

ARKANSAS STATE BOARD OF HEALTH
RULES PERTAINING TO
MILK BANK STANDARDS



Promulgated Under Authority of Act 216 of 2019

Effective on _____

Arkansas Department of Health
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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. Procedure Manual

- 2.1 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 3. Building and Facility

- 3.1 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:
 - 3.1.1 Provide sufficient space for placement of equipment and storage materials to permit sanitary operations and production of donor human milk.
 - 3.1.2 Permit the use of proper precautions to reduce the potential for contamination of milk, milk-contact surfaces, or milk-packaging materials.
 - 3.1.3 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.
 - 3.1.4 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.
 - 3.1.5 Do not allow persons unnecessary to milk processing into the milk preparation area while open containers of milk are being processed.
 - 3.1.6 Properly identify cleaners and sanitizers, which are stored in dedicated containers and kept away from the milk in processing.

- 3.1.7 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.
- 3.1.8 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.
- 3.1.9 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.
- 3.1.10 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.
- 3.1.11 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.
- 3.1.12 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.
- 3.1.13 Provide a water supply in compliance with city, state, or township ordinances for potable water.

Section 4. Equipment

- 4.1 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.
- 4.2 Freezers are locked or in a secured area.
- 4.3 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.
- 4.4 Refrigerators used for storing thawed or processed milk are held no higher than 4°C (or 40°F).
- 4.5 Storage and processing equipment are calibrated every six (6) months, or according to manufacturers' instructions.
- 4.6 All equipment manuals are available to milk bank personnel at all times.

- 4.7 Equipment intended for human milk banking – processing or storing – is used only for milk banking purposes.
- 4.8 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.
- 4.9 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.
- 4.10 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.
- 4.11 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.
- 4.12 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.
- 4.13 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 5. Thermometers

- 5.1 Monitoring temperatures in milk banks is critical to the safety of the milk distributed.
- 5.2 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.
- 5.3 Thermometers in freezers and refrigerators
 - 5.3.1 A minimum of two (2) calibrated thermometers are used to monitor temps in freezers and refrigerators.
 - 5.3.2 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.

Section 6. Thermometers used in the Pasteurization Process

Note: 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.

- 6.1 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.
 - 6.1.1 In addition to the quarterly calibration, thermometers should be calibrated if dropped, damage, or at any time the accuracy is in question.
 - 6.1.2 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 7. Thermometer Calibration Procedure

- 7.1 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.
- 7.2 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 8. Milk Analyzers

- 8.1 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:
 - 8.1.1 The instrument is maintained following manufacturer's directions.
 - 8.1.2 The milk bank reports annually to recipient hospitals about what instrument it is using for analysis.

- 8.1.3 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.
- 8.1.4 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.
- 8.1.5 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 9. Handling

- 9.1 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.
- 9.2 The methods for maintaining cleanliness include, but are not limited to:
 - 9.2.1 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.
 - 9.2.2 Maintaining adequate personal cleanliness.
 - 9.2.3 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.
 - 9.2.4 Not washing hands in sinks used for milk preparation or washing equipment. Keeping hand-washing facilities in a clean condition and in good repair.
 - 9.2.5 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.
 - 9.2.6 Covering hair with hair nets, caps, or other effective hair restraints; include beard covers when appropriate. Dangling earrings must be tucked under hair net.
 - 9.2.7 No eating food, chewing gum, drinking beverages, or using tobacco in areas where milk may be exposed or where equipment or utensils are washed.

- 9.2.8 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.
- 9.2.9 Reporting potential exclusion to a milk bank staff member designated to decide appropriateness of potential exclusion.
- 9.2.10 Preparing milk in a dedicated clean space with facilities for aseptic technique.
- 9.2.11 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.
- 9.2.12 Making clean sinks and sanitizing dispensers available in the milk-handling area.
- 9.2.13 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.
- 9.2.14 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.
- 9.2.15 Ensuring that competent supervisory personnel take responsibility for assuring compliance by all lab personnel.
- 9.2.16 Cleaning all food-contact surfaces, including utensils and food-contact surfaces of equipment, as frequently as necessary to protect against contamination of food.

Section 10. Logging of Incoming Milk

- 10.1 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 11. Defrosting and Pooling

11.1 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.

11.1.1 Pooling of fresh raw or defrosted fresh-frozen milk is conducted under clean conditions.

Section 12. Requirements of Raw Frozen Milk Distribution

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

12.2 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 13. Heat Processing

13.1 Aliquoting

13.1.1 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.

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

13.1.3 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.

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

13.1.5 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.

13.2 Heat Processing

Note: When using equipment specifically designed for human milk pasteurization, the procedures for use of the machine are followed: The following guidelines refer to shaking water baths only.

- 13.2.1 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.
- 13.2.2 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.
- 13.2.3 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.
- 13.2.4 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.
- 13.2.5 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.
- 13.2.6 Milk temperature and bath temperature are monitored and recorded.
- 13.2.7 Air bubbles released from milk containers indicate insecure caps – such bottles are discarded.

13.3 Chilling and Storage

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

- 13.3.1 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.)
- 13.3.2 An aliquot of processed milk from each batch is cultured for bacteria count.
- 13.3.3 Milk is promptly labeled and frozen for storage.
- 13.3.4 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.

13.4 Labeling of Milk

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

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

13.5 Bar-coding of Milk

NOTE: Barcode or other automatic tracking systems are not included as a minimum requirement for milk banks. However, if a milk bank chooses to use an automatic tracking system, it is used within the following parameters:

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

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

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

13.6 Bacteriological Testing

13.6.1 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). Individual milk banks ensure that the microbiology lab performing the testing is in compliance with the procedures.

13.6.2 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.

13.6.3 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.

13.7 Shipping

13.7.1 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.

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

Section 14. Milk Dispensing

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

- 14.2 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 15. Transfer of Human Milk

- 15.1 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.
- 15.2 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.