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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 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 milk (PDHM) from a human milk bank to a hospital or other entities appropriate to receive milk (e.g., researchers, family with a prescription).
- 2.5 **Donor Human Milk Bank**—A donor human milk bank is a service established for the purpose of recruiting and collecting milk from donors, and processing, screening, storing and distributing donated milk, in accordance with these rules, to meet the specific needs of individuals.
- 2.6 **Donor Human Milk**—Donor human milk is milk expressed and donated by lactating women, pasteurized using the Holder Pasteurization Method, and dispensed for use by a recipient who is not the donor’s own baby. Milk banks may use the following additional terms; if terms are used, they comply with the following definitions:
 - 2.6.1 **Fresh-raw milk** – Human milk expressed within 72 hours and stored at or below 4°C.
 - 2.6.2 **Fresh-frozen milk** – Fresh raw human milk that has been frozen at -18°C for not longer than 12 months from date of collection.
 - 2.6.3 **Holder pasteurized milk** – Fresh-raw and/or fresh-frozen milk that has been heated to 62.5°C, for 30 minutes.
 - 2.6.4 **Pooled milk** – Human milk combined with deposits from more than one donor.
 - 2.6.5 **Preterm milk** – Human milk expressed within the first 4 weeks postpartum by a mother who delivered at or before 36 weeks gestation.
 - 2.6.6 **Term milk** – Human milk pumped by mothers giving birth after 36 weeks, or before 36 weeks but after 4 weeks postpartum.
 - 2.6.7 **Reduced fat milk** – 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 milk** – Milk that is collected from term mothers (>37 weeks gestation) during the first month of lactation.
- 2.6.9 **Dairy restricted** – Milk expressed by mothers who report avoidance of explicit and inexplicit dairy products (including all processed foods).
- 2.6.10 **Pasteurized donor human milk (PDHM)** – Donor human milk that has been collected, processed, and dispensed according to these rules.
- 2.7 **Donor Human Milk-Contact Surfaces**—All surfaces that contact donor human 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 Milk Depot**—A donor human milk depot is an agency affiliated with a donor human milk bank that collects and stores donor milk that is then transported to the affiliated milk bank for processing. The milk bank accepts responsibility for all screening, processing and distributing of milk.
- 2.9 **Donor Human Milk Distribution Site**—A donor human milk distribution site is an agency affiliated with a milk bank that stores and distributes donor milk that was processed by a milk bank, and distributes the 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 **Milk Donor**—A lactating woman who voluntarily contributes milk to a human milk bank. A donor may or may not be remunerated.
- 2.12 **Milk-Processing Centers**—For-profit entities that collect human milk and produce human milk-based products.
- 2.13 **Milk Sharing**—The practice of one mother giving her milk to another person without payment.
- 2.14 **Processing**—The use of evidence-based methodologies, including pasteurization, to prepare safe milk for recipients.
- 2.15 **Processing Fees**—Fees assessed by the donor milk bank to offset the cost of donor screening, milk processing, storing, distribution, and record keeping.
- 2.16 **Product Recall**—The formal process of recalling all dispensed milk within a batch or batches that are suspected may potentially cause harm.
- 2.17 **Product Replacement**—The process of dispensing additional milk to a recipient or recipients after the initial dispensed 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 milk bank operations are overseen by qualified nursing, medical, or other milk bank personnel with education and training critical to the provision of safe donor human milk.
- 3.2 Donor 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 milk bank director when appropriate.
- 3.3 All 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 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 milk bank makes efforts to offer an appropriate translator to help with the screening process, or a 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 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 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 ~~within no more than~~ 6 months prior to the first donation. A CLIA certified high complexity clinical laboratory or an ISO 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 milk bank.

4.4.3.1 Communication with a 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 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 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, 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 milk expression must be investigated.
- 4.4.4.4 Donors should be advised that if they begin taking any medication once approved and donating milk, they should contact the 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 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 (medroxyprogesterone injection), micronor or Nor-QD (norethindrone), Yaz and Beeyaz (drospironone, Implanon or Nexplanon FDA (etonogestrel implant)
- 4.4.4.5.6.4 Seasonale, Seasonique, and Lybrel (longacting norgestrel 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 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 Criteria

- 6.1 Note: Potential donors are excluded based on the following clinical issues unique to human milk and infants, and on current AABB, US CDC, and Health Canada Guidelines.
- 6.2 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 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 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 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 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.
 - 6.7 Current use of marijuana for medical or casual use.
 - 6.8 Use of tobacco or nicotine products, including gum, patches, or e-cigarettes. This includes casual or occasional use of such products.
 - 6.9 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.
 - 6.10 Daily use of over-the-counter medications or systemic prescriptions.
 - 6.11 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 Total vegetarians (vegans) who do not supplement their diet with vitamin B12.
 - 6.13 Use of illegal drugs within the past 12 months.
 - 6.14 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.
 - 6.15 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.
 - 6.16 Incarceration, or incarceration of sexual partner, for more than 72 consecutive hours in the last 12 months
 - 6.17 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.

- 6.17.1 Receipt of human pituitary-derived growth hormone, dura mater (or brain covering) graft, or bovine insulin.
- 6.17.2 Family history of Creutzfeldt-Jakob disease.
- 6.17.3 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:
 - 6.17.3.1 Albania
 - 6.17.3.2 Austria
 - 6.17.3.3 Belgium
 - 6.17.3.4 Bosnia-Herzegovina
 - 6.17.3.5 Bulgaria
 - 6.17.3.6 Croatia
 - 6.17.3.7 Czech Republic
 - 6.17.3.8 Denmark
 - 6.17.3.9 Federal Republic of Yugoslavia (also known as Serbia and Montenegro)
 - 6.17.3.10 Finland
 - 6.17.3.11 France
 - 6.17.3.12 Germany
 - 6.17.3.13 Greece
 - 6.17.3.14 Hungary
 - 6.17.3.15 Italy
 - 6.17.3.16 Lichtenstein
 - 6.17.3.17 Luxembourg
 - 6.17.3.18 Macedonia
 - 6.17.3.19 Netherlands (also known as Holland)
 - 6.17.3.20 Norway
 - 6.17.3.21 Poland

- 6.17.3.22 Portugal
- 6.17.3.23 Republic of Ireland (also known as Ireland)
- 6.17.3.24 Romania
- 6.17.3.25 Slovak Republic (also known as Slovakia)
- 6.17.3.26 Spain
- 6.17.3.27 Sweden
- 6.17.3.28 Switzerland
- 6.17.3.29 United Kingdom
- 6.17.4 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.
- 6.17.5 Received a blood or blood-component transfusion in the UK or France since 1980.
- 6.18 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.
- 6.19 Exposure to hand, foot and mouth disease is not a reason for deferral unless medication is required.
- 6.20 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.

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 bank 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 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 test 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 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 milk from this potential donor, that has already been donated and is being held at the milk bank, is disposed of according to institutional protocols. In the absence of institutional protocols, expressed 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 milk.

Section 9. Donor Approval

- 9.1 Each 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 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. Milk banks must engage in, and document, ongoing communication with donors at a minimum of every 2 months.
- 9.2 Milk banks can determine individual circumstances under which they received milk before a donor is approved; however, returning raw donated milk to the approved or unapproved milk donor is not recommended. The final decision on a request for milk return is up to each 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 milk bank is responsible for having a disaster plan covering emergencies affecting their individual milk bank. These plans should include how to protect milk in the case of power outage, and notification plans for staff, community, and other milk banks or effected entities in case of inability to dispense or receive milk.

Section 11. Donor Education and Procedures

- 11.1 To ensure the highest level of safety and quality of donated milk, milk donors are instructed on the appropriate methods for clean expression, handling, storage, and transportation of human milk.
- 11.2 Donors are given written instructions covering:
- 11.2.1 Clean technique for milk collection, including:
 - 11.2.1.1 Washing pump parts
 - 11.2.1.2 Handwashing
 - 11.2.1.3 Appropriate containers for storing donor milk
 - 11.2.1.4 Handling of milk containers

- 11.2.2 Those times when the donor should refrain from donating, and life style choices that may affect her eligibility as donor.
- 11.2.3 Labeling of donated milk, which includes donor identification and date of collection.
- 11.2.4 Optimal freezing and storage of milk.
- 11.2.5 Transporting milk safely to the bank.
 - 11.2.5.1 In situations where the milk was collected before the donor contacted the milk bank, the screening process includes discussion and evaluation of how the donor expressed and stored the milk, as well as what medications or supplements the donor took during the collection period.

Section 12. Procedure Manual

- 12.1 A milk bank maintains a detailed procedures manual, available to 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 processing buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for 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 milk.
 - 13.1.2 Permit the use of proper precautions to reduce the potential for contamination of milk, milk-contact surfaces, or 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 milk, milk-contact surfaces, or 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 milk or milk-contact surfaces, and milk-packaging materials.
 - 13.1.4 Allow no pests in any area of the milk bank. Effective measures are taken to exclude pests from the processing areas and to protect against the contamination of 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 milk, milk-contact surfaces, and milk-packaging materials.

- 13.1.5 Do not allow persons unnecessary to milk processing into the milk preparation area while open containers of milk are being processed.
- 13.1.6 Properly identify cleaners and sanitizers, which are stored in dedicated containers and kept away from the 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 milk occur in one room with a separate door, which is closed whenever 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 milk processing is complete.
- 13.1.10 Provide designated areas or rooms for the receiving, handling, and storage of returned (recalled) milk and milk products. Freezer space for the returned product must not be comingled with raw frozen or pasteurized milk, although both raw and processed milk can be in different sections of the same freezer.
- 13.1.11 Provide separate freezers to store incoming raw-frozen donor milk and pasteurized milk. Minimally, 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 milk and/or 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 bank personnel investigate and resolve discrepancies in thermometer readings.
- 14.2 Freezers are locked or in a secured area.
- 14.3 Milk is stored in dedicated freezers that maintain 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 milk remains frozen.

- 14.4 Refrigerators used for storing thawed or processed 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 milk bank personnel at all times.
- 14.7 Equipment intended for human milk banking – processing or storing – is used only for milk banking purposes.
- 14.8 Processed 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 milk bank.
- 14.9 All equipment used in the 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 milk composition analysis equipment.
- 14.10 All 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 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. Milk-contact surfaces are corrosion-resistant when in contact with milk. They are made of nontoxic materials and designed to withstand the environment of their intended use and the action of milk, and, if applicable, cleaning compounds and sanitizing agents. Milk-contact surfaces are maintained to protect milk from being contaminated by any source, including unlawful indirect milk additives.
- 14.11 Seams on 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 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 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 an ISO/IEC 17025 accredited calibration laboratory that is accredited by an ILAC recognized accreditation body, for the calibration of (or similar agency) 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 milk bank must keep records of the calibration and verification records.

Section 16. Thermometers used in the Pasteurization Process

- 16.1 When using equipment specially designed for human 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 milk during heating and cooling phases should be NIST-certified or calibrated no less often than quarterly using an NIST-certified reference thermometer. The 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 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. Milk Analyzers

- 18.1 Nutritional analysis of milk is not a minimum requirement for milk banks. However, if a 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 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 banks that use human 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 milk, milk-contact surfaces, and milk-packaging materials adhere to hygienic practices while on duty to the extent necessary to protect against contamination of 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 that protects against the contamination of milk, milk-contact surfaces, or 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 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 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 milk-processing and milk-handling areas.
- 19.2.9 Reporting potential exclusion to a milk bank staff member designated to decide appropriateness of potential exclusion.
- 19.2.10 Preparing milk in a dedicated clean space with facilities for aseptic technique.
- 19.2.11 Cleaning and sanitizing 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 milk-handling area.
- 19.2.13 Ensuring that personnel responsible for identifying sanitation failures or 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 milk.
- 19.2.14 Ensuring that 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 Milk

- 20.1 All donated milk is identified as relating to a specific approved milk donor. Donated milk is packaged securely with identification visible, and maintained in a frozen state until chosen for processing. Logging of incoming milk includes estimating the volume of milk, as well as observing for foreign matter or other sources of contamination such as broken storage containers. 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 is generally thawed in refrigerators in a manner that prevents the milk from becoming adulterated or contaminated. Final thawing may occur outside of the refrigerator as long as temperature expectations are met. Milk should be maintained at 45°F or 7.2°C or below, both while in the refrigerator and out. 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 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 milk is conducted under clean conditions.

Section 22. Requirements of Raw Frozen Milk Distribution

- 22.1 Each pool of milk has a sample taken for bacteriologic screening using sterile technique.
- 22.2 Only milk from pools with $\leq 10^4$ CFU/ml of normal skin flora (e.g., coagulase negative staphylococcus, diphtheroids, Staphylococcus epidermis, or Streptococcus viridans) is acceptable to dispense raw. The presence of any pathogens is unacceptable.

Section 23. Aliquoting and Heat Processing

- 23.1 Aliquoting
- 23.1.1 Pooled 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 is examined during pouring for foreign matter. Milk is strained and visually examined before heat processing. Any foreign matter should be removed, and, if not removable, the milk is discarded.

23.1.4 All containers are tightly closed with clean caps to prevent contamination of 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 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 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 milk or water as the most filled container of milk in the batch is fitted with a calibrated thermometer to register 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 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 temperature and bath temperature are monitored and recorded.

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

23.3 Chilling and Storage

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

- 23.3.2 Following heat processing, the milk is rapidly cooled to 4°C (39°F) using either the processing equipment manufactured to cool 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 milk from each batch is cultured for bacteria count.
 - 23.3.4 Milk is promptly labeled and frozen for storage.
 - 23.3.5 Cooled, heat-processed 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 can then be frozen for later use if not needed immediately.
- 23.4 Labeling of Milk
- 23.4.1 Containers are labeled with batch number and expiration date of not more than 1 year from earliest pumping date of milk in pool.
 - 23.4.2 Containers are labeled with the name of the milk bank where the processing occurred.
- 23.5 Bar-coding of Milk
- 23.5.1 Barcode or other automatic tracking systems are not included as a minimum requirement for milk banks.
 - 23.5.2 If a 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 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 is unacceptable for heat-processed 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 milk banks ensure that the microbiology lab performing the testing is in compliance with the procedures.

- 23.6.2 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 milk is discarded.
- 23.6.3 The bottle of milk for the microbiological sample is chosen randomly from each batch of 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 banks follow the standard guidelines of the shipper for ensuring that 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 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. Milk Dispensing

- 24.1 All milk dispensed is heat-processed unless a prescribing healthcare provider requests fresh frozen or fresh chilled raw milk.
- 24.2 In the event that a milk bank is unable to supply the needs of its recipients, it should contact other milk banks for assistance in supplying milk. If unable to locate additional supplies of donor milk, it dispenses the milk available on a priority basis to the recipients in greatest need. The 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 milk use.

Section 25. Transfer of Human Milk

- 25.1 Milk may be transferred from milk bank to another upon request. The transferring milk bank transfers milk from approved donors only and establishes a transfer agreement with the receiving bank. The transferring milk bank sends its own donor identification number associated with the milk deposits, allowing for tracking and recall if a problem occurs, and also allowing for protection of the donors' privacy.
- 25.2 Pasteurized 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. 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 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 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 milk from a specific batch reaches a minimum age of 21, or longer, according to individual state or hospital rules or regulations.
- 26.4 Milk bank administrative records include:
 - 26.4.1 Identification of donors whose milk deposits comprise each pool, and the destination of each pool.
 - 26.4.2 Batch information, including date of heat treatment, volume of 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 bank financial records as appropriate per institution, documenting processing fees per volume of 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 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 Milk

- 27.1 A system of tracking donor milk from donor to recipient is maintained.
- 27.2 A mock recall to test the milk bank's ability to track a donation from donor to recipient in 6 hours or less is carried out and documented in a 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 milk bank.
- 27.4 Individual 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 milk bank immediately investigates a suspected release of 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 milk bank's responsibility to gather all data investigating the risk level associated with the suspected error.

Section 28. Research

- 28.1 A milk bank may decide whether or not to provide milk for an external research project.
- 28.2 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 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.