

WAC 246-720-070 Milk bank minimum operating standards. A milk bank must meet the following minimum operating standards to register with the department:

(1) A milk processing facility must be suitable in size, construction, and design to ensure sanitary operations for milk processing activities and comply with all United States Food and Drug Administration food manufacturing safety requirements for food manufacturing facilities.

(2) Equipment intended for milk processing must be used only for milk banking purposes or processing of human milk-derived products.

(3) Equipment must be cleaned and maintained according to manufacturer's instructions or in a method other than the manufacturer's recommendation only when otherwise validated as appropriate by the FDA.

(4) Equipment and utensils must be designed and made from noncorrosive food grade material that can be adequately cleaned and maintained. The design, construction, and use of equipment and utensils must not result in contamination of milk.

(5) Freezers must be locked or located in a secured area and inaccessible to the public.

(6) Freezer temperatures must be maintained at -18°C (0°F) or less.

(7) Refrigerator temperatures must be maintained between 1°C and 4°C (40°F).

(8) Commercial dish washing machines must reach a minimum boost temperature of 82.2°C (180°F) with every cycle.

(9) Dish washing machine sanitizers and rinse agents must be food safe and appropriate for the make and model of the dish washing machine.

(10) Thermometers must be calibrated to a National Institute of Standards and Technology (NIST) reference thermometer each quarter, or more often if dropped, damaged, or any time a thermometer's accuracy is in question.

(11) Each milk bank must have a quality assurance program that includes, at a minimum:

(a) cGMP program monitoring and recordkeeping, including:

(i) Sanitation and pest control schedules and checklists;

(ii) Staff education and training records;

(iii) Equipment maintenance and calibration schedules and records.

(b) Verification and validation activities, including:

(i) Dish washing machine temperature verification;

(ii) Sanitizer and disinfectant chemical concentration verification;

(iii) Milk donor and batch record self-audits to validate critical limits are met.

(c) Records of safety meetings and root cause analyses.

(d) Mock donor human milk recalls.

(e) Annual standard operating procedure and FSP review and revision. An FSP must include a hazard analysis, preventive controls, monitoring actions, corrective actions, verifications and validations, supply chain management programs, a recall plan, and records of actions to support the food safety plan.

(12) A milk bank must comply with the Food Safety Modernization Act (FSMA) and register with the FDA as a food manufacturer biannually. Milk banks must maintain records of passing FDA inspections and provide those records to the department upon request.

[Statutory Authority: 2022 c 236. WSR 23-17-149, § 246-720-070, filed 8/22/23, effective 9/22/23.]