not required to obtain a permit or pay the required fees.

(d) To obtain a permit, the transporter shall submit forms as listed in 20 CAR § 53-422 to the department's Medical Waste Program at least:

- (1) Forty-five (45) days before the anticipation of the permit issue date; and
- (2) Thirty (30) days before the expiration of an existing permit.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-402. Plans and procedures for transporting medical waste.

(a) Commercial medical waste transporters shall have a written operating plan/procedure for handling and transport of commercial medical waste.

(b) The plan/procedure shall include the following:

(1) A method of handling medical waste separately from other waste which prevents unauthorized persons from having access to or contact with the waste;

(2) A method of loading and unloading of medical waste which limits the number of persons handling the waste and minimizes the possibility of exposure of employees and the public to medical waste;

(3) A method of decontaminating emptied reusable medical waste containers, transport vehicles, or facility equipment which are or are believed to be contaminated with medical waste;

(4)(A) The provision and required use of personal protective equipment for persons manually loading or unloading containers of medical waste on or from transport vehicles.

(B) Contaminated protective equipment shall be disposed of as medical waste or cleaned and decontaminated;

(5)(A) A description of the means of decontamination of any person having had bodily contact with medical waste while transporting the waste or while handling or disposing of the waste.

(B) These procedures shall include decontamination procedures and procedures for medical care; and

(6) A procedural plan for handling any transportation incidents involving containers or vehicles transporting commercial medical waste, including:

(A) Notification of the authorities as outlined in 20 CAR § 53-414;

(B) Clean up; and

(C) Decontamination.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-403. Vehicle construction.

Each truck, trailer, semitrailer, vacuum tank, cargo tank, or container used for transporting commercial medical waste shall be designed and constructed and its contents so limited, that under conditions incident to transportation, there shall be no release of medical waste to the environment.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-404. Transporting medical waste with nonmedical waste.

Commercial medical waste may not be transported with other types of waste or nonwaste materials (with the exception of medical waste equipment and supplies), and the cargo body or compartment shall be separated by a solid barrier from the driver and passengers.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-405. Vehicle compartments.

All vehicle/trailer compartments in which commercial medical waste is stored for transport shall remain locked at all times except when loading and unloading.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-406. Safety equipment for vehicles.

All vehicles which transport commercial medical waste shall carry, at a minimum, the following safety equipment:

- (1) Spill containment and clean-up kits designed for infectious waste and include at a minimum:

- (A) Absorbent material;
 - (B) Approved disinfectant in a sprayer capable of dispersing its charge in a mist and in a stream;
 - (C) Additional plastic medical waste bags that meet the requirements of 20 CAR § 53-303(b);
 - (D) Boundary-marking tape;
 - (E) Scoop shovel;
 - (F) Push broom and bucket;
 - (G) Protective eye covering and cloths;
 - (H) Boots; and
 - (I) Gloves that are designed for handling sharps;
- (2) Emergency reflectors, triangles, or flashing lanterns;
 - (3) First aid kit;
 - (4) Fire extinguisher; and
 - (5) Spill management procedures and operation plan.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-407. Vehicle markings.

All vehicles transporting commercial medical waste shall be marked with letters or symbols four inches (4") tall on a contrasting color background as "MEDICAL WASTE", "INFECTIOUS SUBSTANCE", "BIOMEDICAL WASTE", or the universal biohazard symbol as listed in 20 CAR § 53-304(c)(1) on the two (2) sides and back of the cargo carrying compartment, unless prohibited by the United States Department of Transportation.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-408. Vehicle insurance.

(a) All vehicles that transport commercial medical waste shall be covered by insurance having a public liability limit of at least one million dollars (\$1,000,000).

(b) Companies providing insurance coverage must have received authority from the State Insurance Department to conduct business in the state.

(c) If a company is self-insured, a letter from the Department of Finance and Administration is required, certifying the company is self-insured under Arkansas Code § 27-19-107 of the Safety Responsibility Act, Arkansas Code § 27-19-101 et seq.

(d) A copy of the insurance provider's certificate of insurance coverage with a certificate for notification of cancellation to the Department of Health is required.

(e) Thirty (30) days prior to insurance cancellation, notice must be sent to the Department of Health.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-409. Delivery of waste to permitted facilities.

Commercial medical waste transporters shall deliver commercial medical waste for storage, treatment, and/or disposal only to a facility that is:

(1) Permitted by the Department of Health as a medical waste storage, treatment, and/or disposal (TSD) facility or an incineration facility permitted by the Division of Environmental Quality; or

(2) Located out of the state that is permitted by the appropriate state agency having jurisdiction to accept such waste.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-410. Weight.

(a) A fee of five dollars (\$5.00) a ton is required for all commercial medical waste that originates or terminates in Arkansas.

(b) Methods of determining the weight of commercial medical waste and associated fees are as follows:

(1) **Weight determination.**

(A) In all cases weights must be verifiable.

(B)(i) Accurate weight tabulation in pounds must be kept monthly on a per vehicle or customer basis.

(ii) Estimates of container weights derived from the container's cubic feet are not permissible.

(C) Weights of the medical waste may be determined as follows:

(i) Net weights of trailer or vehicle loads of medical waste may be determined by subtracting the weight of the empty vehicle/trailer from the total weight of the trailer/vehicle and load contents; or

(ii) Net weights of trailer or vehicle loads may be determined by scale tickets, manifest/tracking papers, or other like documentation; or

(iii)(a) Where a trailer/vehicle load of medical waste is mixed with medical waste not originating or terminating in the state and not subject to the fee, manifests/tracking papers for the medical waste not subject to the fee or documented customer weights must be used to verify that portion of the load.

(b) The sum of the weights of all containers in a load minus the portion not subject to the fee must be verified by scale tickets, manifest/tracking papers, or other like documentation; and

(iv) The required documentation must be kept for three (3) years from the time of transport and must be made available to the Department of Health upon request; and

(2) Fees.

(A) The commercial medical waste transporter must pay a fee of five dollars (\$5.00) per ton of waste transported.

(B) The fee is calculated by multiplying the fee per ton by the weight of the waste as determined in subdivisions (b)(1)(C)(i), (b)(1)(C)(ii), or (b)(1)(C)(iii) of this section in pounds divided by two thousand (2000).

(C) The division should be carried to the second decimal and rounded to the nearest tenth as follows:

$$\text{Weight of Waste in Pounds} \times \$5.00 = \text{fee 2000 pounds}$$

(D) Weight tabulations and fees are calculated each calendar quarter.

(E)(i) Weight tabulations and fee payment for the previous quarter are due forty-five (45) days from the end of the quarter.

(ii) Quarters are based on the periods:

(a) January 1 to March 31;

(b) April 1 to June 30;

(c) July 1 to September 30; and

(d) October 1 to December 31.

(F) Payments are to be made to the Medical Waste Program.

Authority. Arkansas Code §§ 20-32-106, 20-32-107, 20-7-109.

20 CAR § 53-411. Log.

(a) Commercial medical waste transporters shall keep a log of their daily pick-up from generators of commercial medical waste.

(b) The log must show, at a minimum, the:

(1) Name and address of the generator;

(2) Date;

(3) Quantity (weight (pounds) or number of containers); and

(4) Final destination.

(c) Manifests/tracking papers must accompany all shipments of commercial medical waste.

(d) Log records and manifests/tracking papers:

(1) Shall be kept on file for three (3) years; and

(2) Must be made available upon request.

(e) The commercial medical waste transporter shall provide the medical waste generator with a copy of the manifest/tracking paper at the time of transfer of the medical waste.

(f) The requirements of the manifest/tracking document are as follows:

(1) The name, address, telephone number, and signature of a representative of the medical waste generator;

(2)(A) The name, address, phone number, permit number, and signature of the commercial transporter upon receipt of the waste.

(B) If additional transporters are used, the same information on any additional transporters is also required;

(3) The name, address, telephone number, and signature of a representative of the facility receiving the waste;

(4)(A) The weight (pounds) or the number of containers of commercial medical waste transported.

(B) The commercial medical waste transporter may provide at the time of pick-up the number of containers if the transporter can track real-time individual waste containers from the point of collection through the point of treatment.

(C) If the weight (pounds) of each container is not provided at the time of transfer, the commercial medical waste transporter must report the weight (pounds) of each container to the generator within forty-five (45) days; and

(5)(A) The commercial medical waste transporter shall provide the medical waste generator with a copy of the manifest/tracking paper after the treatment, storage, and/or disposal facility accepts the waste or treats the medical waste, if requested.

(B) If the medical waste is going out of the state and the receiving state has different requirements for a manifest/tracking paper, the stricter of the state's requirements shall be used.

(C) In case of conflict, the Department of Health should be contacted for a determination of the requirements on the manifest/tracking paper.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-412. Vehicle inspections.

Commercial medical waste transportation vehicles with a gross vehicle weight rating of greater than ten thousand pounds (10,000 lbs.) must pass an annual federal motor carrier inspection.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-413. Training.

(a) All personnel involved in the transport and handling of commercial medical waste shall be properly trained in the identification, handling, and transportation of medical waste for their own protection and others.

(b) The commercial medical waste transporter shall have a written training program.

(c) Training shall:

- (1) Occur before the initial job assignment; and
- (2) Be repeated at least annually.

(d) Written documentation is required of employee training.

(e) This training shall include, but not be limited to, the following:

(1) Transporter's written operation plan/procedure and spill management plan as outline in 20 CAR § 53-402;

(2) This part, Pertaining to the Management of Regulated Medical Waste from Healthcare-Related Facilities;

(3) United States Occupational Safety and Health Administration Bloodborne Pathogen Standard, 29 C.F.R. § 1910.1030, as applicable;

(4) Mechanisms by which disease transmission may occur;

(5) Proper use of protective measures to prevent contact with medical waste by both the transporter and the public;

(6) Selection, use, and decontamination/disposal of appropriate protective equipment; and

(7) Procedures to be taken in the event of a transportation incident involving commercial medical waste, including notification of the appropriate authorities as outlined in 20 CAR § 53-414.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-414. Accidental release of medical waste.

(a) All incidents involving the release of medical waste to the environment or other incidents involving medical waste shall be reported verbally as soon as possible, but within twelve (12) hours to the Department of Health with a follow-up written report on forms provided by the department in five (5) working days from the incident.

(b) The department shall be notified at (501) 661-2621 or (501) 661-2000 during working hours and (501) 661-2136 after normal working hours.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-415. Annual report.

(a) Commercial medical waste transporters shall submit to the Department of Health an annual summary report of their activities from January 1 to December 31 of each year.

(b) The report shall be submitted no later than March 1 of the year following the end of the reporting period.

(c) The report shall include the following information on forms provided by the department:

(1) Name or names and address or addresses, registration or permit numbers, and the amount of waste in pounds deposited/unloaded at each facility in Arkansas where the medical waste was deposited/unloaded;

(2) The amount of waste in pounds shipped into the state, the amount of waste shipped out of the state, and the amount of waste shipped within the state; and

(3) For commercial medical waste generated in Arkansas, the name and address of each generator for which commercial medical waste is transported and the amount of commercial medical waste transported for each generator may be required to be listed in the annual report.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-416. Transfer of waste between vehicles.

(a) Commercial medical waste shall not be transferred between vehicles unless the transfer occurs at a generator's facility or on the premises of transporter's facility or a permitted treatment, storage, or disposal facility except as listed below.

(b)(1) In case of transport vehicle malfunction, the waste shipment may be transferred to an operational vehicle and the Department of Health shall be notified of the incident verbally as soon as possible within twenty-four (24) hours and a follow-up written report within five (5) working days.

(2) The incident report shall list all vehicles involved in transporting the medical waste and the cause of the vehicle malfunction.

(c)(1) In case of a traffic accident, the waste shipment may be transferred to an operating vehicle if necessary.

(2) If medical waste containers are damaged or released to the environment, the procedures of the facility/transporter's operation/spill plan shall be implemented immediately, dependent on safety factors.

(3) The reporting requirement is the same as outlined in 20 CAR § 53-414.

(d) For transfer between vehicles other than as listed in subsection (b) and (c) of this section and not on the property of the permitted commercial waste transporter or generator, the department shall be notified and approve of the transfer of medical waste before the transfer takes place.

(e) Permitted medical waste transporters may apply to be approved for having a medical waste transfer facility after providing the following items to the department:

- (1) A completed and signed application on forms provided by the department;
- and
- (2) Other documentation or information as requested by the department.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-417. Storage.

(a) Commercial medical waste shall not be stored on the permitted medical waste transporter's property or at their transfer facility for longer than ten (10) days without having a storage facility permit as outlined in 20 CAR § 53-501 et seq., unless authorized by the Department of Health.

(b) Medical waste held on the transporter's site or transfer facility for more than seventy-two (72) hours shall maintain a storage temperature of forty-five degrees Fahrenheit (45°F) or less.

(c) Storage on the transporter's property shall also meet the requirements of 20 CAR § 53-305(a) – (c).

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-418. Commercial regulated medical waste transportation permits.

(a) Commercial regulated medical waste transportation permits are issued for a period of one (1) year.

(b) Permits are nontransferable.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-419. Registration changes.

Commercial medical waste transporters shall notify the Department of Health, by letter, within fifteen (15) days of any changes to their registration if:

- (1) The office or place of business is moved and/or the mailing address changes;
- (2) The name of registrant or owner of the operation is changed;
- (3) The name or names of the partners, corporate directors, or corporate officers change; or
- (4) New trucks or trailers that were not originally listed on the permit application are added.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-420. Revocation or denial of permits.

Revocation or denials of permit procedures are as follows:

- (1) If the commercial transporter has a history of noncompliance with any law or regulation of this state or any other jurisdictions, particularly those regulations pertaining to the protection of the environment and the protection of the health and safety of the public, the Department of Health may refuse to issue a permit;
- (2) If a history of noncompliance is discovered after a permit is issued, the department may require bonding as outlined in 20 CAR § 53-421, modify the permit, or revoke the permit;
- (3) Examples of noncompliance include, but are not limited to, the following:
 - (A) Falsification of application or medical waste manifest/tracking forms;
 - (B) Delivery of untreated medical waste to a facility not authorized to handle the waste;
 - (C) Failure to maintain complete and accurate records as required in this part;
 - (D)(i) Failure to maintain vehicles involved in the transportation of medical waste in safe working order as evidenced by citations from the Division of Arkansas State Police or Arkansas Highway Police Division of the Arkansas Department of Transportation or local traffic law agencies.

(ii) The Department of Health may use the Motor Carrier Management Information Carrier Operations and Safety Ratings (Safety Net) as a compliance tool;

(E) Failure to comply with any rule or order issued by the Department of Health pursuant to the requirements of this part;

(F) Failure to submit an annual report;

(G) Failure to submit required quarterly fees; or

(H) Illegal disposal of untreated or treated medical waste; and

(4) Procedures for filing a "Notice of Contest" for violations cited by the Department of Health are outlined in 20 CAR § 53-601 et seq.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-421. Bonding.

(a) As outlined in 20 CAR § 53-420, bonding may be required by the Department of Health.

(b) The permittee will be notified if bonding is required.

(c) Bonding requirements are as follows:

(1)(A) A nonaccumulating surety bond in the amount of one hundred thousand dollars (\$100,000) must be procured.

(B) Proof of bond procurement is required;

(2) Bonds will be forfeited for noncompliance with site clean up or other major noncompliance as determined by the department; and

(3) Bonds can only be cancelled after thirty (30) days written notice has been given to the department.

(d) Lawsuits under the bond must be brought to determination within one (1) year of filing.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-422. Commercial medical waste transportation permit process.

To obtain a commercial medical waste transportation permit, the commercial transporter shall submit at least forty-five (45) days before the anticipation of the permit issue date and thirty (30) days before the expiration date of an existing permit to the Department of Health, Medical Waste Program each of the following:

- (1) An application fee of two hundred-fifty dollars (\$250);
- (2) A completed and signed application on forms provided by the Department of Health for a commercial medical waste transportation permit;
- (3) Certification form provided by the Department of Health of a duly authorized representative of the company stating the company understands and is/will be in full compliance with all applicable portions of the following:
 - (A) This part, Rules Pertaining to the Management of Regulated Medical Waste from Healthcare Related Facilities;
 - (B) United States Occupational Safety and Health Administration Bloodborne Pathogen Standard, 29 C.F.R § 1910.1030, as applicable;
 - (C) United States Department of Transportation Hazardous Materials Regulations, 49 C.F.R. pts. 171, 172, 173, and 178 in relationship to medical waste, as applicable; and
 - (D) United States Department of Transportation Federal Motor Carriers Safety Regulations, 49 C.F.R. pts. 383 – 399, as applicable;
- (4) Certification by a duly authorized representative of the company on forms provided by the Department of Health that all vehicles transporting commercial medical waste shall meet the requirements listed below:
 - (A) Each truck, trailer, semitrailer, vacuum tank, cargo tank, or container used for transporting medical waste shall be designed and constructed and its contents so limited, that under conditions incident to transportation, there shall be no release of medical waste to the environment;
 - (B) It is against the policy of the company to transport commercial medical waste with other types of waste or nonwaste materials (with the exception of

medical waste equipment and supplies) and that the cargo body or compartment shall be separated by a solid barrier from the driver and passengers; and

(C) All vehicle/trailer compartments in which medical waste is stored for transport shall remain locked at all times except when loading and unloading;

(5)(A) A list of all vehicles and type of containers to be used by the permittee for transporting commercial medical waste shall be maintained.

(B) A copy of the registration paper for each vehicle/trailer shall be submitted with the application and copies of all required inspection documents as outlined in 20 CAR § 53-412;

(6)(A) A written copy of the company's operating plan for the handling and transport of commercial medical waste meeting the requirements of 20 CAR § 53-402 is required with the permit application.

(B) For renewal of the permit, the operating plan need be submitted only if changes have occurred to the plan;

(7) A copy of the permit of an approved treatment, storage, or disposal facility to which the medical waste is being transported is required with the application;

(8)(A) A copy of the transporter's training program is required with the application.

(B) For renewal of the permit, the training program need be submitted only if changes have occurred in the program;

(9)(A) Copies are required with the permit application of any inspections, reviews, etc., conducted by any government agencies (federal, state, or local) of the transporter, transporter's equipment, or personnel as related to commercial medical waste during the preceding twelve (12) months.

(B) If no such inspections or reviews exist, the transporter must reveal that fact;

(10) A copy of the insurance provider's certificate of insurance coverage is required, listing the Department of Health as certificate holder for cancellation notice or, when self-insured, a copy of the letter from the Department of Finance and Administration certifying the company is self-insured; and

(11) A copy of the Department of Health-issued transfer facility permit, as applicable.

Authority. Arkansas Code §§ 20-32-106, 20-32-107, 20-7-109.

Subpart 5. Requirements for Commercial Medical Waste Treatment, Storage, and/or Disposal Facilities (TSD) and Commercial Mobile Treatment Systems

20 CAR § 53-501. Permits.

(a)(1) All commercial medical waste treatment, storage, and/or disposal (TSD) facilities and commercial mobile treatment/disposal systems shall obtain a permit before construction or modification begins.

(2) Mobile systems may be already constructed.

(b)(1) Commercial medical waste incinerator facilities shall obtain an incinerator permit from the Division of Environmental Quality.

(2) Incineration facilities are not required to have a storage permit.

(3) Storage requirements will be outlined in the operating license.

(c) All other commercial medical waste nonincinerator treatment, storage, and/or disposal facilities and mobile treatment/disposal systems shall obtain a permit from the department.

(d) In addition, all incineration and nonincineration treatment, storage, and/or disposal (TSD) facilities and mobile medical waste treatment systems shall obtain an annual operating license from the department before storage, treatment, and/or disposal begins, as outlined in 20 CAR § 53-520.

(e)(1) Facilities that were in operation before the effective date of this part shall have ninety (90) days to obtain an operating license after the effective date.

(2) Required fees for treatment/disposal shall begin upon issuance of the operating license.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-502. Prohibitions on facility location.

Pursuant to Arkansas Code § 20-32-109, a proposed nonincinerator medical waste treatment, storage, and/or disposal (TSD) facility will not be issued a permit for the construction or operation of a facility in which any of the following factors are present:

(1) The location of the facility is within a "regulatory floodway" as adopted by communities participating in the National Flood Insurance Program managed by the Federal Emergency Management Agency;

(2) The location of the facility overlies any portion of a significant surface or subsurface sand aquifer or its primary recharge zone or high-yield bedrock aquifer, as defined by the Department of Health;

(3) The location of the facility could pose a threat to fisheries, wildlife, or other natural resources or a sanctuary, refuge, preserve, critical habitat, or fish hatchery;

(4) The location of the facility does not comply with zoning regulations of the locality in which the facility is proposed; or

(5) The location of the facility is within the boundary of a state or federal park or designated wilderness area.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-503. Additional application requirements.

At least thirty (30) days prior to submitting a permit application for a TSD facility, the applicant shall have completed the following:

(1)(A) A written notification by certified mail to each property owner or resident of any property adjacent to the proposed facility site.

(B) A copy must also be provided to the Medical Waste Program;

(2)(A) Publication of a public notice in the largest newspaper in each county where the property is proposed for construction and in at least one (1) newspaper with a statewide circulation of the intent to apply for a commercial medical waste treatment, storage, or disposal permit to construct and operate the facility.

- (B) A copy must also be provided to the Medical Waste Program; and
- (3) The Department of Health shall be notified of a facility's intent to apply for a permit application before initiating the requirements of subdivisions (1) and (2) of this section.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

Codification Notes. "TSD" means treatment, storage, and/or disposal.

20 CAR § 53-504. Proposed treatment techniques.

- (a) All proposed treatment techniques, with the exception of incineration, shall:
 - (1) Be approved by the Department of Health; and
 - (2) Meet the following levels of microbial inactivation:
 - (A) Inactivation of representative samples of mycobacteria, at a level of 6 log 10 (99.9999%) reduction or greater, as determined by the department; and
 - (B) Inactivation of *Geobacillus stearothermophilus* endospores or *Bacillus atrophaeus* endospores at a level of 4 log 10 (99.99%) reduction or greater, as determined by the department.
- (b) After the department approves the proposed technology, on-site treatment efficacy testing is required before an operation license is issued, with the exception of incineration technologies.
- (c) Total destruction technologies must receive approval from the department for the type, use, or waiver of efficiency testing.
- (d) One (1) or more representative surrogate microorganisms from each microbial group shall be used in the treatment efficacy evaluation, unless waived by the department.
- (e) The department shall determine the appropriate microorganisms to serve as representative surrogate microorganisms.
- (f) Protocols developed for efficacy testing shall incorporate, as applicable, recognized standard procedures.

(g) Guidelines for testing and approval of medical waste treatment technologies may be obtained from the department.

(h) The department shall be notified at least twenty (20) working days before efficacy testing begins.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-505. Operating license required.

(a) No person may operate a commercial medical waste incineration or nonincineration treatment, storage, and/or disposal facility or a mobile system, not to include a POTW, without first obtaining an operating license from the Department of Health.

(b) The operating license will be issued for a period of one (1) year.

(c) Storage capacity, efficacy testing, and operating rates will be outlined in the operating license.

(d) The Division of Environmental Quality may set the operating rates for incineration technologies.

(e) Procedures for obtaining an operating license are outlined in 20 CAR § 53-520.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-506. Accepting medical waste.

(a) Commercial medical waste treatment, storage, and/or disposal (TSD) facilities can only accept medical waste from permitted commercial medical waste transporters or primary generators.

(b) Mobile treatment systems can only accept medical waste from the on-site generator or its affiliated services, unless authorized by the Department of Health to accept off-site generated medical waste.

(c) Commercial medical waste must be accompanied with a tracking paper/manifest that meets the requirements of 20 CAR § 53-411 in order for a medical

waste treatment, storage, and/or disposal (TSD) facility to accept the waste unless being treated on-site by a mobile treatment system or delivered by the primary generator.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-507. Commercial mobile treatment locations.

Commercial mobile treatment systems shall treat commercial medical waste only on the premises of the generation facility or a designated location as approved by the Department of Health.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-508. Storage facility temperature.

Permitted storage facilities shall maintain a storage temperature of forty-five degrees Fahrenheit (45°F) or less for medical waste held for more than seventy-two (72) hours and shall also meet the requirements of 20 CAR § 53-305(a) – (c).

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-509. Facility signage.

(a) Treatment, storage, and/or disposal (TSD) facilities must prevent the unknowing entry, and minimize the possibility of the unauthorized entry of persons into the active portion of the facility by either an artificial or natural barrier (e.g., a fence in good repair or a fence combined with a cliff) which completely surrounds the active portions of the facility, and is at least seven feet (7') tall for all facilities approved after the effective date of this part.

(b)(1) Signs with the legend "Danger - Unauthorized Personnel Keep Out" or the biohazard legend as listed in 20 CAR § 53-304(c)(1) shall be posted at each entrance to

the active portion of a facility and at other locations in sufficient numbers that may be seen from any approach to the active portion.

(2) The signs shall be legible from at least twenty-five feet (25').

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-510. Weight.

(a) A fee of five dollars (\$5.00) a ton is required for all commercial untreated medical waste that is treated or disposed of in Arkansas.

(b) Methods of determining the weight of commercial medical waste and associated fees are as follows:

(1) **Weight determination.**

(A) In all cases weights shall be verifiable.

(B)(i) Accurate weight tabulation in pounds must be kept monthly on a per vehicle or transporter basis.

(ii) Estimates of container weights derived from the containers are not permissible.

(C) Weights of the medical waste may be determined as follows:

(i) Net weights of trailer or vehicle loads may be determined by subtracting the weight of the empty vehicle/trailer from the total weight of the trailer/vehicle and load contents;

(ii) Net weights of trailer or vehicle loads may be determined by scale tickets, manifest/tracking papers, or other like documentation; and

(iii) The required documentation shall be kept for three (3) years from the time of receipt of the medical waste and shall be made available to the Department of Health upon request; and

(2) **Fees.**

(A) The commercial medical waste TSD facility shall pay a fee of five dollars (\$5.00) per ton of medical waste treated/disposed.

(B) The fee is calculated by multiplying the fee per ton by the weight of the waste as determined in subdivisions (b)(1) or (2) of this section in pounds divided by two thousand (2,000).

(C) The division should be carried to the second decimal and rounded to the nearest tenth as follows:

$$\frac{\text{Weight of Waste in Pounds}}{2000} \times \$5.00 = \text{fee}$$

(D) Weight tabulations and fees are calculated each calendar quarter.

(E)(i) Weight tabulations and fee payment for the previous quarter are due forty-five (45) days from the end of the quarter.

(ii) Quarters are based on the periods:

(a) January 1 to March 31;

(b) April 1 to June 30;

(c) July 1 to September 30; and

(d) October 1 to December 31.

(F) Payments are to be made to the medical waste disposal program.

Authority. Arkansas Code §§ 20-32-106, 20-32-107, 20-7-109.

Codification Notes. "TSD" means treatment, storage, and/or disposal.

20 CAR § 53-511. Logs and tracking papers.

(a) TSD facilities shall keep a log of their daily receipts from generators and commercial transporters of medical waste.

(b) The log shall show, at a minimum, the:

(1) Name and address of the permitted transporter or generator;

(2) Transporter permit number;

(3) Date of acceptance;

(4) Weight (pounds); and

- (5) Final date of treatment/disposal.
- (c) Manifests/tracking papers shall accompany all shipments of commercial medical waste.
- (d) Log records and manifests/tracking papers shall be:
 - (1) Kept on file for three (3) years; and
 - (2) Made available to the Department of Health upon request.
- (e) The commercial medical waste treatment, storage, and/or disposal (TSD) facility shall provide the medical waste generator or permitted transporter, which ever delivers the medical waste, with documentation of facility's receipt of the medical waste and/or treatment/destruction after medical waste has been treated or disposed, if requested.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

Codification Notes. "TSD" means treatment, storage, and/or disposal.

20 CAR § 53-512. Training.

- (a) All personnel involved in the management, storage, and treatment/disposal of commercial medical waste shall be properly trained in the identification, handling, and safety requirements of medical waste for their own protection and others.
- (b) The commercial medical waste treatment, storage, and/or disposal (TSD) facility shall have a written training program.
- (c) Training shall:
 - (1) Occur before the initial job assignment; and
 - (2) Be repeated at least annually.
- (d) Written documentation is required of employee training.
- (e) This training shall include, but not be limited to, the following:
 - (1) Treatment, storage, and/or disposal (TSD) facility's written operation plan/procedure as outlined in 20 CAR § 53-520;

(2) This part, Rules Pertaining to the Management of Regulated Medical Waste from Healthcare Related Facilities;

(3) Mechanisms by which disease transmission may occur;

(4) Requirements of the United States Occupational Safety and Health Administration Bloodborne Pathogen Standard, 29 C.F.R. § 1910-1030;

(5) Proper use of protective measures to prevent contact with medical waste by both facility personnel and the public;

(6) Selection, use, and decontamination/disposal of appropriate protective equipment; and

(7) Procedures to be taken in the event of an incident involving commercial medical waste, including the:

(A) Notification of the appropriate authorities; and

(B) Facility's implementation of its contingency/spill management plan.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-513. Equipment filter requirement.

Equipment such as shredders, choppers, etc., that have the potential to produce aerosols must be fully contained under negative air pressure and exhausted through a HEPA filter.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

Codification Notes. "HEPA" means high-efficiency particulate absorbing.

20 CAR § 53-514. Annual report.

(a) Commercial medical waste treatment, storage, and/or disposal (TSD) facilities and commercial mobile treatment systems shall submit to the Department of Health an annual summary report of their activities from January 1 to December 31 of each year.

(b) The report shall be submitted no later than March 1 of the year following the end of the reporting period.

(c) The report shall include the following information on forms provided by the department:

(1) Name or names and address or addresses, transportation or storage permit numbers, and the amount of waste in pounds deposited/unloaded by each transporter, storage facility, or generator that transferred/unloaded medical waste to the facility or commercial mobile system;

(2) The amount of waste in pounds treated/disposed on-site by the facility;
and

(3) The amount of medical waste in pounds/tons stored on-site that was not treated/disposed during the reportable year.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-515. Facility permit process.

(a) To apply for a permit, the commercial medical waste treatment, storage, and/or disposal (TSD) facility shall submit each of the following to the Department of Health's Medical Waste Program:

(1) A completed and signed application for a commercial medical waste treatment, storage, and/or disposal (TSD) facility or permit including the legal owner, proposed physical facility address, and mailing address and organization status of the applicant on forms provided by the department;

(2) The legal description of the property and a plot plan and area map;

(3)(A) Written process description and process flow diagram sufficient in detail to provide the department an understanding of the process.

(B) A detailed description of the medical waste treatment equipment, including manufacturer's instructions and equipment specifications, operating procedures and conditions, including as applicable, treatment times, temperatures, pressures, chemical concentrations, and irradiation doses, etc.;

(4) Proposed operating rates including the:

(A) Type and amount of commercial medical waste to be treated, stored, or disposed; and

(B) Proposed maximum operating hours per day, hours per month, days per week, and weeks per year;

(5)(A) Detailed engineering and architectural construction documents and specifications of the facility and equipment.

(B) Documents and specifications must be reviewed and bear the seal of an Arkansas-registered architect or engineer;

(6) Certification forms provided by the department that the facility will comply with the:

(A) Arkansas Mechanical Code, 17 CAR pt. 260;

(B) Arkansas Fire Prevention Code, 12 CAR pt. 15;

(C) Arkansas Plumbing Code, 17 CAR § 65; and

(D) National Electrical Code;

(7) Documentation showing the requirements of 20 CAR § 53-502 and 20 CAR § 53-503(1) and (2) have been met;

(8) Documentation demonstrating that the treatment method meets microbial inactivation as outlined in 20 CAR § 53-504(a)(2) and required testing protocols, including a detailed description of:

(A) The test procedures and calculations used in fulfilling designated performance standards verifying efficacy of user verification methodology; and

(B) Microbial culturing protocols that ensure traceability, purity, and concentration on forms provided by the department;

(9) Documentation for occupational safety and health assurance by describing the medical waste treatment equipment's safety systems such as:

(A) Warning signals;

(B) Operating zone restrictions;

(C) Lock out procedures; and

(D) Personal protection equipment requirements;

(10)(A) Documentation of all point and nonpoint source discharges from the facility or facility's equipment.

(B) Appropriate permit applications for those discharges must be submitted, as applicable, or letters from the Division of Environmental Quality indicating the applicable permits are not required;

(11) A description of waste residues generated (i.e., liquid, solid, shredded, hazardous constituents), waste designation (i.e., general, special, hazardous), disposal mechanisms, and recycling efforts, if anticipated;

(12) A copy of the facility's proposed closure plan outlining the methods to meet the requirements of 20 CAR § 53-701(a)(2)(D) and (b); and

(13) Other documentation or information as requested by the department.

(b) The department may levy up to one hundred dollars (\$100) per hour not to exceed five thousand dollars (\$5,000) for permit application processing costs incurred by the department.

(c) All costs imposed by the department, such as outside consultants, will be documented and submitted on a billing form.

Authority. Arkansas Code §§ 20-32-106, 20-32-108, 20-7-109.

20 CAR § 53-516. Commercial mobile treatment/disposal system permit requirement.

Commercial mobile treatment/disposal systems must meet the following requirements to receive a permit:

(1) The requirements of 20 CAR § 53-504 (microbial inactivation);

(2) The requirements of 20 CAR § 53-515(a)(4), (5), (9), and (10);

(3)(A) Documentation of all point and nonpoint source discharges from the mobile equipment.

(B) Copies of all appropriate permit applications for those discharges must be submitted, as applicable, or letters from the Division of Environmental Quality or other regulatory agencies indicating the applicable permits are not required;

(4) A description of waste residues generated (i.e., liquid, solid, shredded, hazardous constituents), waste designation (i.e., general, special, hazardous), disposal mechanisms and recycling efforts, if anticipated; and

(5) Other documentation or information as requested by the Department of Health.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-517. Modification permits.

(a)(1) Before any substantial changes can be made at a commercial nonincineration medical waste treatment, storage, and/or disposal (TSD) facility or a commercial mobile treatment system, a modification permit application must be issued.

(2)(A) Substantial changes include, but are not limited to:

- (i) Change in the treatment/disposal method;
- (ii) Major changes to the process rates and equipment;
- (iii) Change of ownership; or
- (iv) Change of location.

(B) Change of treatment location for mobile systems is not considered a substantial change.

(b) Permits are nontransferable.

(c) To apply for a permit modification, the commercial nonincineration medical waste treatment, storage, and/or disposal (TSD) facility or mobile treatment system owner shall submit each of the following to the Department of Health's Medical Waste Program:

(1) A notice of intent, signed by an authorized representative of the company, on forms provided by the department;

(2)(A) Detailed engineering and architectural construction documents and specifications of all substantial changes to the facility and/or equipment.

(B) Documents and specifications must be reviewed and bear the seal of an Arkansas-registered architect or engineer;

(3) Cases of location change, with the exception of commercial mobile units, will require 20 CAR § 53-502 and 20 CAR § 503(1) and (2) to be met;

(4) Cases where the treatment or disposal techniques change will require 20 CAR § 53-515(a)(9) – (12) to be met; and

(5) Other documentation or information as requested by the department.

(d) The department may levy up to one hundred dollars (\$100) per hour not to exceed five thousand dollars (\$5,000) for permit modification application processing costs incurred by the department.

(e) All costs imposed by the department, such as outside consultants, will be documented and submitted on a billing form.

Authority. Arkansas Code §§ 20-32-106, 20-32-108, 20-7-109.

20 CAR § 53-518. Permit for nonincinerator facility.

Before a permit or permit application for a nonincinerator commercial medical waste treatment, storage, and/or disposal (TSD) facility is granted, the following conditions will be met by the Department of Health:

(1) Notice by certified mail to the mayor of the city and the county judge of the county or counties where the property is the subject matter of the permit application is located; and

(2) A public hearing shall be held in the county or counties in which the facility is to be located.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-519. Permit cancellation.

The Department of Health may cancel a permit or modification permit if construction or modifications are:

(1) Not begun within eighteen (18) months from the date of the permit; or

(2) Suspended for eighteen (18) months or more from the date of permit issuance.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-520. Operating license.

To apply for an operating license, the commercial medical waste treatment, storage, and/or disposal (TSD) facility or mobile treatment system shall submit each of the following to the Department of Health's Medical Waste Program:

(1) An annual fee of two hundred fifty dollars (\$250) which includes the operating license annual fee for a mobile treatment system fleet operated by an applicant;

(2)(A) A completed and signed application for a commercial medical waste treatment, storage, and/or disposal (TSD) or mobile treatment system operating license which includes the legal owner or owners, proposed physical facility address, mailing address, and organization status of the applicant on forms provided by the department.

(B) For mobile treatment systems, the facility's address where on-site treatment will occur must be included;

(3) The legal description of the property and a plot plan and area map, unless previously submitted to the department or operation as a mobile on-site treatment system;

(4) Written process description and process flow diagram sufficient in detail to show the processes used in managing medical waste;

(5) Proposed operating rates, including the type and amount of medical waste to be treated, stored, or disposed and proposed maximum operating hours per day, hours per month, days per week, and weeks per year;

(6) For a commercial medical waste incinerator treatment, storage, and/or disposal (TSD) facility, a copy of an incineration permit issued by the Division of Environmental Quality;

(7) Certification forms provided by the department of a duly authorized representative of the company stating the company understands and is/will comply with all applicable portions of the following:

(A) This part, Rules Pertaining to the Management of Regulated Medical Waste from Healthcare Related Facilities; and

(B) The United States Occupational Safety and Health Administration Bloodborne Pathogen Standard, 29 C.F.R. § 1910.1030, as applicable; and

(8)(A) A written operating plan/procedure for the handling, treatment, storage, and disposal of medical waste.

(B) The following plan/procedure shall include the following:

(i) A method of receiving and handling medical waste separately from other waste until treatment/disposal which prevents unauthorized persons access to or contact with the waste;

(ii) A method of unloading and processing the medical waste which:

(a) Limits the number of persons handling the waste; and

(b) Minimizes the possibility of exposure of employees and the public to medical waste;

(iii)(a) A method of decontaminating emptied reusable medical waste containers, transport vehicles, or facility equipment that are or are believed to be contaminated with medical waste.

(b) **Note.** All transport cargo compartments, facility equipment, or other items shall be disinfected when contaminated or when it is believed to be contaminated.

(c) All disinfectants shall meet the requirements of 20 CAR § 53-307(d)(2)(B);

(iv)(a) The provision and required use of personal protective equipment for persons manually unloading or handling containers of medical waste.

(b) Contaminated protective equipment shall be disposed of as medical waste or cleaned and decontaminated;

(v) A description of the means of decontaminating any person having had bodily contact with medical waste while transporting, managing, treating, or disposing of the waste;

(vi)(a) Procedures to be followed in the event an individual or individuals have bodily contact with medical waste.

(b) These procedures shall include decontamination procedures and procedures for medical care; and

(vii) Procedures to be followed in response to equipment failure, utility failure, fire, explosion, spills, leaks, and/or releases which could threaten public health or the environment.

Authority. Arkansas Code §§ 20-32-106, 20-32-107, 20-7-109.

Subpart 6. Inspections of Medical Waste Generators, Commercial Medical Waste Treatment, Storage, or Disposal (TSD) Facilities, Commercial Mobile Treatment Systems, Commercial Transporters of Medical Waste

20 CAR § 53-601. Inspections.

(a) The Department of Health is authorized to conduct inspections of generators, transporters, medical waste treatment, storage and/or disposal (TSD) facilities, and mobile treatment systems where commercial medical waste is:

- (1) Generated;
- (2) Transported;
- (3) Stored;
- (4) Treated;
- (5) Destroyed;
- (6) Disposed;
- (7) Transferred; or
- (8) Otherwise managed.

(b)(1) The inspections may be announced or unannounced.

(2) The inspection may include the taking of photographs, samples, and copies of records, and/or any other information relevant to the management of medical waste.

(3) Biological monitoring may be conducted.

(4) Inspections shall be conducted during the facility's normal business hours unless the department determines an immediate inspection is necessary to protect the public health.

(c)(1) A written report of the inspection findings, recommendations, and required corrective action, including any proposed time frames, will be provided to an authorized representative of the facility within forty-five (45) working days of the conclusion of the inspection.

(2) The inspection reports are subject to the Freedom of Information Act of 1967, Arkansas Code § 25-19-101 et seq.

(d) If, in the opinion of the Medical Waste Program, apparent violations of other applicable regulations (United States Occupational Safety and Health Administration, United States Department of Transportation, United States Environmental Protection Agency, Division of Environmental Quality, etc.) are of a serious nature, the appropriate agency will be contacted and notified of the inspection results.

(e)(1) The facility will have fifteen (15) working days from receipt of the inspection report in which to file a "Notice of Contest" of all or any portion of the inspection results.

(2) This notice shall:

(A) Be sent to the Medical Waste Program;

(B) State which part or parts of the inspection results are in contention;

and

(C) Provide supporting documentation for any reasoning contrary to the inspection results.

(f) If a Notice of Contest is filed, the Medical Waste Program shall schedule a conference with an authorized representative of the facility to review the facts and discuss any further recommendations or requirements.

(g)(1) Final appeal of a ruling by the Medical Waste Program may be made to the State Board of Health.

(2) Notice of the appeal must be made within fifteen (15) working days after the conclusion of the conference as outlined in subsection (f) of this section, above.

(h)(1) Failure to correct violations of this part or regulations of other agencies (United States Occupational Safety and Health Administration, United States Department of Transportation, United States Environmental Protection Agency, the division, etc.) shall be grounds for review of the facility/company's permit.

(2) This may result in additional permit requirements, bonding as outlined in 20 CAR § 53-421, monetary penalties, or revocation of the permit.

(i)(1) The length of time responsible parties shall keep records required is automatically extended in the event a regulatory agency initiates an enforcement action, for which those are relevant.

(2) For the purpose of this part, relevant records are those which reference or refer to the matter subject to the enforcement action.

(3) In such cases, the parties shall keep relevant records until the conclusion of the enforcement action.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

Subpart 7. Closure of Commercial Regulated Medical Waste Treatment, Storage, and Disposal Facilities

20 CAR § 53-701. Closure of facilities.

(a)(1) A minimum of ninety (90) days prior to closure of any facility in which commercial medical waste was either treated, stored, or disposed, a Notice of Closure shall be submitted to the Department of Health.

(2) The Notice of Closure shall include the following:

(A) Proposed date of closure;

(B) Current inventory of untreated and treated medical waste currently on site;

(C) Date of last shipment of medical waste to be received by the facility;

(D) Proposed methods of decontamination of equipment, treatment areas, and air systems related to the treatment areas, buildings, etc., including planned quality control/quality assurance procedures to verify the absence of pathogenic organisms; and

(E)(i) Projected date decontamination will begin and end.

(ii) The department shall be notified twenty (20) working days in advance of the decontamination procedures.

(iii) Failure to notify the department shall result in the requirement to redecontaminate the facility.

(b)(1) Wastes generated during decontamination of facility equipment, treatment areas, buildings, etc., which potentially became contaminated with medical waste must be treated as medical waste.

(2) All other wastes not regulated as medical must be handled and disposed in accordance with the Division of Environmental Quality rules and/or any local ordinances, as applicable.

(c)(1) Upon final closure, the department will review all quality control/quality assurance data to verify the absence of pathogenic organisms and conduct an onsite inspection.

(2) When all conditions of clean closure have been completed to the satisfaction of the department, a letter of clean closure will be provided to the facility/company.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

Subpart 8. Responsibility

20 CAR § 53-801. Generally.

Any person generating, transporting, treating, storing, or disposing of medical waste, unless exempted as outlined in 20 CAR § 53-201 et seq., or transporting or treating, storing, and/or disposing of commercial medical waste, shall be responsible for compliance with this part and all other federal, state, and local laws related to medical waste.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-802. Illegal dumping.

(a) Any person who is convicted of illegally dumping medical waste in violation of the Litter Control Act, Acts 1977, No. 883, shall be guilty of a Class C misdemeanor and the penalties for such shall be those established under the Arkansas Criminal Code.

(b)(1) Persons found to have committed the prohibited acts as listed in subsection (a) of this section in furtherance of or as a part of a commercial enterprise, shall be guilty of "commercial littering" and as such shall be guilty of a Class A misdemeanor and the penalties shall be those prescribed under the Arkansas Criminal Code.

(2) Additionally, those convicted may be required to remove any litter disposed in violation of the Litter Control Act, Acts 1977, No. 883.

(c)(1) When the Department of Health is notified of the presence and location of illegally dumped or abandoned medical waste, an investigation will be conducted in an effort to determine the responsible party.

(2) If the offender is identified, it will be the offender's responsibility to properly dispose of the waste and conduct any decontamination as required.

(3) In instances where responsibility cannot be determined, the department will be responsible for arranging the appropriate clean-up, disposal, and any decontamination of the area by properly trained and protected personnel.

(4) If the responsible party is identified after the department has properly decontaminated the area and disposed of the medical waste, the responsible party shall be liable for all costs incurred in addition to any penalties, as applicable.

Authority. Arkansas Code §§ 20-32-106, 20-7-109.

20 CAR § 53-803. Violations concerning nonincineration TSD facilities.

(a)(1) Any person who violates any provision of this part concerning commercial medical waste nonincineration TSD facilities shall be guilty of a felony.

(2) Upon conviction, that person shall be subject to imprisonment for not more than one (1) year and a fine of not more than twenty-five thousand dollars (\$25,000) or both.

(b)(1) In addition, any person who violates any provision of this part concerning commercial medical waste nonincineration TSD facilities may be subject to a civil penalty by the State Board of Health.

(2) The penalty shall not exceed ten thousand dollars (\$10,000) for each violation.

(c)(1) Any person, carrier, or any officer, employee, agent, or representative thereof, while operating any vehicle transporting medical waste, or which is authorized to transport medical waste, who shall violate any of the rules, including safety rules, prescribed or hereafter prescribed by the State Highway Commission pursuant to the provisions of Title 23 of the Arkansas Code or who shall violate any rule of the Department of Health which specifically relates to the transportation of medical waste, shall be deemed guilty of a misdemeanor.

(2) Upon conviction, that carrier, or office, employee, agent, or representative thereof, shall be fined not more than five hundred dollars (\$500) for the first offense and not less than five hundred dollars (\$500) nor more than one thousand dollars (\$1,000) for any subsequent offenses.

(d) Violations of any provision of this part for commercial medical waste may be grounds for permit modifications, restrictions, bonding, or termination of the permit as outlined in 20 CAR § 53-420.

(e)(1) Pursuant to Arkansas Code § 20-32-105, the Division of Arkansas State Police and the enforcement officers of the Arkansas Highway Police Division of the Arkansas Department of Transportation are authorized to:

(A) Stop vehicles suspected of transporting commercial medical waste to ensure that all required permits for transporting commercial medical waste have been obtained; and

(B) Enforce all laws and rules relating to the transportation of commercial medical waste.

(2) The enforcement officers of the Arkansas Department of Transportation are authorized to:

(A) Conduct vehicle safety inspections of those vehicles transporting or intending to be utilized to transport commercial medical waste;

(B) Inquire into the history of any safety or equipment regulation violations of the transporter in any state; and

(C) Advise the Department of Health of the results of such inspections and inquiries.

(f) **Note.**

(1) Transporters, mobile treatment systems and facilities that treat, store, and/or dispose of commercial medical waste must have a permit from the Department of Health.

(2) Incineration facilities must obtain an incinerator permit from the Division of Environmental Quality.

(3) All facilities that treat, store, and/or dispose of commercial medical waste must have an operating license.

(g) Application forms and information may be obtained by contacting the Arkansas Department of Health's Medical Waste Program, 4815 West Markham, Slot 32, Little Rock, AR 72205-3867, Phone (501) 661-2621.

Authority. Arkansas Code §§ 20-32-103, 20-32-106, 20-7-109.

Codification Notes. "TSD" means treatment, storage, and/or disposal.