



# HMBANA Standards for Donor Human Milk Banking: An Overview

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## **HMBANA Guidelines Committee**

Kim Updegrove, MSN, MPH, RN, CNM, FACNM\*; Chairperson

Ashlynn Baker, BSN, RN, IBCLC\*

Jannette Festival, BN, RN, IBCLC\*

Harley Ginsberg, MD, FAAP

Raechel Hackney, BSN, RN, IBCLC

Frances Jones, MSN, RN, IBCLC

Summer Kelly, MS, RN, IBCLC\*

Pauline Sakamoto, MS, RN, PHN\*

Lisa Stellwagen, MD, FAAP

Amy Vickers, MSN, RN, IBCLC, ASQ-CQA\*

*\*PCQI certified*

## **HMBANA**

The Human Milk Banking Association of North America (HMBANA) mobilizes the healing power of donor milk by accrediting nonprofit milk banks in the United States and Canada and setting international standards for milk banking.

### **Mission**

HMBANA advances the field of nonprofit milk banking through member accreditation, development of evidence-based best practices, and advocacy of breastfeeding and human lactation to ensure an ethically sourced and equitably distributed supply of donor human milk.

### **Vision**

HMBANA believes in a world where all infants have access to human milk through support of breastfeeding and use of donor human milk.

### **Section I: Introduction**

This overview of *HMBANA Standards for Donor Human Milk Banking (HMBANA Standards)*, previously known as the *Guidelines for the Establishment and Operation of a Donor Human Milk Bank*, summarizes the safety measures that HMBANA-accredited milk banks utilize to ensure the safety and quality of pasteurized donor human milk, hereinafter referred to as donor milk. This public document provides useful background for clinicians, healthcare organizations, and public health agencies that are interested in learning more about HMBANA milk banking procedures.

The complete version of *HMBANA Standards for Donor Human Milk Banking* is proprietary and is provided to each HMBANA-accredited member milk bank, along with accreditation documents and other tools. HMBANA accreditation provides evidence that a milk bank is compliant with *HMBANA Standards* and maintains a comprehensive system of preventive controls, safety checks, verifications, validations, and corrective actions. HMBANA accreditation audits consist of onsite inspections, plant walkthroughs,

record audits, standard operating procedure (SOP) and food safety plan review, sanitation assessments, staff training evaluations, mock recalls, critical control point audits, staff interviews, and additional rigorous safety evaluations. HMBANA auditors are certified preventive controls qualified individuals (PCQIs) through the Food Safety Preventive Controls Alliance (FSPCA) and receive additional auditor training on an annual basis.

Please note that adherence to the donor screening standards contained in this brief overview does not provide assurance that informally shared or sold milk is safe or that HMBANA-approved donors are qualified to provide milk to others outside of milk banking. Pasteurization is required to safeguard donor milk from biological hazards, such as viral and bacterial contaminants. Organizations that identify as milk banks, but lack HMBANA accreditation, do not have access to the proprietary version of *HMBANA Standards* and cannot claim adherence to *HMBANA Standards*.

## **Section II: Definitions**

**Current Good Manufacturing Practices (cGMPs)** — the minimum standards for safe and sanitary food manufacturing outlined in FDA Title 21, Part 117, Subpart B.

These include staff training, staff hygiene and illness reporting, equipment calibration and maintenance, sanitation procedures, and pest control.

**Food Safety Plan (FSP)** — a written plan to minimize or prevent biological, chemical, and physical hazards. An FSP includes a hazard analysis, preventive controls, monitoring actions, corrective actions, verifications and validations, sanitation controls, and a recall plan.

**Milk Donor** — a healthy lactating mother who voluntarily, without receiving remuneration from any party, donates her milk.

**Preventive Controls Qualified Individual (PCQI)** — a food safety professional who completes risk-based preventive controls education approved by the FSPCA.

**Standard Operating Procedure (SOP)** – instructions that outline how to perform an activity in a concise, consistent, and step-by-step manner, divided into sections including supplies and materials, rationale, and references.

### Section III. Administrative Structure

#### Business and Regulatory Requirements

In the United States, HMBANA member milk banks are nonprofit organizations that maintain IRS 501(c)3 status and good standing with their state’s charitable bureau. In addition, US milk banks are required to register biannually as food facilities with the FDA. In Canada, milk banks are designated by the Canada Revenue Agency as charitable organizations. All North American milk banks are required to adhere to local regulations related to:

- Licensing
- Food facility registration
- Zoning requirements
- Health department requirements

Trained personnel fill the following roles:

- **Director/Coordinator:** An individual who manages the organization, serves as a liaison between HMBANA and the milk bank, and ensures adherence to *HMBANA Standards* and regulatory requirements
- **Lab manager/Person-in-charge:** A food safety manager, or their trained designate, who is responsible for safe operations and lab staff supervision
- **PCQI:** A certified PCQI who approves the milk bank’s food safety plan
- **Lab technician:** An individual who receives extensive education and training in current good manufacturing practices, maintains a current food handler certification, and meets the FDA’s definition of a qualified individual: “a person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties”

- **Donor coordinator/donor screener:** An individual who receives extensive training and demonstrates competencies related to donor communication and medical record keeping, assesses donors per *HMBANA Standards*, determines deferrals based on medication use and health status, and maintains privacy and confidentiality
- **Medical director/adviser:** An individual who is licensed to practice medicine
- **Licensed medical professional (RN, physician, or physician’s assistant):** An individual who approves donors
- **Milk bank medical advisory board:** A group of specialists from the following disciplines:
  - Pediatrics
  - Obstetrics
  - Infectious diseases
  - Lactation

## Section IV. Donor Screening

Donor qualifications are based on regulatory guidance, current research, best practices, and clinical data. Donor screening standards are updated continuously to reflect new research, emerging diseases, new pharmaceutical agents, and new health risks.

### Donor Screening Summary

- Donors are screened verbally, as well as in writing, and provided educational materials that meet HMBANA’s minimal donor education requirements.
- Accommodations for non-English speaking donors are made, when possible.
- Milk banks establish and maintain a personal, trusting relationship with each donor. Milk banks communicate with the donor continuously during the donation period to update changes in the donor’s health, medical status, and medication use.
- Potential donors are screened serologically for HIV, HTLV, hepatitis B, hepatitis C, and syphilis.

Temporary deferral periods or a permanent donor exclusion may apply in the following situations:

- Smoking or use of tobacco products
- Alcohol consumption (requires a deferral)
- Use of illegal recreational drugs
- Use of cannabis or CBD products
- Use of non-approved medications, vaccines, or herbal supplements
- Positive serological test results for HIV, HTLV, hepatitis B or C, or syphilis
- Recent history of blood transfusion
- Risk of blood-borne illnesses
- Risk of Creutzfeldt-Jakob disease (CJD)
- Organ or tissue transplant
- At-risk sexual practices

### **Milk Handling Restrictions**

- Milk may not be donated if it has been heat-treated in any way by the donor.
- Milk may be temporarily stored in the refrigerator for a maximum of 96 hours before being moved to the freezer for long-term storage.
- Milk expires one year from the date of collection.

## **Section V. Donor Education**

To ensure the highest level of safety and quality of donor milk, donors are instructed both verbally and in writing about potential risks and deferrals (e.g., medication use, illnesses, and at-risk behavior). Donors are instructed to contact the milk bank to report household illness and any changes in health status or medication use.

Donors are given written instructions covering:

- Clean technique for milk collection, including:
  - Proper hand hygiene
  - Washing and sanitizing pump parts and containers
  - Appropriate containers for storing donor milk

- Handling of milk containers, both while storing milk and during transit to the milk bank
- Labeling of donor milk, which includes donor identification and date of collection
- Optimal freezing and storage of milk
- Transporting milk safely to the milk bank or depot

To ensure that donors are fully informed of their rights and responsibilities, donors are provided with the following written information:

- A statement that approval as a milk donor does not indicate that a donor's milk is safe to share or sell informally
- An explanation of the required serology tests and what actions are taken when positive tests are received, in accordance with state or provincial regulations

## **Section VI. Milk Bank Standard Operations, Safety, Quality, and Processing**

US milk banks are regulated and inspected as food manufacturers by the FDA and their local health departments. All US milk banks comply with the Food Safety Modernization Act (FSMA). Canadian milk banks are subject to regulation and inspection by Canada Food Inspections Agency (CFIA). All HMBANA milk banks comply with the FDA's Current Good Manufacturing Practices (cGMPs).

### **Standard Operating Procedures**

Milk banks maintain detailed SOPs that are available to all staff and are updated annually. SOPs include (but are not limited to):

- Donor screening and serological testing
- Sanitation and cGMPs
- Receipt, storage, and transportation of donor milk
- Pasteurization
- Microbiological testing
- Distribution, tracking, and recall
- Emergency preparedness

## Plant Design

Milk processing facilities are suitable in size, construction, and design to ensure sanitary operations for milk processing activities and are compliant with FDA safety requirements for food manufacturing facilities.

## Equipment

General requirements:

- Equipment intended for human milk bank processing is used only for milk banking purposes.
- Equipment is cleaned, sanitized, and maintained according to the manufacturer's instructions.
- Equipment and utensils are designed and made from non-corrosive food-grade material. The design, construction, and use of equipment and utensils must not result in the contamination of milk.

Pasteurizers:

- Pasteurizers are calibrated and maintained to meet HMBANA time and temperature requirements.

Freezers and refrigerators:

- Freezers are locked or located in a secured area that is inaccessible to the public.
- Freezer temperatures are held at  $-18\text{ }^{\circ}\text{C}$  [ $0\text{ }^{\circ}\text{F}$ ] or less.
- Refrigerator temperatures are held between  $1\text{ }^{\circ}\text{C}$  and  $4\text{ }^{\circ}\text{C}$  [ $34\text{--}39\text{ }^{\circ}\text{F}$ ].

Dishwashers:

- Commercial dishwashers must reach a rinse temperature of  $82\text{ }^{\circ}\text{C}$  [ $180\text{ }^{\circ}\text{F}$ ] with every cycle.
- Dishwasher sanitizers and rinse agents are food safe and appropriate for the machine.

Thermometers:

- NIST-certified thermometers are calibrated on a regular schedule.
- Milk banks follow HMBANA specification standards for thermometers that monitor freezers, refrigerators, pasteurizers, and pasteurization control bottles.



## **Milk Processing & Distribution**

### Receiving:

- Milk banks use a robust electronic inventory system to account for every ounce of milk received, processed, dispensed, discarded, and used for research.
- Milk is traced to a specific milk donor throughout every step in the process.
- Detailed logistics records include: incoming shipping records, receiving date, volume, condition of milk, and waste/disposal.

### Thawing:

- Donor milk may be gradually thawed in a manner that prevents contamination per the FDA Food Code, with careful monitoring and recordkeeping that document adherence to time and temperature requirements.

### Pooling/Mixing:

- Milk from multiple donors is pooled together to create a uniform batch of donor milk.
- Pooling is performed with aseptic technique under clean conditions.
- Milk is adequately mixed to ensure an even macronutrient distribution throughout the batch.

### Bottling:

- Milk is strained with a food-grade filter before bottling.
- Processed donor milk is stored in glass or food-grade plastic bottles that meet FDA packaging requirements.
- Bottles are airtight and leakproof.

### Pasteurization:

- Bottled milk is heat-treated via Holder pasteurization at 62.5 °C [144.5 °F] for 30 minutes.
- Following pasteurization, milk is rapidly chilled by using either the processing equipment manufactured to cool milk or ice baths.

**Bacteriological testing:**

- HMBANA’s microbiological sampling protocol ensures that each batch of pasteurized milk is tested for bacteria before being approved for dispensation.
- Post-pasteurization bacteriological testing is conducted by a third-party accredited lab. Clinical labs maintain Clinical Laboratory Improvement Amendments (CLIA) or equivalent certification, and food testing labs meet ISO/IEC 17025 standards.

**Distribution:**

- Donor milk is shipped and received in a frozen state.
- HMBANA member milk banks follow strict prioritization guidelines to ensure that the needs of small vulnerable newborns are met first.

**Quality Assurance Program**

Each HMBANA-accredited milk bank has a robust quality assurance program that includes:

- cGMP program monitoring and record keeping
  - Sanitation and commercial pest control schedules and checklists
  - Staff education and training records
  - Equipment maintenance and calibration schedules and records
- Verification and validation activities
  - Commercial dishwasher temperature verification
  - Sanitizer and disinfectant chemical concentration verification
  - Donor and batch record audits to validate that critical limits are met
- Corrective action, safety meeting, and root cause analysis records
- Mock recalls
- Annual SOP and FSP review and revision
- Customer complaint logs

**Section VII. Accreditation and Standards**

HMBANA member milk banks are required to complete an annual HMBANA audit to demonstrate compliance with the *HMBANA Standards* for accreditation. HMBANA’s audit program relies on quality auditing principles (e.g., American Society for Quality),

utilizing a peer review process similar to hospital accreditation programs (e.g., The Joint Commission). Onsite audits are completed by a trained and experienced HMBANA auditor who is PCQI certified.

HMBANA Standards are continuously updated to incorporate new clinical evidence, federal food safety regulations, and guidance from the Centers for Disease Control and Prevention. Since 1985, safety, quality, and the ethical treatment of human milk donors and recipients have been HMBANA's highest priorities.