EXHIBIT C

DEPARTMENT OF HEALTH, STATE BOARD OF HEALTH

SUBJECT: Standards Pertaining to Human Breast Milk Banks

DESCRIPTION:

Background

The purpose of these Standards is to comply with the requirements of Act 225 of 2021 regarding appropriate safety standards in the transporting, processing, and distributing of commercial human breast milk to protect the citizens of Arkansas.

Key Points

These changes were required to reflect legislation, Act 225 (Ark. Code Ann. § 20-7-140), during the 2021 legislative session.

Discussion

It is proposed to modify the Rules Pertaining to Human Breast Milk Banks as follows:

1. Update rule name to reflect language in Act 225 of 2021.
2. Update cover page including effective dates, Secretary of Health, and State Health Officer information.
3. 4.4.2 (page 7), we have removed the statement regarding the requirement for a baby's healthcare provider to provide a statement of known health or medical risks is no longer a requirement.
4. 4.4.4 (page 7), replaces the term Members of the Medications Committee to Medical Director and approved by the human breast milk bank's panel of consultants. This panel is referred to in section 3.2 and reflects what was already in the rules.
5. 4.4.4.5 (Page 8-9), removes a written list of specific medications that do not defer a potential donor; refers back to 4.4.4. and the Medical Director and panel of consultants determining which medications are permissible and which ones are not.
6. Section 6, 6.1 – 6.14 (page 10-13), these have been updated to reflect current practices. The reasons for disqualification, either temporarily or totally, have been revised, and reflect current regulatory guidelines from AABB (Association for the Advancement of Blood and Biotherapies), US CDC, and other regulatory bodies, and these reasons are recognized and used by the Human Milk Bank Association of North America.
7. 6.15-6.19 (page 13) have been removed as these are no longer seen as reasons to disqualify individuals from donating milk, or they are thought to be covered by another listed reason.
8. Completely removed Section 7 (page 13-15), Temporary Disqualification, as concerns are addressed in Section 6.
9. Section 22.2 (page 23-24), updated spelling.

The following changes were made in response to public comment:

- Revised Section 4.4.3 to include language "that achieved accreditation from an International Laboratory Accreditation Cooperation recognized accreditation body…"
- Revised Section 15.3.2 regarding calibration of thermometers.
- Struck language from Section 26.1.3 for consistency with Section 4.4.2.

PUBLIC COMMENT: No public hearing was held on this rule. The public comment period expired on February 28, 2024. The agency provided the following public comment summary:

Commenter's Name: Randall Querry, Director Government Relations, American Association for Laboratory Accreditation (A2LA)

COMMENT: We appreciate the opportunity to provide comments directed at the proposed rule "Standards Pertaining to Human Breast Milk Banks." Specifically, we write regarding laboratory testing and calibration requirements and the related laboratory accreditation standards. By way of background, A2LA is a non-profit, accreditation body with over 4200 actively accredited certificates representing all 50 states and international, and 30 organizations accredited in Arkansas including the Arkansas Public Health Laboratory. We have been granting accreditation to laboratories in various industries since 1979.

The criteria forming the basis for our testing and calibration laboratory accreditation programs is ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories. We also provide accreditation to clinical laboratories to ISO 15189 Medical laboratories – Requirements for quality and competence; and achieved and maintain Centers for Medicare and Medicaid Services (CMS) Deem Status as an accreditation organization to accredit clinical laboratories to the Clinical Laboratory Improvement Amendments (CLIA) requirements. We ourselves, as an accreditation body, have been evaluated against rigorous standards in providing these accreditation services and we are the only accreditation body in the world that is recognized globally as an International Laboratory Accreditation Cooperation (ILAC)-recognized accreditation body and CMS deemed status accreditation organization.

We offer the following comments for your consideration. Our recommended language is inserted in bold: In section 4.4.3, the requirements specify "A CLIA certified high complexity clinical laboratory, or an ISO 17025 accredited clinical laboratory does the tests…" Please note that an additional ISO standard exists that is based on ISO/IEC 17025 and ISO 9001 but specifies requirements for quality and competence that are particular to medical laboratories. This ISO standard is ISO 15189 and has been in use for close to twenty years. We recommend that 4.4.3 be revised to "A CLIA certified high complexity ~~**clinical**~~ laboratory or an ISO/IEC 17025 **or ISO 15189** accredited clinical laboratory, **which achieved accreditation from an International Laboratory Accreditation Cooperation recognized accreditation body,** does the tests…"

In section 8.1, consider revising certified laboratory to the following: "A certified or accredited laboratory is to conduct screening blood tests…"

Section 10.1 provides requirements for the breast milk bank to have disaster plans. We support this requirement; however, we advise that a provision be included to require periodic testing of the disaster plans to ensure that they are effective. We recommend that Section 10.1 be amended by adding a third, final sentence "**The disaster plan shall be testing at periodic intervals to determine effectiveness.**"

In section 15.3.2, the requirements specify, "Thermometers may be certified calibrated by National Institute of Standards and Technology(NIST) (or similar agency) or calibrated quarterly by the milk bank using an NIST certified reference thermometer. The milk bank must keep records of calibration." It is industry practice to rely on NIST calibration or rely on an ISO/IEC 17025 accredited calibration laboratory that is accredited by an ILAC recognized accreditation body for calibration of the reference thermometers. Then the milk bank may verify working thermometers against the reference thermometers. This can be more cost effective to the milk bank than as currently written in the proposed rule. We recommend the following revision to section 15.3.2: "Thermometers may be calibrated **by a national metrology institute (NMI) such as** the National Institute of Standards and Technology (NIST) **or an ISO/IEC 17025 accredited calibration laboratory that is accredited by an ILAC recognized accreditation body, for the calibration of the reference thermometers. The milk bank shall verify working thermometers against the calibrated reference thermometers at least quarterly.** The milk bank must keep records of **the** calibration **and verification records**."

In Section 14.1, second sentence, we recommend the following addition: Two distinct and appropriately calibrated (see section 15.3.2) thermometers – whether electronic, or indwelling, or mercury—monitor freezers. Also note that the EPA has launched an effort to reduce the use of mercury-filled non-fever thermometers. As referenced on the EPA website: EPA has launched an effort (https://www.epa.gov/mercury/mercury-thermometers) to reduce the use of mercury-filled non-fever thermometers used in industrial settings where suitable alternatives exist. As part of a partnership EPA developed with the National Institute of Standards and Technology (NIST), NIST no longer provides calibration services for mercury thermometers. You can read more about the impact the decision will have in NIST's February 2011 press release announcing the change.

Section 26.1.3 appears to be inconsistent with section 4.4.2, where language was struck out concerning the baby. Section 26.1.3 still includes a requirement for the infant. This may need to be reviewed further to consider striking the infant requirement.

Section 27.5, requirements are in place to initiate a root cause analysis. We respectfully recommend that this language be improved upon. We recommend a fourth and final sentence added to 27.5 that states "**Following implementation of a corrective action, (e.g. three months), audit the correction to determine its effectiveness.**"

RESPONSE: The Department has revised the Standards in response to public comment.

Lacey Johnson, an attorney with the Bureau of Legislative Research, made the following observation and received the following response:

Q. Section 26.1.3 is similar to § 4.4.2, which was amended, but no changes were made to § 26.1.3. Just wanted to flag this. **RESPONSE:** For § 26.1.3, that is a correct catch. The information regarding the medical release for an infant did need to be removed, and we have made the change. It is essentially a typo and not substantive.

The proposed effective date is pending legislative review and approval.

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

LEGAL AUTHORIZATION: "The Department of Health shall establish, by rule, standards for transporting, processing, and distributing commercial human breast milk on a for-profit or nonprofit basis in this state." Ark. Code Ann. § 20-7-140(a).

Arkansas Department of Health

4815 West Markham Street • Little Rock, Arkansas 72205-3867 • Telephone (501) 661-2000

Governor Sarah Huckabee Sanders

Renee Mallory, RN, BSN, Secretary of Health

Jennifer Dillaha, MD, Director

PROPOSED REVISIONS TO THE STANDARDS PERTAINING TO HUMAN BREAST MILK BANKS

PURPOSE

The Arkansas Department of Health (Department) proposing amendments to the Standards Pertaining to Human Breast Milk Banks.

BACKGROUND

The purpose of these Standards is to comply with the requirements of Act 225 of 2021 regarding appropriate safety standards in the transporting, processing, and distributing of commercial human breast milk to protect the citizens of Arkansas.

KEY POINTS

These changes were required to reflect legislation, Act 225 (Ark. Code Ann. § 20-7-140), during the 2021 legislative session.

DISCUSSION

It is proposed to modify the Rules Pertaining to Rabies Control as follows:

1. Update rule name to reflect language in Act 225 of 2021.

2. Update cover page including effective dates, Secretary of Health, and State Health Officer information.

3. 4.4.2 (page 7), we have removed the statement regarding the requirement for a baby's health care provider to provide a statement of known health or medical risks is no longer a requirement.

4. 4.4.4 (page 7), replaces the term Members of the Medications Committee to Medical Director and approved by the human breast milk bank's panel of consultants. This panel is referred to in section 3.2 and reflects what was already in the rules.

5. 4.4.4.5 (Page 8-9), removes a written list of specific medications that do not defer a potential donor; refers back to 4.4.4. and the Medical Director and panel of consultants determining which medications are permissible and which ones are not.

6. Section 6, 6.1 – 6.14 (page 10-13), these have been updated to reflect current practices. The

reasons for disqualification, either temporarily or totally, have been revised, and reflect current regulatory guidelines from AABB (Association for the Advancement of Blood and Biotherapies), US CDC, and other regulatory bodies, and these reasons are recognized and used by the Human Milk Bank Association of North America.

7. 6.15-6.19 (page 13) have been removed as these are no longer seen as reasons to disqualify individuals from donating milk, or they are thought to be covered by another listed reason.

8. Completely removed Section 7 (page 13-15), Temporary Disqualification, as concerns are addressed in Section 6.

9. Section 22.2 (page 23-24), updated spelling.

QUESTIONNAIRE FOR FILING PROPOSED RULES WITH THE ARKANSAS LEGISLATIVE COUNCIL

DEPARTMENT Arkansas Department of Health
BOARD/COMMISSION Center for Health Advancement
BOARD/COMMISSION DIRECTOR Cristy Sellers
CONTACT PERSON Laura Shue, General Counsel
ADDRESS 4815 West Markham Street, Slot 31, Little Rock, AR 72205
PHONE NO. (501) 661-2297 **EMAIL** Laura.Shue@arkansas.gov
NAME OF PRESENTER(S) AT SUBCOMMITTEE MEETING
Laura Shue; Cristy Sellers
PRESENTER EMAIL(S) Laura.Shue@arkansas.gov; Cristy.Sellers@arkansas.gov

INSTRUCTIONS

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

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

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

Please answer each question completely using layman terms.

****

1. What is the official title of this rule?
Standards Pertaining to Human Breast Milk Banks

2. What is the subject of the proposed rule? The purpose of these Standards is to comply with the requirement

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

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

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

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

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

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

On what date does the emergency rule expire?_____

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

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

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

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

Ark. Code §20-7-140

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

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

The proposed amendments to the existing rule are to comply with Act 225 of 2021.

8. Is this a new rule? Yes ☐ No ☑

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

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

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

Ark. Code §20-7-140

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

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

Act 225 of 2021

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

The purpose of these Standards is to comply with the requirements of Act 225 of 2021 regarding appropriate safety standards in the transporting, processing, and distributing of commercial human breast milk to protect the citizens of Arkansas.

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

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

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

If yes, please complete the following:

Date: _____

Time: _____

Place: _____

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

14. On what date does the public comment period expire for the permanent promulgation of the rule? Please provide the specific date. 02/28/2024

15. What is the proposed effective date for this rule? 5/1/2024

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

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

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

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

If yes, please explain.

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY.

DEPARTMENT Arkansas Department of Health
BOARD/COMMISSION Center for Health Advancement
PERSON COMPLETING THIS STATEMENT Laura Shue, General Counsel
TELEPHONE NO. (501) 661-2297 **EMAIL** Laura.Shue@arkansas.gov

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

TITLE OF THIS RULE Standards Pertaining to Human Breast Milk Banks

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

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

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

   If no, please explain:

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

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

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

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

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

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

Current Fiscal Year	**Next Fiscal Year**
General Revenue_____	General Revenue_____
Federal Funds_____	Federal Funds_____
Cash Funds_____	Cash Funds_____
Special Revenue_____	Special Revenue_____
Other (Identify)_____	Other (Identify)_____
Total $0.00	Total $0.00

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

Current Fiscal Year	**Next Fiscal Year**
General Revenue_____	General Revenue_____
Federal Funds_____	Federal Funds_____
Cash Funds_____	Cash Funds_____
Special Revenue_____	Special Revenue_____
Other (Identify)_____	Other (Identify)_____
Total $0.00	Total $0.00

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

Current Fiscal Year	**Next Fiscal Year**
$_____	$_____

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

Current Fiscal Year	**Next Fiscal Year**
$_____	$_____

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

Yes ☐ No ☑

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

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

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

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

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

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

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

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

NOTICE OF PUBLIC COMMENT PERIOD

The Arkansas Department of Health (ADH) is accepting public comments on the Standards pertaining to Human Breast Milk Banks from January 29, 2024 to February 28, 2024. The comment period is provided to allow interested parties and the public to provide any comments. The proposed rule revision with a summary of changes can be viewed online at https://www.healthy.arkansas.gov/proposed-amendment-to-existing-rules or you may request a copy from our office at 501-614-5221.

Comments on the proposed changes can also be mailed to Arkansas Department of Health, Comments/Slot 41, 4815 West Markham, Little Rock Arkansas, 72205, or emailed to cristy.sellers@arkansas.gov.

ARKANSAS DEPARTMENT OF HEALTH

~~RULES~~ STANDARDS PERTAINING TO HUMAN BREAST MILK BANK ~~STANDARDS~~

PROMULGATED UNDER THE AUTHORITY OF

ARK. CODE ANN. §20-7-140

Effective ~~February 15, 2021~~

Arkansas Department of Health
~~José R. Romero, MD, FAAP, FPIDS, FAAAS~~ Renee Mallory, RN, BSN
Secretary of Health ~~and State Health Officer~~

Jennifer Dillaha, MD
Director and State Health Officer

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Section 1. Authority and Purpose

1.1 Pursuant to Act 216 of 2019, the Department of Health establishes the following standards for transporting, processing, and distributing commercial human breast milk on a for-profit or nonprofit basis. See Ark. Code Ann. § 20-7-140.

Section 2. Definitions

2.1 **Clean**—Physically remove dirt and debris by using detergents and water. An example of an appropriate detergent is common kitchen dish detergent.

2.2 **Collection**—The act of obtaining donor human breast milk.

2.3 **Disinfect**—Destroy or inactivate most microorganisms on hard surfaces. Disinfection requires specific times of exposure to agents; follow manufacturer's instructions.

2.4 **Distribution**—The delivery of pasteurized donor human breast milk (PDHBM) from a human breast milk bank to a hospital or other entities appropriate to receive breast milk (e.g., researchers, family with a prescription).

2.5 **Donor Human Breast Milk Bank**—A donor human breast milk bank is a service established for the purpose of recruiting and collecting breast milk from donors, and processing, screening, storing, and distributing donated breast milk, in accordance with these rules, to meet the specific needs of individuals.

2.6 **Donor Human Breast Milk**—Donor human breast milk is milk expressed and donated by lactating women, ~~pasteurized using the Holder Pasteurization Method~~subjected to a validated pathogen inactivation method, and dispensed for use by a recipient who is not the donor's own baby. Human Breast Milk banks may use the following additional terms; if terms are used, they comply with the following definitions:

2.6.1 **Fresh-raw breast milk** – Human breast milk expressed within 72 hours and stored at or below 4°C.

2.6.2 **Fresh-frozen breast milk** – Fresh raw human breast milk that has been frozen at -18°C for not longer than 12 months from date of collection.

2.6.3 **Holder pasteurized breast milk** – Fresh-raw and/or fresh-frozen breast milk that has been ~~heated to 62.5°C, for 30 minutes~~subjected to a validated method of pathogen reduction.

2.6.4 **Pooled breast milk** – Human breast milk combined with deposits from more than one donor.

2.6.5 **Preterm breast milk** – Human breast milk expressed within the first 4 weeks postpartum by a mother who delivered at or before 36 weeks gestation.

2.6.6 **Term breast milk** – Human breast milk pumped by mothers giving birth after 36 weeks, or before 36 weeks but after 4 weeks postpartum.

2.6.7 **Reduced fat breast milk** – Breast Milk that is separated and de-fatted for chylothorax patients or other patients requiring low fat milk (<1g/dl fat content).

2.6.8 **Early term breast milk** – Breast Milk that is collected from term mothers (>37 weeks gestation) during the first month of lactation.

2.6.9 **Dairy restricted** – Breast Milk expressed by mothers who report avoidance of explicit and inexplicit dairy products (including all processed foods).

2.6.10 **Pasteurized donor human breast milk (PDHBM)** – Donor human breast milk that has been collected, processed, and dispensed according to these rules.

2.7 **Donor Human Breast Milk-Contact Surfaces**—All surfaces that contact donor human breast milk during the normal course of operations. This includes utensils and food-contact surfaces of equipment, such as flasks, bottles, and caps.

2.8 **Donor Human Breast Milk Depot**—A donor human breast milk depot is an agency affiliated with a donor human breast milk bank that collects and stores donor breast milk that is then transported to the affiliated breast milk bank for processing. The breast milk bank accepts responsibility for all screening, processing, and distributing of milk.

2.9 **Donor Human Breast Milk Distribution Site**—A donor human breast milk distribution site is an agency affiliated with a breast milk bank that stores and distributes donor breast milk that was processed by a breast milk bank, and distributes the breast milk to hospitals or outpatients according to these rules.

2.10 **Equipment, Clean**—Equipment that is cleaned and maintained according to manufacturer's instructions and to applicable local and federal regulations for commercial food preparation.

2.11 **Breast Milk Donor**—A lactating woman who voluntarily contributes milk to a human breast milk bank.

2.12 **Breast Milk-Processing Centers**—For-profit entities that collect human breast milk and produce human breast milk-based products.

2.13 **Breast Milk Sharing**—The practice of one mother giving her breast milk to another person without payment.

2.14 **Processing**—The use of evidence-based methodologies, including pasteurization, to prepare safe breast milk for recipients.

2.15 **Processing Fees**—Fees assessed by the donor breast milk bank to offset the cost of donor screening, breast milk processing, storing, distribution, and record keeping.

2.16 **Product Recall**—The formal process of recalling all dispensed breast milk within a batch or batches that are suspected may potentially cause harm.

2.17 **Product Replacement**—The process of dispensing additional breast milk to a recipient or recipients after the initial dispensed breast milk has been identified as unacceptable, but not unsafe.

2.18 **Quality Control Operation**—A planned and systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of the Code of Federal Regulations, Title 21, reserved for rules of the U.S. Food and Drug Administration.

2.19 **Sanitize**—Reduce microbial load to increase safety and decrease risk of contamination without adversely affecting the product or its safety for the consumer. An example of a sanitizing agent is 70% or higher isopropyl alcohol.

2.20 **Sterilize**—Destroy all microorganisms, including spores, via autoclave or other method(s) of sterilization.

Section 3. Administrative Structure

3.1 The breast milk bank operations are overseen by qualified nursing, medical, or other breast milk bank personnel with education and training critical to the provision of safe donor human breast milk.

3.2 Donor breast milk banks should have a panel of consultants that include specialist in neonatology/pediatrics, lactation, and microbiology/infectious diseases; and may include representation from, but not limited to, the following specialties: nursing, immunology, pharmacology, nutrition, public health, obstetrics, pathology, food technology, law, and consumer representation. These consultants agree to be accessible to the breast milk bank director when appropriate.

3.3 All breast milk banks are expected to operate under rules of the Health Insurance ~~and~~ Portability and Accountability Act (HIPAA).

Section 4. Donor Qualifications/Screening

4.1 Donor qualifications are based on best practices and clinical data, and must be updated continuously to reflect emerging diseases and new pharmaceutical agents.

4.2 Screening must include in-person or on-the-phone contact, and must never be limited to electronic communication.

4.3 Two appropriately trained staff members must review, approve, and sign or document the completed donor screening.

4.4 Acceptable donors are healthy lactating women with surplus expressed breast milk, and who meet the following requirements:

4.4.1 They have been screened verbally and in writing, and given educational materials informing them of characteristics of the high-risk groups or activities that might put them at risk for transmitting blood-borne diseases.

4.4.1.1 In cases where English is not a primary language for the donor applicant, and indications are that a translator is required, the contacted breast milk bank makes efforts to offer an appropriate translator to help with the screening process, or a breast milk bank employee who is trained in screening will be present (or available by phone) during the interview with a third-party translator. The translator may also be someone who knows the would be donor and has the donor's permission to translate. This choice is made with discretion, as the breast milk bank screener must feel comfortable that the translator is not manipulative of the would-be donor and is sufficiently mature to handle content.

4.4.1.1.1 If a suitable translator is not available, the donor applicant can be referred to another donor breast milk bank. If no bank is able to find a suitable translator, the donor applicant is deferred due to inadequate screening.

4.4.2 Potential donors have statements of known health/medical risks signed by their licensed health care providers. ~~and their baby's licensed health care provider (exception: their baby is not in their care, such as in the case of mothers whose babies have died or been given up for adoption).~~

4.4.3 Potential donors are screened serologically for HIV-1 and -2, HTLV-1 and -2, Hepatitis C, Hepatitis B, and syphilis ~~no more than~~within 6 months prior to the first donation. A CLIA certified high complexity clinical laboratory or an ISO ~~17025~~ 15189 accredited clinical laboratory, that achieved accreditation from an International Laboratory Accreditation Cooperation recognized accreditation body, does the tests, and results are valid throughout the time of donation unless life-style or medical issues suggest an increased risk for donation, in which case deferral or retesting is at the discretion of the individual breast milk bank.

4.4.3.1 Communication with a breast milk donor regarding her health and lifestyle is expected to be no less frequent than every 2 months and documented in the donor's record. Donors thought to be at risk for a blood-borne disease are immediately deferred.

4.4.4 Certain medications are permitted during donation of milk, and others are a cause for deferral. Permissible medications should be reviewed by the Medical Director and approved by the breast milk bank's panel of consultants ~~Members of the Medications Committee~~ at least annually and updated based on research and information from the U.S. Centers for

Disease Control and Prevention, the U.S. Food and Drug Administration, Health Canada, pharmaceutical and blood-banking industry and other sources. Members of the panel ~~Medications Committee~~ draw from specialties including neonatology, pharmacology, and pediatrics.

4.4.4.1 The determination of any medication's risk takes into consideration characteristics such as molecular weight of a medication, lipid solubility and plasma affinity, and weight of the likely recipient.

4.4.4.2 Prospective donors taking medications on the permissible list but with a deferral time can be accepted. However, breast milk expressed during the deferral period cannot be used to feed babies.

4.4.4.3 If a potential donor is donating previously expressed breast milk, medication and herb use during the time of breast milk expression must be investigated.

4.4.4.4 Donors should be advised that if they begin taking any medication once approved and donating breast milk, they should contact the breast milk bank to discuss deferral dates or the need to retire as a donor. Moreover, if a prospective or approved donor is taking a medication used for a diagnosis that is outside of the category for the medication, please ask for the dose and forward the information to the medical director, so that a determination can be made about safety.

4.4.4.5 Prospective donors taking medications as determined in Section 4.4.4 ~~that are limited to the following list~~ do not need deferral.~~:~~

~~4.4.4.5.1 Topical medications applied to the skin away from the breast; topical medications applied to the breast should be washed off before expressing milk for donation~~

~~4.4.4.5.2 Drugs given to mothers orally that are not absorbed systemically (e.g., aluminum, calcium, or magnesium antacids, stool softeners, fibers, simethicone)~~

~~4.4.4.5.3 Inhaled drugs for asthma, colds, and allergies~~

~~4.4.4.5.4 Non-sedating antihistamines:~~

~~4.4.4.5.4.1 Allegra (fexofenadine) (Canadian equivalent—Allegra, Fexidine, Telfast, Fastofen, Tilfur, Vifas, Tel-fexo, Allerfexo)~~

~~4.4.4.5.4.2 Clarinex (desloratadine) (Canadian equivalent—Neo-Calrityn, Deselex, Aviant, Delot)~~

~~4.4.4.5.4.3 Claritin (loratadine)~~

~~4.4.4.5.4.4 Zyrtec (cetirizine) (Canadian equivalent—Zyrtec Reactine) or Xyzal~~

~~4.4.4.5.5 Eye drops~~

~~4.4.4.5.6 Selected birth control methods:~~

~~4.4.4.5.6.1 Spermicides~~

~~4.4.4.5.6.2 Copper IUDs—Mirena or ParaGard, for example~~

~~4.4.4.5.6.3 Progestin-only or low-dose estrogen (<25mcg) birth control methods. Common examples of these include Depo Provera (medroxyprogeste one injection), micronor or Nor-QD (norethindrone), Yaz and Beeyaz (drospironome, Implanon or Nexplanon FDA (estonogestrel implant)~~

~~4.4.4.5.6.4 Seasonale, Seasonique, and Lybrel (longacting norgestral oral contraceptive pills), ortho tricycline lo, and Lo/Ovral 28~~

~~4.4.4.5.7 Hormonal replacement drugs that are normally found in milk:~~

~~4.4.4.5.7.1 Thyroid replacement~~

~~4.4.4.5.7.2 Hydrocortisone~~

~~4.4.4.5.7.3 Insulin~~

~~4.4.4.5.7.4 Inactivated vaccines, intranasal influenza vaccine, toxoids, and allergy shots~~

~~4.4.4.5.8 Selected human immune globulin products~~

~~4.4.4.5.8.1 Intravenous immunoglobulin~~

~~4.4.4.5.8.2 Rhogam~~

~~4.4.4.5.8.3 Tetanus~~

~~4.4.4.5.8.4 Rabies~~

~~4.4.4.5.9 Selected supplements:~~

~~4.4.4.5.9.1 Vitamins~~

~~4.4.4.5.9.2 Minerals~~

~~4.4.4.5.9.3 Fish oils~~

~~4.4.4.5.9.4 Omega-3-fatty acids~~

~~4.4.4.5.9.5 Lecithin~~

~~4.4.4.5.9.6 Probiotics~~

4.4.4.6 The use of other medications on a temporary basis may be acceptable if the appropriate deferral period is followed. For most medications, this deferral is~~n~~ 5 times the half-life of the medications.

Section 5. Drugs or Classes That Require Longer Waiting Periods

5.1 Certain Drugs or Classes require longer waiting periods:

5.1.1 Radiopharmaceuticals (e.g., radio-iodine) – 2 months

5.1.2 Live-virus vaccines – 2 months

5.1.2.1 Measles mumps rubella varicella (MMRV – this vaccine is not used in the US)

5.1.2.2 Polio (oral)

5.1.2.3 Rotavirus

5.1.2.4 Varicella ("chicken pox vaccine") (VAR or MMRV)

5.1.2.5 Yellow fever

5.1.2.6 Live typhoid vaccine (there is an inactivated vaccine that requires no deferral period)

Section 6. ~~Exclusion~~ Disqualification Criteria (Temporary Deferral and/or Total Exclusion)

6.1 Note: Potential donors may be temporarily deferred or totally excluded ~~are excluded~~ based on the following clinical issues unique to human breast milk and infants, and on current AABB, US CDC, or other regulatory guidelines ~~and Health Canada Guidelines~~.

6.2 Recent history of blood transfusion ~~Receipt of blood transfusion or blood products, except Rhogam®, within the last 6 months. If the donor has received blood products or transfusion, donor has serological testing at 6 months after the receipt. This deferral period is based on current CDC identification of the window period for HIV another blood-borne illnesses – the period of time from exposure to sero-conversion to a positive HIV or hepatitis status.~~

6.3 Organ or tissue transplant ~~Receipt of an organ or tissue transplant within the last 12 months. If the donor has received an organ or tissue transplant, donor has~~

~~serological testing as 12 months after the receipt. If testing is negative, she may donate milk that was pumped during the waiting period.~~

6.4 Body piercing, tattoos, or permanent makeup ~~Within the last 6 months: Ear or other body piercings with other than single-use instruments, tattooing from a nonregulated site, or permanent makeup applied by needle. (Note: Multiple-person dye pots or needles may be used by nonregulated sites, leading to a risk of blood-borne disease transmission.) If any of these situations has occurred, donor has serological testing at 6 months after the event. Refer to section on temporary restrictions on piercings and tattoos obtained from regulated sites.~~

6.5 Positive serological test results for HIV, HTLV, Hepatitis B or C ~~Accidental needle stick in the past 6 months requires serological testing at 6 months after the event, unless the donor has access to medical records of person on whom needle was first used, can verify that person was immediately tested for HIV and hepatitis, and results were negative. In such a case, waiting 4 months for serological testing is sufficient. If the patient's testing is positive, wait 6 months for donor's serological testing. If testing is negative, she may donate milk that was pumped during that waiting period.~~

6.6 Risk of Creutzfeldt-Jakob Disease (CJD)

~~Risk of Creutzfeldt-Jakob disease. Note: many public health entities have slight variations on risks of CJD with body fluids. These risks are based on those defined by the AABB and Canadian Blood Services and also on hypothetical risks about who may or may not be able to transmit the disease. CJD has never been fully identified in breast milk, but its transfer cannot yet be ruled out. An adult who, as an infant was exposed to CJD because of her mother's location, is deferred from donating.~~

~~Receipt of human pituitary-derived growth hormone, dura mater (or brain covering) graft, or bovine insulin.~~

~~Family history of Creutzfeldt-Jakob disease.~~

6.6.1 Travel deferrals related to CJD risk ~~Time spent in the following countries is restricted for US. Total of 3 months or more in the United Kingdom between 1980 and 1996. Total of 5 years or more in Europe from 1980 to the present in the following countries:~~

~~6.6.1.1 Albania~~

~~6.6.1.2 Austria~~

~~6.6.1.3 Belgium~~

~~6.6.1.4 Bosnia-Herzegovina~~

~~6.6.1.5 Bulgaria~~

~~6.6.1.6 Croatia~~

~~6.6.1.7 Czech Republic~~

~~6.6.1.8 Denmark~~

~~6.6.1.9 Federal Republic of Yugoslavia (also known as Serbia and Montenegro)~~

~~6.6.1.10 Finland~~

~~6.6.1.11 France~~

~~6.6.1.12 Germany~~

~~6.6.1.13 Greece~~

~~6.6.1.14 Hungary~~

~~6.6.1.15 Italy~~

~~6.6.1.16 Lichtenstein~~

~~6.6.1.17 Luxembourg~~

~~6.6.1.18 Macedonia~~

~~6.6.1.19 Netherlands (also known as Holland)~~

~~6.6.1.20 Norway~~

~~6.6.1.21 Poland~~

~~6.6.1.22 Portugal~~

~~6.6.1.23 Republic of Ireland (also known as Ireland)~~

~~6.6.1.24 Romania~~

~~6.6.1.25 Slovak Republic (also known as Slovakia)~~

~~6.6.1.26 Spain~~

~~6.6.1.27 Sweden~~

~~6.6.1.28 Switzerland~~

~~6.6.1.29 United Kingdom~~

~~6.6.1.30 Current or former US or Canadian military personnel, civilian military employees, or their dependents who resided at military bases in Northern Europe (Germany, Belgium and the Netherlands [Holland]) for a total of 6 months or more from 1980 through 1990, or elsewhere in Europe (Greece, Turkey, Spain, Portugal, and Italy) from 1980 through 1996.~~

~~6.6.1.31 Received a blood or blood-component transfusion in the UK or France since 1980.~~

6.7 Risk of food borne illnesses

6.8 Vegans not supplementing with B12~~ Total vegetarians (vegans) who do not supplement their diet with vitamin B12.~~

6.9 Alcohol consumption ~~Daily use of more than 1.5 ounces of hard liquor, 12 ounces of beer, 5 ounces of wine, and/or 10 ounces of wine cooler in 24 hours. Based on data from the U.S. Centers for Disease Control and Prevention, milk banks must have a chart on specific elimination times per type of alcohol.~~

6.10 Smoking or use of tobacco /nicotine products ~~Use of tobacco or nicotine products, including gum, patches, or e-cigarettes. This includes casual or occasional use of such products.~~

~~Secondhand smoke: Little data exist to describe relevance of secondhand smoke; however, it is known to transfer via breast milk. There are insufficient data to determine reasons for exclusion of donors due to exposure to secondhand smoke, therefore individual milk banks must determine if secondhand smoke exposure requires exclusion.~~

6.11 Medication use (non-approved medications) ~~Daily use of over-the-counter medications or systemic prescriptions.~~

~~Regular use of mega-dose vitamins (at least 20 times the RDA) and/or herbal products use as medication, including vitamin/herb combinations.~~

6.12 Use of illegal recreational drugs ~~Use of illegal drugs within the past 12 months.~~

6.13 At risk sexual partner ~~A sexual partner in the past 12 months who is at risk for HIV, HTLV, or hepatitis (including anyone with hemophilia or anyone who has used a needle for injection of illegal or nonprescription drugs). This includes sexual partner in the past 12 months who has had, within the same time period, tattoos with nonsterile needles or multi-person use dyes from a nonregulated site, permanent makeup applied with nonsterile needles, ear or other body parts pierced with other than single-use instruments, been accidentally stuck with a contaminated needle or received a transfusion or an organ or tissue transplant. If any of these situations have occurred with the partner, donor must wait the required lengths of time described above.~~

6.14 Breast Milk that has been heat-treated in any way by the donor ~~Milk may not be donated if it has been heat-treated in any way by the donor. This includes warming, scalding, boiling, or thawed after freezing~~

6.15 ~~Exposure to Ebola virus requires a 28-day deferral, at which time donors may resume donating milk if they have not become ill. Ebola has a 21-day window for symptoms to appear; 28 days is used to allow for any question of actual exposure date.~~

6.16 ~~Exposure to hand, foot and mouth disease is not a reason for deferral unless medication is required.~~

6.17 ~~Incarceration, or incarceration of sexual partner, for more than 72 consecutive hours in the last 12 months~~

6.18 ~~Current use of marijuana for medical or casual use~~

6.19 ~~Chronic infections (e.g., HIV, HTLV, active TB, etc.) relevant to breastfeeding; a history of hepatitis B or C; a history of leukemia or lymphoma; or treatment for any other cancer within the last 3 years. Some low-risk cancers, including squamous or basal cell cancers of the skin, may be exempted on a case-by-case basis. Critical to allowance is whether or not the cancer was in situ and removed without further treatment.~~

Section 7. ~~Temporary Disqualification~~

7.1 ~~Donors are instructed to report all illness in the household to the milk bank for evaluation of communicability and contamination of milk. Illnesses and exposures not related to milk safety – such as the common cold, conjunctivitis, and seasonal flu do not require deferral periods as long as deferred medications are not needed. Qualified milk bank personnel (the same people with the authority to approve the donor) temporarily disqualify donors for illness or medication issues. After a temporary disqualification, milk donation can resume at the discretion of qualified milk ban personnel.~~

7.2 ~~Active donors are temporarily disqualified from donating milk under the following conditions:~~

7.2.1 ~~During any acute infection requiring unapproved medication, including clinical mastitis, and monilial and fungal infections of the nipple or breast. This includes a reactivation of a chronic illness requiring medication, such as an autoimmune disorder, for example, lupus. The deferral periods include periods of time when the donors experienced adverse health symptoms, were at risk for transmitting illness, and/or were using medication, and those periods recommended for clearance of medication from the donor mother's system.~~

7.2.2 ~~If the donor herself has varicella (chicken pox), exclude all milk pumped 3 days before the first lesion appears until the last lesion has crusted over. If a household member has varicella, place a temporary donor exclusion from 3 days before the first lesion through 21 days after the last lesion has crusted over. If donor does not develop varicella during the time, the temporary exclusion may be lifted and the milk may be used.~~

7.2.3 ~~During reactivation of latent infection with herpes simplex virus (HSV) or varicella zoster (shingles) of the breast or thorax, starting 3 days before the first lesion and ending 1 week after the last lesion has crusted over.* (* Prospective donors taking antiviral suppressive medications are deferred according to the medication schedule.)~~

7.2.4 ~~If a donor is newly diagnosed with hepatitis A, she is deferred for the 4 weeks leading up to the symptoms and for 1 week after the onset of jaundice. If milk has already been dispensed, it should be presumed positive, and recalled.~~

7.2.5 ~~Alcohol consumers must avoid donating for 6 hours after consuming 1 alcoholic drink. Consuming more than 1 alcoholic drink requires a 12-hour period of deferral. "One drink" equals 1.5 ounces of hard liquor, 5 ounces of wine, 12 ounces of beer, and 10 ounces of wine cooler.~~

7.2.6 ~~During the 21 days after the donor (or anyone with whom she has household contact) has received the smallpox vaccination without complications, or until the scab has separated spontaneously—whichever occurs later.~~

7.2.7 ~~In the US, a donor is deferred 8 days following donor's or donor's partner's receipt of a tattoo administered in a regulated site using sterile needles and single-use-only needles and single-use only dyes. A regulated site is subject to state rules on sterile, individual-use only needles and single-use only dye parts. If there are no symptoms of skin infection, donor may donate milk pumped during the specific interval.~~

7.2.8 ~~Consumption of any over-the-counter or prescription medication – including self-prescribed or physician-prescribed mega-dose vitamins, homeopathic remedies, galactogogues, and herbs – is reported to the milk bank. Qualified milk bank personnel temporarily disqualify the donor, using the medication deferral times contained in this document or using restrictions imposed by the individual milk bank.~~

Section 8. Serological Tests

8.1 A certified laboratory is to conduct screening blood tests (HIV-1 and -2, HTLV-1 and -2, hepatitis C, hepatitis B, and syphilis) within 6 months prior to a woman's becoming a donor.

8.2 The prenatal care or postpartum care providers may submit testing if it was done within this time frame. Negative test results do not require confirmatory testing.

8.3 Screening tests for the following disease are required:

8.3.1 HIV-1, HIV-2

8.3.2 HTLV-1, HTLV-2

8.3.3 Hepatitis B

8.3.4 Hepatitis C

8.3.5 Syphilis

8.4 Screening tests apply to all individuals who apply to be donors. If a screening test is positive, the breast milk bank can defer that donor or follow up with a confirmatory diagnostic test. A confirmatory diagnostic test cannot be a repeat of the same test but must be more specific and less subject to a false positive, according to medical standards. Screening tests include:

8.4.1 HIV antibodies for both types (HIV, group O is included in HIV-1)

8.4.2 HTLV antibodies for both types

8.4.3 Hepatitis B surface antigen

8.4.4 Hepatitis C antibody

8.4.5 Syphilis RPR (this test has the highest likelihood of indicating a false positive)

8.5 Confirmatory tests may be ordered after obtaining a positive or indeterminate screening test, rather than deferring the potential donor. Confirmatory tests include:

8.5.1 HIV PCR (measurement of viral particles)

8.5.2 HTLV PCR

8.5.3 Hepatitis B PCR

8.5.4 Hepatitis C PCR

8.5.5 FTA (florescent treponemal antibody – confirmatory test for syphilis)

8.6 Breast Milk banks are not required to run diagnostic tests; however, they may do so. Diagnostic test results override screening test results.

8.7 Donors are deferred indefinitely for any positive result on a diagnostic/confirmatory serological test. A donor deferred for positive blood testing is to be referred to a health care provider of her choice. The follow-up is done in compliance with the state/federal regulations. Any breast milk from this potential donor, that has already been donated and is being held at the breast milk bank, is disposed of according to institutional protocols. In the absence of institutional protocols, expressed breast milk may be disposed of in a sink or a trash can.

8.8 In all cases, whether or not screening tests are negative, a donor is deferred if her lifestyle or medical risks suggest that she could have harmful substances in her breast milk.

Section 9. Donor Approval

9.1 Each breast milk bank defines who is designated to approve or defer donors, based on their credentials, education, and training; and to verify that the screening process is complete, and breast milk is appropriate for processing and dispensing. Donors are notified once they are approved; and communication regarding changes in health, medical, and lifestyle status of the donor and/or anyone in the household

are actively encouraged on a regular basis. Breast ~~Milk~~ milk banks must engage in, and document, ongoing communication with donors at a minimum of every 2 months.

9.2 ~~Milk~~ Breast milk banks can determine individual circumstances under which they received breast milk before a ~~door~~ donor is approved; however, returning raw donated breast milk to the approved or unapproved breast milk donor is not recommended. The final decision on a request for breast milk return is up to each breast milk bank and their medical and legal advisors.

Section 10. Public Health or Medical Crisis

10.1 In the case of a medical or public health crisis, each breast milk bank is responsible for having a disaster plan covering emergencies affecting their individual breast milk bank. These plans should include how to protect breast milk in the case of power outage, and notification plans for staff, community, and other breast milk banks or effected entities in case of inability to dispense or receive breast milk.

Section 11. Donor Education and Procedures

11.1 To ensure the highest level of safety and quality of donated breast milk, breast milk donors are instructed on the appropriate methods for clean expression, handling, storage, and transportation of human breast milk.

11.2 Donors are given written instructions covering:

11.2.1 Clean technique for breast milk collection, including:

11.2.1.1 Washing pump parts

11.2.1.2 Handwashing

11.2.1.3 Appropriate containers for storing donor breast milk

11.2.1.4 Handling of breast milk containers

11.2.2 Those times when the donor should refrain from donating, and lifestyle choices that may affect her eligibility as donor.

11.2.3 Labeling of donated breast milk, which includes donor identification and date of collection.

11.2.4 Optimal freezing and storage of breast milk.

11.2.5 Transporting breast milk safely to the bank.

11.2.5.1 In situations where the breast milk was collected before the donor contacted the breast milk bank, the screening process includes discussion and evaluation of how the donor expressed and stored the breast milk, as well as what medications or supplements the donor took during the collection period.

Section 12. Procedure Manual

12.1 A breast milk bank maintains a detailed procedures manual, available to breast milk bank personnel at all times. The procedures manual is reviewed annually and signed by the medical doctor, hospital department head, or other qualified individual overseeing the milk bank.

Section 13. Building and Facility

13.1 ~~Milk~~ Breast milk processing buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for breast milk-processing purposes. The building and facilities:

13.1.1 Provide sufficient space for placement of equipment and storage materials to permit sanitary operations and production of donor human breast milk.

13.1.2 Permit the use of proper precautions to reduce the potential for contamination of breast milk, breast milk-contact surfaces, or breast milk-packaging materials.

13.1.3 Are constructed in such a manner that floors, walls, and ceilings may be adequately kept clean and in good repair. Any droplets or condensates from fixtures, ducts, and pipes do not contaminate breast milk, breast milk-contact surfaces, or breast milk-packaging materials. Aisles or working spaces are provided between equipment and walls, and are adequately unobstructed and of adequate width to permit employees to perform duties and to protect against contaminating breast milk or breast milk-contact surfaces, and breast milk-packaging materials.

13.1.4 Allow no pests in any area of the breast milk bank. Effective measures are taken to exclude pests from the processing areas and to protect against the contamination of breast milk on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of breast milk, breast milk-contact surfaces, and breast milk-packaging materials.

13.1.5 Do not allow persons unnecessary to breast milk processing into the breast milk preparation area while open containers of breast milk are being processed.

13.1.6 Properly identify cleaners and sanitizers, which are stored in dedicated containers and kept away from the breast milk in processing.

13.1.7 Provide adequate hand-washing facilities, including a lavatory fixture (sink) with either hot/cold or warm running water, soap, or detergent and individual sanitary towels.

13.1.8 Provide that pasteurizing, pouring, cooling, and labeling of breast milk occur in one room with a separate door, which is closed whenever breast milk containers are open.

13.1.9 Provide a separate room for the cleaning of equipment and containers. In the absence of separate rooms, the cleaning of equipment is done after breast milk processing is complete.

13.1.10 Provide designated areas or rooms for the receiving, handling, and storage of returned (recalled) breast milk and breast milk products. Freezer space for the returned product must not be comingled with raw frozen or pasteurized breast milk, although both raw and processed breast milk can be in different sections of the same freezer.

13.1.11 Provide separate freezers to store incoming raw-frozen donor breast milk and pasteurized breast milk. Minimally, breast milk can be stored in the same freezer but must be clearly separated, labelled, and identifiable in the same freezer.

13.1.12 Provide toilet facilities that do not open directly into any room in which breast milk and/or breast milk products are processed. Restrooms must be completely enclosed, with the door kept closed, and include signage for handwashing. Lab staff must scrub back into lab after use of the restroom.

13.1.13 Provide a water supply in compliance with city, state, or township ordinances for potable water.

Section 14. Equipment

14.1 Recording thermometers monitor freezer temperatures, or freezers are equipped with temperature-sensitive alarms. Two distinct and appropriately calibrated thermometers – whether electronic, indwelling, or mercury -- monitor freezers. ~~Milk~~ Breast milk bank personnel investigate and resolve discrepancies in thermometer readings.

14.2 Freezers are locked or in a secured area.

14.3 ~~Milk~~ Breast milk is stored in dedicated freezers that maintain breast milk in a frozen state. Freezer temperature is held no higher than -18°C (or 0°F) and any lower temperature is acceptable. Brief fluctuations in temperature secondary to opening the doors or self-defrosting cycles are acceptable as long as breast milk remains frozen.

14.4 Refrigerators used for storing thawed or processed breast milk are held no higher than 4°C (or 40°F).

14.5 Storage and processing equipment are calibrated every six (6) months, or according to manufacturers' instructions.

14.6 All equipment manuals are available to breast milk bank personnel at all times.

14.7 Equipment intended for human breast milk banking – processing or storing – is used only for breast milk banking purposes.

14.8 Processed breast milk is stored in glass or food-grade plastic that meets FDA requirements for both freezing and heating temperatures used in processing. Documentation of such is maintained in the breast milk bank.

14.9 All equipment used in the breast milk bank is cleaned and maintained according manufacturer's instructions, including, but not limited to, freezers, refrigerators, pasteurizers, shaking water baths, dishwashers, thermometers, alarms, and breast milk composition analysis equipment.

14.10 All breast milk bank equipment and utensils are designed and made from material that can be adequately cleaned and maintained. The design, construction, and use of equipment and utensils do not result in the adulteration of breast milk with lubricants, fuel, metal fragments, contaminated water, or any other contaminants. All equipment should be installed and maintained to facilitate the cleaning of the equipment and of all adjacent spaces. Breast ~~Milk~~milk-contact surfaces are corrosion-resistant when in contact with breast milk. They are made of nontoxic materials and designed to withstand the environment of their intended use and the action of breast milk, and, if applicable, cleaning compounds and sanitizing agents. ~~Milk~~Breast milk-contact surfaces are maintained to protect breast milk from being contaminated by any source, including unlawful indirect breast milk additives.

14.11 Seams on breast milk-contact surfaces are smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter, and thus minimize the opportunity for growth of microorganisms.

14.12 Equipment that is in the manufacturing or milk-handling area and that does not come into contact with breast milk is constructed so that it can be kept in a clean condition.

14.13 Holding, conveying, and manufacturing systems – including gravimetric, pneumatic, closed, and automated systems – are of a design and construction that enables them to be maintained in an appropriate sanitary condition.

Section 15. Thermometers

15.1 Monitoring temperatures in milk banks is critical to the safety of the breast milk distributed.

15.2 The quality and accuracy of thermometers used to monitor temperatures in refrigerators and freezers and at critical points in the pasteurization process must be verified.

15.3 Thermometers in freezers and refrigerators

15.3.1 A minimum of two (2) calibrated thermometers are used to monitor temps in freezers and refrigerators.

15.3.2 Thermometers may be certified calibrated by a national metrology institute (NMI) such as the National Institute of Standards and Technology (NIST) ~~(or similar agency)~~or an ISO/IEC 17025 accredited calibration laboratory that is accredited by an ILAC recognized accreditation body, for the calibration of ~~or calibrated quarterly by the milk bank using an NIST-certified~~ reference thermometers. The milk bank shall verify working thermometers against the calibrated reference thermometers at least quarterly. The breast milk bank must keep records of calibration and verification records.

Section 16. Thermometers used in the Pasteurization Process

16.1 When using equipment specially designed for human breast milk pasteurization, the procedures for the use of the machine are followed and the machine is calibrated and maintained per manufacturer's guidelines. Documentation that equipment is maintained per manufacturer's guidelines is required.

16.2 When pasteurizing using manual equipment (reciprocal shaking water baths): Thermometers used in control bottles to record the temperature of breast milk during heating and cooling phases should be NIST-certified or calibrated no less often than quarterly using an NIST-certified reference thermometer. The breast milk bank must keep records of calibration.

16.2.1 In addition to the quarterly calibration, thermometers should be calibrated if dropped, damage, or at any time the accuracy is in question.

16.2.2 Thermometers used to monitor the heat processing and cooling of donor breast milk using manual equipment should have as small a standard deviation range as is practical. Thermometers with a standard deviation of +/- 0.2° Celsius or less are recommended.

Section 17. Thermometer Calibration Procedure

17.1 Use the ice-point method: Insert the thermometer probe and the reference thermometer probe into a container of ice and water. Allow the temperature to stabilize. Compare readings and adjust thermometer to reference thermometer reading according to the manufacturer's directions and/or service or replace thermometer.

17.2 Hot-point calibration method: Immerse the thermometer probe and the reference thermometer probe into water set at 65°Celsius. Allow the temperature to stabilize. Compare readings and adjust thermometer to reference thermometer reading according to manufacturer's directions and/or service or replace thermometer.

Section 18. Breast Milk Analyzers

18.1 Nutritional analysis of breast milk is not a minimum requirement for breast milk banks. However, if a breast milk bank chooses to use a nutritional analyzer, it is used within the following parameters:

18.1.1 The instrument is maintained following manufacturer's directions.

18.1.2 The breast milk bank reports annually to recipient hospitals about what instrument it is using for analysis.

18.1.3 The instrument uses data based on credible scientific statistical analysis, with attention to false-positive and false-negative values, variation from the mean and median, and standard deviation.

18.1.4 ~~Milk~~ Breast milk banks that use human breast milk analyzers are responsible for the accuracy of results and should ensure they follow the Food and Drug Administration (FDA) Good Laboratory Practices regarding regular calibration and record keeping.

18.1.5 The Food and Drug Administration (FDA) states in its 2013 Food Labeling Guide, "FDA has not stated how a company should determine the nutrient content of their product for labeling purposes…Regardless of its source, the company is responsible for the accuracy and the compliance of the information presented on its label."

Section 19. Handling

19.1 All persons working in direct contact with breast milk, breast milk-contact surfaces, and breast milk-packaging materials adhere to hygienic practices while on duty to the extent necessary to protect against contamination of breast milk.

19.2 The methods for maintaining cleanliness include, but are not limited to:

19.2.1 Wearing outer garments suitable to the operation in a manner at protects against the contamination of breast milk, breast milk-contact surfaces, or breast milk packaging materials. Wear a gown, apron, or lab coat that covers clothing.

19.2.2 Maintaining adequate personal cleanliness.

19.2.3 Washing and sanitizing hands and arms from elbows downward thoroughly before starting work, whenever work area is left and become soiled or contaminated. Immediately dry hands and arms with an individual single-use-only towel. Put on disposable gloves after washing hands.

19.2.4 Not washing hands in sinks used for milk preparation or washing equipment. Keeping hand-washing facilities in a clean condition and in good repair.

19.2.5 Removing all unsecured jewelry or other objects that might fall into breast milk, equipment, or containers. Rings may be left on fingers and covered by gloves after hands are washed.

19.2.6 Covering hair with hair nets, caps, or other effective hair restraints; include beard covers when appropriate. Dangling earrings must be tucked under hair net.

19.2.7 No eating food, chewing gum, drinking beverages, or using tobacco in areas where breast milk may be exposed or where equipment or utensils are washed.

19.2.8 Excluding everyone with an illness – e.g., vomiting, diarrhea, jaundice, sore throat with fever, and open lesion, or other abnormal source of microbial contamination – from the breast milk-processing and breast milk-handling areas.

19.2.9 Reporting potential exclusion to a breast milk bank staff member designated to decide appropriateness of potential exclusion.

19.2.10 Preparing breast milk in a dedicated clean space with facilities for aseptic technique.

19.2.11 Cleaning and sanitizing breast milk-contact surfaces and work areas by a process that is effective in destroying microorganisms of public health significance before handling or processing milk and after any interruption in processing that may lead to contamination.

19.2.12 Making clean sinks and sanitizing dispensers available in the breast milk-handling area.

19.2.13 Ensuring that personnel responsible for identifying sanitation failures or breast milk contamination have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe breast milk.

19.2.14 Ensuring that breast milk handlers and supervisors receive appropriate training in proper food-handling techniques and food-production principles and that they are informed of the danger of poor personal hygiene and unsanitary practices.

19.2.15 Ensuring that competent supervisory personnel take responsibility for assuring compliance by all lab personnel.

19.2.16 Cleaning all food-contact surfaces, including utensils and food-contact surfaces of equipment, as frequently as necessary to protect against contamination of food.

Section 20. Logging of Incoming Breast Milk

20.1 All donated breast milk is identified as relating to a specific approved breast milk donor. Donated breast milk is packaged securely with identification visible, and maintained in a frozen state until chosen for processing. Logging of incoming breast milk includes estimating the volume of breast milk, as well as observing for foreign

matter or other sources of contamination such as broken storage containers. ~~Milk~~ Breast milk is discarded if contamination is suspected or if foreign matter is present and unable to be extracted without contamination.

Section 21. Defrosting and Pooling

21.1 ~~Milk~~ Breast milk is generally thawed in refrigerators in a manner that prevents the breast milk from becoming adulterated or contaminated. Final thawing may occur outside of the refrigerator as long as temperature expectations are met. ~~Milk~~ Breast milk should be maintained at 45°F or 7.2°C or below, both while in the refrigerator and out. ~~Milk~~ Breast milk taken from refrigerators for pouring is kept out of direct sunlight and at least 6 feet from any heat source, and refrigerated after pouring. If a water bath is used for thawing, the lids of all containers are kept above the water line. ~~Milk~~ Breast milk should be maintained at 45°F or 7.2°C or below, both while in the refrigerator and out.

21.1.1 Pooling of fresh raw or defrosted fresh-frozen breast milk in conducted under clean conditions.

Section 22. Requirements of Raw Frozen Breast Milk Distribution

22.1 Each pool of breast milk has a sample taken for bacteriologic screening using sterile technique.

22.2 Only breast milk from pools with $\leq 10^4$CFU/ml of normal skin flora (e.g., coagulase negative staphylococcus, ~~diptheroids~~ diphtheroids, Staphylococcus epidermis, or Streptococcus ~~viridans~~ viridians) is acceptable to dispense raw. The presence of any pathogens is unacceptable.

Section 23. Aliquoting and Heat Processing

23.1 Aliquoting when using the Holder Pasteurization Method

23.1.1 Pooled breast milk is aliquoted into clean containers. Original containers may be used as long as they have been maintained under clean conditions, manufacturers' documentation confirms that they have multiple-use approval, and they have been appropriately sanitized.

23.1.2 Containers are filled leaving adequate air space in the container to allow for expansion during freezing.

23.1.3 All containers are filled to the same approximate level. ~~Milk~~ Breast milk is examined during pouring for foreign matter. ~~Milk~~ Breast milk is strained and visually examined before heat processing. Any foreign matter should be removed, and, if not removable, the breast milk is discarded.

23.1.4 All containers are tightly closed with clean caps to prevent contamination of breast milk during heat treatment.

23.1.5 Multiple batches may be created from one pool. A "batch" is the set of bottles that fit into a single pasteurizer or shaking water bath at one time.

23.2 Heat Processing

23.2.1 When using equipment specifically designed for human breast milk pasteurization, the procedures for use of the machine are followed.

23.2.2 The following guidelines refer to shaking water baths only:

23.2.2.1 Aliquots of breast milk are processed by completely submerging the containers in a well-agitated or shaking water bath preheated to a minimum of 62.5°C.

23.2.2.2 A control bottle containing the same amount of breast milk or water as the most filled container of breast milk in the batch is fitted with a calibrated thermometer to register breast milk temperature during heat processing. The control bottle follows the same process as the rest of the batch at all times.

23.2.2.3 The thermometer is positioned such that approximately 25% of the breast milk volume is below the measuring point of the thermometer, or according to manufacturer's instructions. Probe should not be touching the bottle in any way.

23.2.2.4 The monitored aliquot is placed into the water bath with all other aliquots and is either positioned at the coldest area of the water bath, as identified during calibration checks, or positioned according to the manufacturer's instructions.

23.2.2.5 After the temperature of the monitored control bottle has reached 62.5°C, the heat treatment continues for 30 minutes, maintaining the temperature, and then ends immediately. Fluctuation during the heating process may be seen for short periods of adjustment, where heat may briefly fluctuate between 62° and 64.5°C.

23.2.2.6 ~~Milk~~ Breast milk temperature and bath temperature are monitored and recorded.

23.2.2.7 Air bubbles released from breast milk containers indicate insecure caps – such bottles are discarded.

23.3 Chilling and Storage

23.3.1 When using equipment specifically designed for human breast milk pasteurization, the procedures for use of the machine are as follows.

23.3.2 Following heat processing, the breast milk is rapidly cooled to 4°C (39°F) using either the processing equipment manufactured to cool breast milk, or ice baths. If using ice baths for cooling, water source must be of

adequate sanitary quality and the ice-creating equipment must be maintained per manufacturer's instructions. (NOTE: Unless using caps and equipment designed for submersion, caps need to remain above water level to prevent possible contamination from water seepage.)

23.3.3 An aliquot of processed breast milk from each batch is cultured for bacteria count.

23.3.4 ~~Milk~~ Breast milk is promptly labeled and frozen for storage.

23.3.5 Cooled, heat-processed breast milk can be stored, sealed, for up to 72 hours at 4°C for dispensing without freezing once bacteriological culture procedures and standards are met. ~~Milk~~ Breast milk can then be frozen for later use if not needed immediately.

23.4 Labeling of Breast Milk

23.4.1 Containers are labeled with batch number and expiration date of not more than 1 year from earliest pumping date of breast milk in pool.

23.4.2 Containers are labeled with the name of the breast milk bank where the processing occurred.

23.5 Bar-coding of Breast Milk

23.5.1 Barcode or other automatic tracking systems are not included as a minimum requirement for breast milk banks.

23.5.2 If a breast milk bank chooses to use an automatic tracking system, it is used within the following parameters:

23.5.2.1 The tracking/coding system is maintained following manufacturer's directions.

23.5.2.2 The breast milk bank reports annually to receipt hospitals about what system is being used for tracking.

23.5.2.3 The system would ideally be used by the recipient hospital also, but this is not required.

23.6 Bacteriological Testing

23.6.1 Any bacteriological growth ~~in~~ is unacceptable for heat-processed breast milk. Individual milk banks have the microbiology Standards of Practice (SOP) available in their banks, distributed by Human Milk Bank Association of North America (HMBANA) or the FDA's Bacteriological Analytical Manual (BAM). Individual breast milk banks ensure that the microbiology lab performing the testing is in compliance with the procedures.

23.6.2 ~~Milk~~ Breast milk that does not meet acceptable bacteriological standards is not distributed to a recipient but may be used for research. If not used for research, the contaminated breast milk is discarded.

23.6.3 The bottle of breast milk for the microbiological sample is chosen randomly from each batch of breast milk and discarded once the sample is taken. It is not resealed and dispensed, and it does not need to be stored for further testing.

23.7 Shipping

23.7.1 ~~Milk~~ Breast milk banks follow the standard guidelines of the shipper for ensuring that breast milk arrives at the destination intact and in a frozen state. Dry ice or blue ice may be used if sufficient in weight or size to keep breast milk frozen.

23.7.2 Cold-chain verification may be required in your state or province. A number of technologies exist to verify temperature.

Section 24. Breast Milk Dispensing

24.1 All breast milk dispensed is heat-processed unless a prescribing healthcare provider requests fresh frozen or fresh chilled raw breast milk.

24.2 In the event that a breast milk bank is unable to supply the needs of its recipients, it should contact other breast milk banks for assistance in supplying breast milk. If unable to locate additional supplies of donor breast milk, it dispenses the breast milk available on a priority basis to the recipients in greatest need. The breast milk bank coordinator/director and/or the medical director makes these decisions, basing them on diagnosis, severity of illness, availability of alternative treatments, and history of previous breast milk use.

Section 25. Transfer of Human Breast Milk

25.1 ~~Milk~~ Breast milk may be transferred from breast milk bank to another upon request. The transferring breast milk bank transfers breast milk from approved donors only and establishes a transfer agreement with the receiving bank. The transferring breast milk bank sends its own donor identification number associated with the breast milk deposits, allowing for tracking and recall if a problem occurs, and also allowing for protection of the donors' privacy.

25.2 Pasteurized breast milk that is transferred to another bank retains its original label indicating where the processing occurred. The recipient bank may add its own label but should not obscure or remove the original label when dispensing.

Section 26. Breast Milk Bank Records

26.1 Donor Records include:

26.1.1 Initial donor screening form, documenting:

26.1.1.1 Medical history

26.1.1.2 History of communicable diseases

26.1.1.3 Lifestyle choices that are risks for donated breast milk, including alcohol and nicotine use

26.1.1.4 Use of medications and/or herbs

26.1.2 Confirmation of negative serology tests within 6 months of donation for HIV-1 and -2, HTLV-1 and 2, Hepatitis B, Hepatitis C, and syphilis, and any additional screening required by the individual bank

26.1.3 Healthcare provider medical release form for both the donor ~~and her infant (unless infant is not in mom's care or is deceased)~~, acknowledging that the provider(s) knows of no risks to the potential donor ~~or the infant~~ should milk be collected for donation.

26.1.4 Birth date and gestational age of donor's infant

26.1.5 Documentation of each donation (deposit)

26.1.6 Signed donor consent form

26.2 Administrative records are confidential. Electronic records must be secure (password-protected or encrypted). Paper records must be kept in a secure private area. ~~Milk~~ Breast milk banks inform donors and recipients of privacy policies and procedures.

26.3 Donor records are maintained for 10 years if an adult recipient – or until every recipient who has received breast milk from a specific batch reaches a minimum age of 21, or longer, according to individual state or hospital rules or regulations.

26.4 Breast ~~Milk~~ milk bank administrative records include:

26.4.1 Identification of donors whose breast milk deposits comprise each pool, and the destination of each pool.

26.4.2 Batch information, including date of heat treatment, volume of breast milk treated, aliquots per batch, and heat-treatment times and temperatures.

26.4.3 Bacteriologic test results by batch after pooling and heat treatment.

26.4.4 Freezer, refrigerator, and pasteurizing temperatures.

26.4.5 Calibration records for all equipment, with calibration cycle and process according to manufacturers' instructions.

26.4.6 ~~Milk~~ Breast milk bank financial records as appropriate per institution, documenting processing fees per volume of breast milk dispensed, financial donations and in-kind gifts, and financial audits, if appropriate.

26.5 Recipient records include:

26.5.1 Name of receiving entity and purchase-order number. If ordered by a medical provider with prescription, name of provider and medical necessity.

26.5.2 Dispensing date, batch numbers, number of bottles, and ounces per bottle of all supplied breast milk.

26.5.3 Other pertinent information (such as diagnoses and medical outcome(s) of recipients, when available).

26.5.4 Documentation of quarterly communication with family or prescriber of outpatient recipients.

Section 27. Tracking and Recall of Donor Human Breast Milk

27.1 A system of tracking donor breast milk from donor to recipient is maintained.

27.2 A mock recall to test the breast milk bank's ability to track a donation from donor to recipient in 6 hours or less is carried out and documented in a breast milk bank's first year of operation and every 2 years thereafter. The need to conduct a true recall in any given year negates the need for a mock recall and resets the calendar until a mock recall is needed.

27.3 Product replacement is conducted at the discretion of the dispensing breast milk bank.

27.4 Individual breast milk banks are responsible for ensuring that they are compliant with their state or federal requirements for operation.

27.5 A person designated by each breast milk bank immediately investigates a suspected release of breast milk that does not meet these rules. If a problem is determined, the designated person initiates a root cause analysis and modifies internal procedures as appropriate. It is the individual recalling breast milk bank's responsibility to gather all data investigating the risk level associated with the suspected error.

Section 28. Research

28.1 A breast milk bank may decide whether or not to provide milk for an external research project.

28.2 ~~Milk~~ Breast milk banks that use milk for internal and external research purposes state this in their informed Consent of Donors.

Section 29. Annual Assessment and Accreditation

29.1 All nonprofit breast milk banks are required to complete an annual Human Milk Banking Association of North America (HMBANA) accreditation. Schedule of assessments for accreditation are set by HMBANA.

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PUBLIC COMMENT REPORT

Proposed Standards Pertaining to Human Breast Milk Bank

PUBLIC COMMENTS:

Public comment period expired February 28, 2024.

The Department received the following public comment regarding laboratory testing and calibration requirements, and the related laboratory accreditation standards:

Randall Querry, Director Government Relations
American Association for Laboratory Accreditation (A2LA)

> *We appreciate the opportunity to provide comments directed at the proposed rule "Standards Pertaining to Human Breast Milk Banks." Specifically, we write regarding laboratory testing and calibration requirements and the related laboratory accreditation standards. By way of background, A2LA is a non-profit, accreditation body with over 4200 actively accredited certificates representing all 50 states and international, and 30 organizations accredited in Arkansas including the Arkansas Public Health Laboratory. We have been granting accreditation to laboratories in various industries since 1979.*
>
> *The criteria forming the basis for our testing and calibration laboratory accreditation programs is ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories. We also provide accreditation to clinical laboratories to ISO 15189 Medical laboratories – Requirements for quality and competence; and achieved and maintain Centers for Medicare and Medicaid Services (CMS) Deem Status as an accreditation organization to accredit clinical laboratories to the Clinical Laboratory Improvement Amendments (CLIA) requirements. We ourselves, as an accreditation body, have been evaluated against rigorous standards in providing these accreditation services and we are the only accreditation body in the world that is recognized globally as an International Laboratory Accreditation Cooperation (ILAC)-recognized accreditation body and CMS deemed status accreditation organization.*
>
> *We offer the following comments for your consideration. Our recommended language is inserted in bold: In section 4.4.3, the requirements specify "A CLIA certified high complexity clinical laboratory, or an ISO 17025 accredited clinical laboratory does the tests…" Please note that an additional ISO standard exists that is based on ISO/IEC 17025 and ISO 9001 but specifies requirements for quality and competence that are*

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particular to medical laboratories. This ISO standard is ISO 15189 and has been in use for close to twenty years. We recommend that 4.4.3 be revised to "A CLIA certified high complexity ~~clinical~~ laboratory or an ISO/IEC 17025 ***or ISO 15189*** *accredited clinical laboratory,* ***which achieved accreditation from an International Laboratory Accreditation Cooperation recognized accreditation body****, does the tests…"*

In section 8.1, consider revising certified laboratory to the following: "A certified ***or accredited*** *laboratory is to conduct screening blood tests… Section 10.1 provides requirements for the breast milk bank to have disaster plans. We support this requirement; however, we advise that a provision be included to require periodic testing of the disaster plans to ensure that they are effective. We recommend that Section 10.1 be amended by adding a third, final sentence "****The disaster plan shall be testing at periodic intervals to determine effectiveness.****"*

*In section 15.3.2, the requirements specify, "Thermometers may be certified calibrated by National Institute of Standards and Technology(NIST) (or similar agency) or calibrated quarterly by the milk bank using an NIST certified reference thermometer. The milk bank must keep records of calibration." It is industry practice to rely on NIST calibration or rely on an ISO/IEC 17025 accredited calibration laboratory that is accredited by an ILAC recognized accreditation body for calibration of the reference thermometers. Then the milk bank may verify working thermometers against the reference thermometers. This can be more cost effective to the milk bank than as currently written in the proposed rule. We recommend the following revision to section 15.3.2: "****Thermometers may be calibrated by a national metrology institute (NMI) such as the National Institute of Standards and Technology (NIST) or an ISO/IEC 17025 accredited calibration laboratory that is accredited by an ILAC recognized accreditation body, for the calibration of the reference thermometers. The milk bank shall verify working thermometers against the calibrated reference thermometers at least quarterly. The milk bank must keep records of the calibration and verification records.****"*

In Section 14.1, second sentence, we recommend the following addition: Two distinct and appropriately calibrated ***(see section 15.3.2)*** *thermometers – whether electronic, or indwelling, or mercury—monitor freezers. Also note that the EPA has launched an effort to reduce the use of mercury-filled non-fever thermometers. As referenced on the EPA website: EPA has launched an effort (https://www.epa.gov/mercury/mercury-thermometers) to reduce the use of mercury-filled non-fever thermometers used in industrial settings where suitable alternatives exist. As part of a partnership EPA developed with the National Institute of Standards and Technology (NIST), NIST no*

longer provides calibration services for mercury thermometers. You can read more about the impact the decision will have in NIST's February 2011 press release announcing the change. Section 26.1.3 appears to be inconsistent with section 4.4.2, where language was struck out concerning the baby. Section 26.1.3 still includes a requirement for the infant. This may need to be reviewed further to consider striking the infant requirement.

*Section 27.5, requirements are in place to initiate a root cause analysis. We respectfully recommend that this language be improved upon. We recommend a fourth and final sentence added to 27.5 that states "**Following implementation of a corrective action, (e.g. three months), audit the correction to determine its effectiveness.**"*

The Department has revised the Standards in response to the public comments.

AGENCY RESPONSE:
Proceed to adoption.