Guidelines for Preparation of Human Milk and Formula in Health Care Facilities

Chapter 1. Physical Facilities

1. If infant feedings are prepared on-site, it is strongly recommended that there be a separate room that
   a. has the appropriate physical separation from direct patient care areas;
   b. has the preparation area divided from the storage and anteroom areas;
   c. is used solely for the purpose of preparing human milk, infant formula, and enteral feedings by aseptic (clean, no-touch) technique.
2. The design of the infant feeding preparation room must facilitate workflow that supports aseptic technique in feeding preparation.
3. A separate handwashing sink with controls for water that do not require the use of hands must be available within the infant feeding preparation area.
4. Feeding preparation and storage areas should be securable to prevent adulteration of formula, human milk, and supplies, and to control the traffic of unauthorized individuals through the room(s).
5. Office space sufficient to support the function of the infant feeding preparation room, including receipt of orders, label preparation, and record keeping, must be available.
6. A clean air supply with appropriate pressure gradient is required for the infant feeding preparation room.
7. The surfaces of the floors, walls, and ceiling of the infant feeding preparation room must be made of material that can be maintained in a sanitary condition.
8. The closet for cleaning supplies should be in close proximity to, but should not open directly into, the infant feeding preparation room.
9. Lighting within the infant feeding preparation room should be easily cleanable, enclosed, and adequate for accurate preparation of formula and maintenance of a sanitary environment.
10. A sufficient number of electrical outlets should be available in the infant feeding room.
11. When there is no feeding preparation room, feeding preparation should not be done at the bedside. A separate infant feeding preparation area should be designated that complies with all construction

considerations for facilities needed to support aseptic technique for preparation of human milk and formula feedings, as described in this chapter.

Chapter 2. Equipment, Utensils, and Supplies

1. The equipment and utensils in the infant feeding preparation room should be in compliance with applicable health regulations and sanitation codes.
2. There should be written guidelines for regularly scheduled preventive and corrective maintenance of equipment in the infant feeding preparation room. The preventive and corrective maintenance must be documented and monitored.
3. Refrigeration must be adequate in capacity to chill ingredient water and to cool prepared formula to 4°C (40°F) within 1 hour of preparation. The refrigerator for infant feedings must be securable to prevent tampering.
4. Freezers used to store expressed human milk should hold milk at –20°C (–4°F) or less.
5. All small equipment and utensils in the infant feeding preparation room must be constructed so that they can be sanitized. This can be accomplished with an autoclave or with a dishwasher that reaches a final temperature of 82°C (180°F).
6. Supplies (eg, gowns, bottles, nipples, sanitizing solutions, utensils, and equipment) must be adequate to implement aseptic technique in the preparation of human milk and infant formula.
7. Single-use bottles and nipples are recommended whenever feasible; they should not be reused. Only specialty products not available as single-use items should be reused.
8. Each mother's expressed human milk must be labeled and stored in a separate bin to discourage misadministration and cross-contamination of feedings.
9. Microwave ovens, upright blenders, and garbage disposals are not recommended for use in infant feeding preparation rooms. Immersion blenders with sticks or whisks that can be sanitized are acceptable.
10. Cleaning supplies must be stored separately from infant formula products and ingredients.
11. Cleaning supplies should be used exclusively for the infant feeding preparation area; cleaning equipment, such as mops, should not be shared with other areas of the facility.
12. Only chilled, sterile ingredient water is recommended for infant feeding preparation.
13. Equipment that ensures that feedings remain chilled to 4°C (40°F) and prevents contamination to the feedings should be available to safely transport infant feedings to the patient care unit.
14. Trash containers in the infant feeding preparation room must be covered and must have a foot-operated lid.

Chapter 3. Personnel

1. Administrative responsibility for the infant feeding preparation room must be assigned to a qualified individual—eg, a registered dietitian, a registered pharmacist, or a registered nurse.
2. The supervisor of the infant feeding preparation room should be experienced in infant formula and human milk handling techniques and preparation operations.
3. Minimum qualifications for infant feeding room technicians should include an ability to read, write, and use mathematic skills at the high school level or above.
4. A dress code that is in keeping with aseptic technique should be defined for feeding preparation room personnel.
5. A written training policy must be developed and implemented that requires an orientation of sufficient duration and substance, training, in-service experiences, and evaluation of competency at appropriate intervals for each staff member responsible for preparation of human milk and infant formulas.

6. A sufficient number of trained staff must be available to ensure the continuity and quality of preparation and distribution of infant feedings.
7. The infant feeding room technician must be in good health, as defined by the employee health policies of the health care facility and appropriate regulatory agencies.
8. Staff working in the infant feeding preparation room must practice good personal hygiene.

Chapter 4. Expressed Human Milk

1. Mechanical expression needs to begin as soon as possible after giving birth, with the use of a hospital-grade electric breast pump.
2. Personal collection kits should be sterilized daily.
3. Human milk expression in the hospital can take place at the infant's bedside or in designated private pump rooms.
4. Mothers must be instructed in writing and/or verbally regarding appropriate pumping, labeling, storage, and transport technique.
5. Human milk must be stored in "food-grade" plastic or glass bottles. Plastic bags designed for this purpose at home are not recommended for inpatient use because of risk of leaking.
6. To discourage errors in human milk delivery, human milk supplied to the facility by the patient's mother must be labeled with complete and accurate information, including infant's name, medical record number, and date and time of pumping.
7. Human milk transported to and from the hospital should be maintained at proper temperatures (2° to 6°C, 35°F to 42°F or frozen), to prevent loss of nutrients and to minimize bacterial growth.
8. Dedicated freezers and refrigerators should be provided for storing human milk. Unless state regulations prohibit, human milk may be stored in the same refrigerator as infant formula. Whenever possible, food should be in a separate refrigerator. If human milk is stored with food, it must be in a labeled, closed bin.
9. Human milk bottles from a single mother should be stored in separate labeled bins or zippered bags to prevent misadministration of human milk and to prevent cross-contamination of that milk with other feedings.
10. For proper human milk storage, refrigerator temperatures should be maintained at 2°C to 4°C (35°F to 40°F) and freezer temperatures at –20°C (–4°F) or less.
11. To prevent unnecessary thawing and loss of frozen milk, freezers should be tilted backward during installation, units should be plugged into the emergency power supply, and an alarm should be installed to alert hospital staff if temperatures go above acceptable levels.
12. A written policy on access to human milk freezers and refrigerators should be established.
13. Fresh human milk can be safely stored at 2°C to 4°C (35°F to 40°F) in the refrigerator for 48 hours.
14. Fortified human milk should be stored in the refrigerator at 2°C to 4°C (35°F to 40°F) and should be used within 24 hours.
15. Frozen milk can be safely stored in a home freezer for 3 months and in a –20°C (–4°F) or lower temperature freezer for 12 months.
16. Unless a NICU has a specific protocol for freezing or pasteurizing the milk of very-low-birth weight (VLBW) infants in an effort to reduce potential pathogens such as cytomegalovirus load, infants should receive fresh milk whenever possible because of the enhanced activity of cellular components.
17. Frozen milk should be used in the order in which it was expressed (oldest milk first).
18. Frozen milk may be placed in the refrigerator to thaw gradually, thawed under running water that does not submerge the lid of the bottle or thawed in a commercial devices designed to thaw human milk. The container must be labeled with the expiration date.
19. Thawed milk must be used within 24 hours.

20. Containers of milk may be warmed under running water or in commercial warmers designed for that purpose. There should be a policy for sanitation of bottle warmers. Microwaves or hot water should *never* be used to warm or thaw human milk. Only milk for bolus feedings should be warmed. Milk used for continuous feedings should not be warmed.
21. Aseptic technique must be used in milk preparation and handling.
22. Fortifiers must be measured accurately, using aseptic technique. If using fortifiers other than commercially available human milk fortifier that is individually packaged, the fortifiers should be premeasured and packaged in the formula room or pharmacy, using techniques described in this chapter. Powdered products must be measured by weight.
23. Bolus tube feeding of human milk is preferred to minimize fat loss and time for bacterial growth.
24. Hang time for feeding human milk should not exceed 4 hours. Syringe and tubing must be changed every 4 hours for continuous feedings.
25. Human milk remaining in a bottle after feeding an infant should be discarded.
26. Health care facilities should have a plan for handling misadministration of human milk (ie, a baby receives human milk other than his or her own mother's milk). The attending physician must be notified, and an incident report may need to be filed. Risk management staff may also be notified, depending on facility protocol for management and follow-up.
27. Any donor milk used for infants *must* be pasteurized. Fresh or thawed pasteurized milk may be stored refrigerated for 48 hours. Acquisition and handling of donor milk should follow current Human Milk Banking Association of North America (HMBANA) guidelines and/or state regulations licensing human milk banks.
28. Hospitals that obtain donor human milk should develop policies related to the ordering, receiving, storage, labeling, and feeding of donor human milk.

Chapter 5. Formula Preparation and Handling

1. There must be written guidelines for safe receiving and storage of infant formula products and ingredients to maintain product integrity.
2. Expired or damaged infant formula products must be discarded in such a way as to prevent human consumption.
3. Care should be taken to avoid freezing temperatures (0°C, 32°F) or excessive heat (35°C, 95°F) in stock storage areas.
4. All cleaning supplies must be stored separately from infant formula products and ingredients.
5. The health care facility should establish a process for identifying suspected problems with a product's integrity or physical appearance (ie, check with the manufacturer).
6. There must be written guidelines for ordering infant feedings, transmitting orders to the feeding preparation room, and maintaining feeding order records for individual patients.
7. The infant feeding order should include the following:
   a. Patient's name
   b. Patient's medical record ID number
   c. Patient's location
   d. Human milk or formula name plus additives
   e. Caloric density/volume/feeding frequency
   f. Name of authorizing physician
   g. Date of order

8. During infant feeding preparation, no other activities (such as heavy cleaning) should take place. Doors to the infant feeding preparation room should be kept closed and secured during feeding preparation. Only authorized personnel should be allowed access to the infant feeding preparation room.
9. In facilities where there is no feeding preparation room, a dedicated clean space with facilities for aseptic technique must be used for formula preparation.
10. Aseptic technique must be practiced for *all* infant feeding preparation. Preparation procedures should be appropriate to the conditions in the specific facility.
11. There must be written guidelines for aseptic technique used in the infant feeding preparation room, including hand hygiene and care of work area, equipment, and supplies. These policies and procedures should address hand soaps and gels.
12. Autoclaving or a thermal process such as a dedicated dishwasher with the capacity to achieve 180°F final temperature is recommended for cleaning equipment used in infant feeding preparation.
13. Single-use containers are recommended for dispensing prepared human milk and formula.
14. Written formulations should be maintained in the infant feeding preparation room for all human milk/infant formulas prepared. Formulations must be verified by two health care professionals for accuracy and appropriateness, preferably by a registered dietitian trained in infant feeding preparation.
15. Commercially sterile ready-to-feed and liquid-concentrate formulas should be used when available and nutritionally appropriate. The powdered form of infant formula should be used *only* when alternative commercially sterile liquid products are not available.
16. Only chilled, commercially sterile ingredient water is suggested for preparation of infant formula. Distilled, deionized, or bottled waters that are not commercially sterile must be sterilized.
17. A new or sanitized container should be used to prepare each formula type, to prevent possible exposure of the patient to allergens.
18. Powdered formula must be measured by weight. The scoop inside the can should be aseptically removed and discarded.
19. Opened cans of formula must be covered and labeled with expiration date. These cans should be stored in a clean, secured location.
20. Written guidelines governing acceptable ingredients that may be added to infant feedings should be available.
21. Medications including electrolytes should *not* be added in the feeding preparation room.
22. Colorants should *not* be added to infant feedings.
23. Prepared infant feedings must *not* be frozen.
24. Terminal heating of infant feedings is not recommended.
25. Generation of labels should occur away from the feeding preparation area (such as in the anteroom), to avoid a break in aseptic technique.
26. Each unit of prepared human milk or formula must have a label that includes the following items:

    a. Patient's name
    b. Patient's medical record/ID number
    c. Patient's location
    d. Human milk or formula name plus additives
    e. Caloric density/volume
    f. Volume in container
    g. Expiration date and time
    h. "For enteral use only"
    i. "Refrigerate until use"

27. Unit of use packaging (single feeding or the appropriate amount for one hang time) of prepared feeding is recommended.
28. In health care facilities, opened, ready-to-feed-formula and house-prepared human milk or formula may be stored in bulk containers and refrigerated for up to 24 hours. All opened human milk or formula products, including liquid concentrate, powders, and additives, should be labeled with an expiration date and time.
29. Dedicated refrigerators with adequate chill capacity (4°C, 40°F) for infant feedings in the preparation room and on the patient care units are recommended. Unless state regulations prohibit, human milk and formula may be stored in the same refrigerator.
30. Labels of human milk and formulas should be verified against the individual patient's feeding order before dispensing the human milk/formula to the patient unit.
31. There must be written guidelines for the safe transport of infant feedings that ensure maintenance of the appropriate temperature (4°C, 40°F) until it reaches the patient care unit refrigerator.
32. There should be written guidelines, developed by the department responsible for preparation of infant feedings and the department of nursing, that prescribe proper clean handling and storage of infant feedings on patient care units.
33. There should be written guidelines for reporting and follow-up of infant feedings that are flawed in any way (eg, defective, adulterated, contaminated, or preparation error).
34. There should be written guidelines for reporting and follow-up of recalled formula products in the health care facility. Formula products recalled by the manufacturer or a regulatory agency should be handled in accordance with their instructions.

Chapter 6. Delivery and Bedside Management of Infant Feedings

1. All expressed human milk, formulas, feeding additives, and supplies should be stored on the patient unit in a secured or limited-access area and under the proper storage conditions.
2. Human milk and formula should not be stored in the same refrigerator as food. If human milk or formula is stored with food, the infant feeding must be in a labeled, closed bin.
3. In the event that feedings are not dispensed in unit-of-use containers, individual feedings poured from a bulk container should be handled on a clean, dry, disinfected surface. The container should be removed from the refrigerator immediately before pouring and returned promptly. Patient information on the container should be verified for current formula order.
4. Any items taken into an individual patient room should not be returned to the storage area or used for other patients.
5. Bottles, nipples, and graduated feeders should be for single use. The exception would be specialized items that can be sanitized between uses.
6. Warming is not recommended for continuous feedings. Warming time for oral or bolus feedings should be limited to no more than 15 minutes. Acceptable methods for warming include electric warming units and warm running water. Water level should not reach the level of the nipple ring or submerge the lid.
7. Microwaves should *never* be used to warm infant feedings.
8. A designated person must verify the formula label before feeding an individual patient.
9. For infants being nipple fed, any feeding remaining in the bottle after 1 hour should be discarded.
10. Medications should be added to feedings only by properly trained personnel and with appropriate checks for compatibility.
11. When available, closed system administration sets should be used. When no closed system is available,

tube-feeding administration systems should be assembled on a clean, dry, disinfected surface, avoiding touch contamination of any portion of the feeding system that will come into contact with the feeding.

12. Aseptic technique should be used when filling, refilling, or changing feeding containers. It is recommended that tube-feeding reservoirs (syringe, bag, or bottles) not be reused in health care facilities.
13. Tubing should be flushed with sterile water or air after intermittent feeds and any medication additions.
14. A policy for hang time for human milk and infant formulas and feeding sets must be established in each facility. Hang times for human milk and formula in the NICU or for other immune-suppressed patients should be 4 hours or less. Ready-to-feed sterile formulas for other patients and closed systems may tolerate longer hang times. Check manufacturer's recommendations for closed systems.
15. Formulas containing probiotics should be fed by bolus administration; it is recommended that they not be fed by continuous infusion.
16. When enteral feeding pumps are used, they should be selected to meet the special feeding needs of infants and neonates.
17. Whenever possible, feeding connections should be distinct from connections used for intravenous or other medical administration systems.
18. The feeding-pump housing should be disinfected before initial use by each patient and on a regular basis during use for a single patient.
19. Modular formula additives should be added to the human milk or formula in the infant feeding preparation room, using aseptic technique whenever possible.
20. If formula additives must be added outside the infant feeding preparation room, premeasured amounts of these additives should be provided. When additives are measured, sterilized measuring devices should be used.
21. Vitamin, mineral, electrolyte, or medication additives are to be added by the appropriate nursing or pharmacy personnel, in compliance with facility and Joint Commission standards for medication administration.
22. Colorants should *not* be added to feedings.
23. A policy should be developed to establish guidelines for parent education for mixing and administering feedings after discharge.
24. Any measuring devices, mixing equipment, or other utensils used at home should be should be clean and dry before coming into contact with human milk, formula, or additives.

Chapter 7. Microbiology and Infection Control

1. Human milk is preferred.
2. Sterile liquid formula products are preferred compared to other formulas; those prepared from nonsterile powdered formula should be used only when a nutritionally appropriate sterile liquid formula is not available.
3. When available, closed enteral feeding systems should be used.
4. Infection control procedures must be in place throughout the enteral feeding process, from procurement to administration.
5. A multidisciplinary committee including nutrition services, nursing, and medicine should approve the infant feeding preparation policies and participate in quality monitoring.
6. The Hazard Analysis and Critical Control Point (HACCP) plan for human milk, infant formula, and enteral feeding should address all aspects of the feeding process, including infection control elements. The key elements of such a plan include the following:

   a. Prevention of exogenous contamination of infant feeding products during receiving, preparation, storage, delivery, and administration
   b. Prevention of growth of organisms present in the prepared feedings during receiving, preparation, delivery, storage, and administration
   c. Detection, as soon as possible, of any infection or toxin that may be due to feeding contamination
7. The infant formula container or ingredient container must be inspected before use. The product must not be used if the expiration date has passed or if the container is damaged, leaking, or swollen.
8. The product contents must be inspected after opening the container. The product must not be used if it appears adulterated, contaminated, or otherwise abnormal (eg, lumpy, grainy liquid or clumped powder).
9. Aseptic technique must be practiced for *all* expressed human milk and formula preparation. Preparation procedures should be appropriate to the conditions in the specific facility.
10. The use of chilled sterile ingredient water is recommended to facilitate achieving formula temperature of 4°C (40°F) quickly.
11. All feedings in the NICU and facility-prepared infant feedings for other patient care units should be packaged in quantities required for a feeding or per 4-hour period.
12. Outside the NICU, commercially sterile feedings that have not been manipulated (no water, modules, or medications added) may extend hang time to 8 hours when fed to immune-competent children.
13. Formulas containing probiotics should not be fed by continuous infusion.
14. The manufacturer should be consulted for questions involving the microbiological quality of the infant formula product or ingredients.
15. Surveillance cultures of infant feedings are not recommended routinely by the Centers for Disease Control and Prevention. State regulations may differ.
16. When patients have symptoms of foodborne illness, consideration of contaminated enteral feedings should be a part of the diagnostic evaluation.
17. Probiotics should be used with caution in high-risk populations.

Chapter 8. Quality Assurance

1. The department responsible for preparation of infant feedings must establish an HACCP plan that includes continuous quality improvement functions as well as corrective action and follow-up, when deemed necessary. A separate HACCP plan may be needed for expressed human milk.
2. The HACCP plan must include measurable indicators for use in monitoring the most important aspects of infant feeding preparation, storage, delivery, and feeding administration.
3. The infant feeding preparation HACCP plan should be integrated into the facility's overall performance improvement program, as described in Chapter 7. The seven steps that must be considered when formulating an interdisciplinary HACCP plan are as follows:
   a. Assess potential hazards.
   b. Identify critical control points (CCPs).
   c. Establish policies and procedures for CCPs.
   d. Monitor CCPs.
   e. Plan for procedure failure, and take corrective action when needed.
   f. Verify that the system is working.
   g. Set up a record-keeping system.
4. Results of continuous monitoring of quality improvement should be routinely reviewed in accordance with the facility's performance improvement plan.
5. Maintenance of safe infant feeding availability should be included in the facility's disaster plan.