



State of New Jersey

N. 3 DEPARTMENT OF INSTITUTIONS AND AGENCIES

P. O. BOX 1237

TRENTON 08625

June 6, 1966

TO: ALL LICENSED AND APPROVED HOSPITALS

RE: STANDARDS FOR FORMULA ROOMS AND FORMULA PREPARATION

The Hospital Licensing Board, on April 7, 1966, recommended approval of Standards for Formula Rooms and Formula Preparation to be applied to all licensed and approved hospitals in the State.

The recommendation was subsequently approved by the State Board of Control on April 27, 1966.

These standards, which have been made a part of the Manual of Standards for Private Hospitals, are attached. We request that you acknowledge their receipt by signing and returning the form furnished below for this purpose. Any question regarding the standards should be directed to our Bureau of Community Institutions.

Sincerely yours,

Lloyd W. McCorkle
Lloyd W. McCorkle
Commissioner

LWMcC:23
Attachment

DETACH AND FORWARD TO:

Bureau of Community Institutions
Department of Institutions and Agencies
P. O. Box 1237
Trenton, New Jersey 08625

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This will acknowledge receipt of the Standards for Formula Rooms and Formula Preparation which are applicable to all licensed and approved hospitals in the State and which were adopted by the State Board of Control on April 27, 1966.

copy 2

Signature of Administrator or
Authorized Representative

Name of Hospital

Date

Address of Hospital

STATE OF NEW JERSEY
Department of Institutions and Agencies

STANDARDS FOR FORMULA ROOMS AND FORMULA PREPARATION *

INTRODUCTION

There are now available to hospitals three general types of formulas for feeding infants:

- (1) "Traditional" formulas which are made up in the hospital according to physicians' prescriptions.
- (2) Commercially prepared formulas which are prepared outside the hospital and delivered to the hospital in complete, assembled and sterilized feeding units, requiring only the removal of a cap or cover before being ready for use.
- (3) Pre-sterilized, packaged formulas made outside the hospital but not completely assembled. These require further handling in the hospital by one of the two following methods:
 - a. Filling the bottle from a container or can, nipping and capping.
 - b. Removing sealed cap and applying the nipple and cover.

Hospitals should have adequate formula preparation rooms for the preparation of special formulas and should be capable of preparing formulas for all infants in the hospital in emergency situations when the factory-prepared formulas may not be available.

* Adopted by State Board of Control on April 27, 1966

FORMULA ROOM

Proper organization and operation of the formula room are essential to the prevention of enteric infections. Preparation of safe feedings depends upon the following basic essentials:

1. The formula room should be used exclusively for the preparation of formulas.
2. Preparation of formulas should be functionally separated from the cleaning of equipment.
3. Thorough cleaning of bottles and utensils is essential. Chemical detergents should be used rather than soaps. Nipples require special attention.
4. If thorough cleansing of equipment and terminal heating are employed, pre-sterilization of bottles and sterile technique are unnecessary and, for efficiency of operation, should be eliminated.
5. Terminal heating of completely assembled units as described on Page 5 under "Sterilizing Formulas" can be relied upon to produce a bacteriologically acceptable formula.
6. A bacteriologically acceptable terminally-heated formula contains fewer than 25 organisms per milliliter, as measured by culture plate count.
7. Formulas should be refrigerated at a temperature of 40°F within one hour after being sterilized to avoid prolonged incubation of organisms surviving terminal heating.
8. Personnel policies should provide for expert supervision of the formula room and observance of proper health practices.

LOCATION

Location of the formula room and supervision of formula preparation will depend upon the personnel available and the hospital's special problems. A separate room must be provided and should be used for no other purpose. It should be situated where danger of contamination is least, and where the most supervision can be given by a dietitian or nurse. It should be near the obstetrical nurseries. It can be near the general diet kitchen or the central supply room, but it should be away from sick patients.

LAYOUT

HOSPITAL PREPARED FORMULA

The formula unit should consist of two rooms, a clean-up room and a formula preparation room, the two being connected only by a controlled passageway or window. Hospitals which cannot meet these standards must make provision for the clean-up process in another area of the hospital or if this activity must be carried out in the room also used for formula preparation, the two activities should be separated by time and space. At no time should the cleaning process be carried on in the formula room during the preparation of formulas. (Reference #2, Page 9)

Space standards suggested by the U.S. Public Health Service are:

Clean-up room - 16'6" x 5'6"
Preparation room - 16'6" x 9'6" (Including area for terminal heating apparatus).

EQUIPMENT

Equipment in the formula unit should be of non-corroding metal, when obtainable, and constructed so that all parts are easily cleaned. (Reference #2, Page 14)

The minimum equipment for the clean-up room is a wash basin, work counter with two sinks, mechanical bottle washer and rinser, shelves, formula racks, and a portable bottle carriage.

The minimum equipment for the preparation room is a formula sterilizer, sink, refrigerator, portable bottle carriages, and cupboards.

PERSONNEL

The supervisor of the formula room should have had special training in formula preparation and in sterilization procedures. She should train and supervise all formula room personnel. Workers in the formula room should have no contact with patients who have infectious conditions.

In hospitals where the formula preparation does not require the full-time services of a nurse or dietitian, the remainder of her working day may be spent in some clean area, such as the central supply room, regular newborn nurseries, or diet kitchens. Formula room personnel must wear scrub dresses and caps. Masks must be worn during the assembling of the pre-packaged type (See #3 in Introduction).

The Hospital Administrator, with the advice of the medical staff, should specify the responsibilities for handling pre-sterilized bulk or bottled formulas and assign them to specific individuals.

These responsibilities include:

1. The receipt of the bulk formula
2. Mixing
3. Bottling
4. Quality and safety control of the formula
5. Distribution of the ready-to-use formula to the infants

Special attention must be given to:

1. The location and supervision of the delivery area.
2. The mechanics of transporting the delivered formulas to areas of use.
3. Cross checking system for insuring delivery of the correct formulas to each infant.

Formulas from outside sources should not be given further heat treatment (sterilization) in the hospital and must be used within 24 hours or be discarded. (Reference #1, Page 12)

FORMULA PREPARATION

WASHING EQUIPMENT

Bottles, caps and nipples from regular nurseries should be rinsed in cold water in the nursery before being returned to the formula room. Water should be forced through the nipple holes to prevent clogging. The bottles, caps and nipples from observation and isolation units and pediatric service should be washed thoroughly, using a detergent, and then boiled fully-immersed for 10 minutes or autoclaved before being returned to the formula room.

In the clean-up section of the formula unit, all bottles, caps and nipples should be thoroughly washed, using a detergent solution (not soap) and a bottle brush or mechanical washing unit. Nipples should be turned inside out during the cleaning process, rinsed in running water and then boiled fully-immersed for 10 minutes or autoclaved.

Detergents* are superior to soap for cleaning of bottles and utensils. Soap combines with milk casein to form a gummy residue which is difficult to remove.

*These should be kept in their original containers and stored where there is no danger of their being mistaken for formula ingredients. If their labels become illegible, they should be discarded and new packages obtained.

PROCEDURE FOR PERSONNEL

1. The personnel working in formula rooms should wear clean caps and scrub dresses.
2. Personnel should thoroughly scrub hands and arms to elbows for 3 minutes and cleanse nails with clean orangewood stick before beginning work. Attention should be given to all surfaces of the fingers.
3. Freshly laundered gowns should be worn over the scrub dresses. (Reference #2, Page 31)

PREPARING MILK MIXTURES

Milk mixtures are made up using clean but not aseptic technique, then transferred to clean bottles, nipples, capped and placed in metal racks. Nipple caps may be of glass, metal, plastic or water-resistant paper, but must not form a tight seal around the shoulder of the nipple or bottle during the sterilization process.

Special mixtures which cannot be subjected to terminal heating must be prepared with aseptic technique using sterile utensils, sterile water and, insofar as possible, sterile ingredients. When the aseptic method is used, personnel must scrub hands and lower arms for 3 minutes and wear sterile cap, gown, mask and gloves.

STERILIZING FORMULAS

The racks of filled bottles are placed in sterilizers and terminally heated, either under 7 lbs. pressure at 230° F for 10 minutes, or by the non-pressure method of steam or water at 212° F for 25 minutes.

COOLING FORMULAS

Upon completion of such terminal sterilization, formulas are removed from the sterilizer, cooled at room temperature for one hour, and then placed in a refrigerator maintained at 40° F. For rapid cooling, special heavy duty refrigeration units are desirable. Cooling in water may introduce the danger of contamination.

All unused terminally-sterilized formulas must be discarded within 24 hours. Formula assembled from pre-sterilized components must be used within 4 hours or discarded.

Formula should never remain at room temperature for more than one hour.

BACTERIOLOGIC EXAMINATION OF FORMULAS

Formula preparation technique should be checked by bacteriologic examination at least once a week. Plate counts on random samples of milk mixtures should not exceed 25 organisms per ml. Sampling should include all nursery units and all nursing duty-periods in random order. Organisms found should be identified, if organisms other than spore formers are found a breakdown in technique is indicated. Responsible hospital and medical authorities should be notified and steps to remedy the breakdown should be taken immediately.

COMMERCIALY PREPARED FORMULA SERVICE

Individually-packaged, ready-for-use formulas made outside of the hospital should be refrigerated immediately on arrival and treated in the same manner as formulas made in the hospital. It should be examined weekly as described above.

LAYOUT

COMMERCIALY-PREPARED AND PRE-PACKAGED FORMULAS

Use of commercially-prepared and pre-packaged formulas may make possible the use of a single clean room for formula preparation. Such a room should be used for no other purpose, should have hand washing facilities and should be located in a clean area as described under "Location" above. This room may be used for preparation of the feeding units and for storage of formula supplies.

It does not need a sterilizer but should be equipped with a sink and cabinets for storage. This room can also be used for preparing formulas in an emergency such as a strike, severe storm which possibly could tie up delivery, etc. making it necessary for those hospitals using the commercially-prepared or pre-packaged formula to make up their own.

THE PRE-PACKAGED FORMULAS

Pre-packaged formulas should be prepared at feeding time only. In assembling the components, only one feeding unit should be prepared at a time, i.e., each should be nipped and capped immediately after opening. They should not be bottled, capped and nipped ahead of time, but should be distributed immediately after assembly. Weekly testing, as described above, should be carried out.

Formulas assembled from pre-sterilized components and contents of partially emptied containers of components must be used within four hours or be discarded.

GUIDE TO PROCEDURES AND LAYOUT

Procedures and Layout for the Infant Formula, published by the American Hospital Association (18 East Division St., Chicago 10, Illinois, \$1.50), should be obtained and studied by those responsible for hospital formula preparation. Supervisors of hospitals not possessing the recommended formula room space or equipment should call upon the Maternal and Child Health Program of the State Department of Health for advice in working out a suitable formula-room routine.

Other information which will be found useful is contained in "Recommendations on Formula Supply in the Hospital", a report of the Committee on Fetus and Newborn of the American Academy of Pediatrics, Evanston, Illinois.

Finally, it is definitely recommended that a formula room should be available in every hospital regardless of the type of formula used.

References:

1. Standards and Recommendations for Hospital Care of Newborn Infants. American Academy of Pediatrics. Evanston, Illinois. Revised 1964.
2. Procedures and Layout for the Infant Formula Room. American Hospital Association. Chicago, Illinois. Copyright 1965. 1965 Edition.