

The Lactarium Service Self-Control Plan of the Tertiary Center for Pediatric Care at the University Hospital Federico II of Naples

Antonio Nardone¹, Anna Di Popolo¹, Serena Coppola^{2,3}, Roberta De Michele⁴, Anna Fiorenza De Giovanni Di Santa Severina^{2,3}, Maria Candida Falco^{2,3}, Andrea Margarita Rivieri^{2,3}, Maria Celeste Puzone^{2,3}, Roberto Berni Canani^{2,3,5,6*}

¹Department of Public Health, University of Naples Federico II, Naples 80131, Italy

²Department of Translational Medical Science, University of Naples Federico II, Naples 80131, Italy

³ImmunoNutritonLab at CEINGE Advanced Biotechnologies, University of Naples Federico II, Naples 80131, Italy

⁴Department of Community Medicine and Primary Care, University of Naples Federico II, Naples 80131, Italy

⁵Task Force on Microbiome Studies, University of Naples Federico II, Naples 80131, Italy

⁶European Laboratory for the Investigation of Food Induced Diseases (ELFID), University of Naples Federico II, Naples 80131, Italy

***Corresponding Author:** Roberto Berni Canani, Department of Translational Medical Science, ImmunoNutriton Lab at CEINGE Advanced Biotechnologies, Task Force on Microbiome Studies, Italy, European Laboratory for the Investigation of Food Induced Diseases (ELFID), University of Naples Federico II, Naples 80131, Italy

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Abstract

Lactation is a hospital service that collects, processes, and distributes formulas for hospitalized infants. Hospital staff adherence to food hygiene rules is the key to avoiding microbiological food contamination. Indeed, hospitalized pediatric patients are more vulnerable than healthy subjects to microbiological and nutritional risks, and to possible infections and complications. The Lactation staff of the Pediatric Unit of the Department of Translational Medical Science at the University Hospital Federico II of Naples has prepared a self-control plan adhering to the Hazard Analysis and Critical Control Points (HACCP) system and the practices of food safety and good manufacturing. This article is reported the self-control plan applied by the Lactation Service of the Pediatric Unit of the University Hospital Federico II of Naples, its organization, and the process of formulas preparation.

Keywords: Food safety, hygiene rules, Hazard Analysis, and Critical Control Points.

1. Introduction

Lactation is a hospital service that collects, processes, and distributes formulas for hospitalized infants [1]. Hospital staff adherence to food hygiene rules is the key to avoiding microbiological contamination [2]. Indeed, hospitalized pediatric patients are more vulnerable than healthy subjects to microbiological and nutritional risks, and to possible infections and complications.

We prepared a self-control plan adhering to the Hazard Analysis and Critical Control Points (HACCP) system to ensure food safety for

target users of the Lactation Service [3]. The self-control plan procedures refer to the whole preparation chain, from the receipt of raw materials to the distribution of the hospitalized infants.

Here we reported the self-control plan applied by the Lactation Service of the University Hospital Federico II of Naples, its organization, and the process of formula preparation.

2. Areas and equipment description

Below are reported the production flows, that have been arranged according to the "forward motion" process and thus to avoid any possible "dirty-clean" intersection.

2.1 Areas and equipment

- **Goods reception and verification area.** This area is located near the elevator and the staircase to facilitate the good's arrival and their verification by visual inspection and by the check of the accompanying document.

- **Goods unpacking area.** This area is bordered by two doors. Here, goods are unpacked from the primary packaging and placed on a carriage for their transport in the storage area.

- **Dirty carriage washing and storage area.** In this area, there are a steel sink and a PVC storeroom for storing the equipment used for washing carriages. The dirty carriages washing and storage area is separated from the storage area for powdered formulas and

unpacked bottles by a door, which only allows the passage of the clean carriages.

- **Storage area for powdered formulas and unpacked bottles.** In this area are stored the disposable packages (bottles, teats) and the packages of formulas of various types (powder, long-life liquid, food supplements, formulas for special medical purposes) in a dedicated locker after the primary packaging removal. In this area, there are 3 load-bearing structures with 28 shelves and a PVC storeroom for storing the unpacked bottles and teats devoid of the primary packaging. This storage area for powdered formulas and unpacked bottles is adjacent but physically separate from the unpacking area and the preparation area.
- **Operator filter area and second carriage washing area.** This is a transition area for the Lactation Service staff who have previously changed their uniforms (from white to blue uniform) in the locker room, to access the preparation area. In this area, there is a sink, a soap dispenser, a roll of disposable paper with a special roll holder, and a locker containing personal protective equipment (PPE) (disposable gown, disposable headgear, mask, and disposable shoes) that the staff wears before entering the preparation area. This area is separated from the preparation area by a door with a one-way opening through a photoelectric cell.
- **Preparation area.** Meal preparation and washing of utensils are made in this area. Meal preparation is carried out using all hygienic safeguards to avoid contamination. In this preparation area, there is a refrigerator with an external detector for low-temperature storage, a pasteurizer, 2 blenders, a hob, 2 worktops (one of which is dedicated to the management of special diets), a steel sink, a staff sink, a dishwasher, a Metalarredinox kettle, 2 pedal-operated waste containers, a disposable paper roll with special roll holder, a soap dispenser, and 3 carriages for transporting equipment/tools, raw materials, pre-distribution temporary bottle storage.
- **Clean carriages storage area for meal distribution.** In this area, there are 2 carriages for the meal distribution to the hospitalized infants.
- **Lactation Service staff filter area.** This area is a transition area for staff who have already changed their clothes and need to enter the Lactation. In this area, there is a locker in which PPE has stored that staff wear before entering the preparation area (disposable gown, disposable head cover, disposable mask, and

disposable footwear).

- **Storage room for cleaning equipment.** In this area, there is a PVC locker for storing detergents for environmental cleaning and a carriage for environmental cleaning.
- **Changing room area.** In this area, there are 4 double-compartment lockers for staff, a wash basin for staff, a disposable paper roll with a special roll holder, and a soap dispenser.
- **Staff toilets.** This area includes a hallway area (ante-bathroom) in which there is a washbasin for staff, a soap dispenser and a disposable paper roll with an appropriate roll holder, and a toilet area in which, in addition to the toilet and bidet, there is a washbasin for staff, a soap dispenser, and a disposable paper roll with appropriate roll holder.
- **Head nurse office area.** In this area, there are a desk, a chair, a card index, and an archives storeroom.

All areas have washable and disinfectable surfaces, and the spaces are sufficiently spacious for the proper movement of staff during processing. Areas and equipment are maintained always in good condition through constant monitoring of the walls and floor conditions. Equipment maintenance is carried out according to the periodicity reported in the manufacturer's data sheets.

All windows are fitted with a manual-type intrusion barrier. Properly trained staff shall, whenever it is necessary to open a window, lower the intrusion barrier after the window is opened. Intrusion barriers are sanitized every seven days or whenever necessary.

The Head of the Lactation Service must:

- ensure that no food processing is carried out during maintenance operations.
- constantly monitor the state of hygiene and cleanliness of areas and equipment, especially after maintenance operations.
- remove any food if maintenance operations may affect the hygienic safety of the food.
- transcribe any non-conformities and corrective actions on the appropriate record as well as any routine or special maintenance work on facilities, equipment, and premises.
- ensure that all equipment and facilities are provided by appropriate emergency and/or automatic shutdown devices and if they have been removed, tampered with, or not functional must prohibit their use and ensure that the conditions are restored to the necessary safety.
- prohibit the use of equipment and areas in poor condition or need of upgrading.

3. Cleaning and sanitizing plan

Environmental cleaning and sanitation are a fundamental critical point for the entire reproductive process, representing a fundamental element of Risk Management. The cleaning and sanitization service is entrusted to a Cleaning Service Contractor. The anti-intrusion barriers are sanitized every seven days or whenever necessary.

The microbiological verification of the effectiveness of the sanitization procedures of the Lactation spaces is conducted every three months by the Hygiene and Occupational and Preventive Medicine staff of the University Hospital Federico II of Naples.

4. Hospital users

The Lactation provides the preparation, transport, and distribution of formulas, special diets, and baby food prepared with sterile water or Ultra High-Temperature cow's milk to the inpatient infants, where these meals are stored at refrigeration temperatures and subsequently heated and distributed to hospitalized infants admitted at:

- Pediatric Surgery section
- Pediatric Infectious Diseases section
- Specialized Pediatrics section
- General and Specialized Pediatrics section
- Neonatal Intensive Care section
- Pediatrics Orthopedics section
- Pediatric otolaryngology section
- Pediatric Neurosurgery section
- Pediatric Neuropsychiatry section
- Nursery section
- Pediatric Cardiac Surgery section

5. Self-control plan organization and responsibility

This plan has been prepared by a multidisciplinary team composed of physicians, nurses, dietitians, and microbiologists responsible for designing and implementing this plan, each for their skills, in compliance with current legislation and taking into consideration the entire production process. In particular, each one according to specific skills and different roles carries out the following tasks:

- Drafting of the HACCP plan
- Coordination of the activities included in the HACCP plan
- Compilation and custody of work forms
- Verification of the effectiveness of the system
- Custody of the self-control plan and non-compliance forms
- Periodic review of the HACCP plan.

6. Type of production

The meals prepared by the Lactation Service are mainly represented by formulas and milky baby food. Moreover, are also prepared meals

for specific nutritional needs, such as infant formula and foods for special medical purposes and mixtures for enteral nutrition.

7. Flowchart

The process phases are described below and are depicted in Figure 1:

- Receipt of raw materials
- Storage
- Preparation
- Carriage to the hospital sections
- Storage in the hospital sections
- Heating
- Distribution
- Carriages' transport to the Lactation Service after distribution to hospital sections.

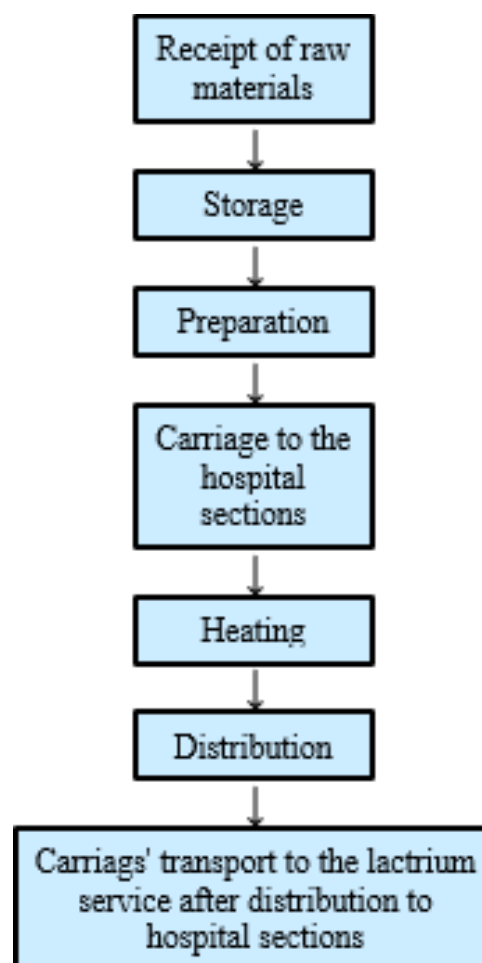


Figure 1: Flowchart of the process phases.

7.1 Receipt of raw materials

The formulas prepared at the Lactarium are liquid (long-life and processed at ultra-high temperature UHT) or powder, while the formulas for special medical purposes are exclusively powdered. The powdered formulas and the different types of formulas for special medical purposes are delivered in original packaging to the Centralized Pharmacy Service of the University Hospital Federico II of Naples. Meals such as long-life UHT milk, cream of rice, cream of corn and tapioca, oil, sugar, tea, salt, low-fat cheese, dry biscuits, yogurt, and bitter cocoa powder are delivered directly to the Lactation Service.

Upon receipt, the raw materials quality control is performed by the Lactarium staff (evaluation of expiration date, integrity of the packaging, presence of dents, swelling, mold, dirt, grease stains, presence of unpleasant odors) and the related monitoring form is completed. If the products don't respect the quality control, the supply is rejected in whole or in part, and the relative "Report of non-conformity" is filled in and sent to the supplier by the Lactation Manager. The handling of these products takes place in a manner that guarantees their integrity.

7.2 Storage

The storage of raw materials represents a very important phase in the production chain. The preventive measures adopted in this phase consist in monitoring the cleaning and sanitizing plan carried out by the cleaning service contractor and a bi-weekly inspection of the raw materials storage area - which are placed on the private shelves of primary packaging - aimed at checking the hygienic-sanitary conditions of the spaces and shelving and packaging (minimum storage term or expiration date, presence of rust or dents, adequate closure of partially used packaging).

7.3 Preparation

The Lactation Service staff access the preparation area after wearing the PPE (gown, headgear, mask, and overshoes) and after washing their hands. The production phase differs depending on whether liquid or powdered formulas to be reconstituted are used. All the bottles are prepared on the same day, according to the requests of the hospital sections, and therefore any form of preparation and recycling is avoided. In the preparation area, there is a refrigerator equipped with a continuous graphic circular temperature recorder, for the possible temporary storage of raw materials and/or intermediate processing products. The preparation of bottles with liquid formulas (UHT) is not very risky because the milk is subject to less manipulation; in the case of powdered formulas, they are reconstituted according to the prescriptions of the University Hospital medical staff.

For both types of formulas, the staff, who access the preparation area after wearing the PPE, comply with the procedures of good hygiene practice, for the control of contamination.

To ensure the product's salubrity 5, it is necessary to have drinking water available for meal preparation. To this end, water checks are executed monthly by the staff of the Hygiene and Occupational and Preventive Medicine University Hospital section. If the water used for the preparations is declared unsuitable, the preparations are made with pre-packaged water.

All the formula bottles undergo the pasteurization process at a temperature of 68 °C for about 1 hour and 30 minutes. The verification of the pasteurization process (temperature, time, and water quality of the Pasteurizer) is carried out every week, in the event of a non-functioning or seriously unsuitable pasteurizer, the distribution of the milk is carried out in shorter times than the usual protocol. Pasteurization is done for most baby bottles. This consists of a cycle that lasts approximately 1 hour and 30 minutes and involves pasteurization temperatures of 68 °C. The effectiveness of the pasteurization process is checked every week, through the control of temperatures and times and the verification of the water of the pasteurizer. If the pasteurizer is not working or is seriously unsuitable, milk is prepared with a reduction in the time between preparation and distribution.

7.4 Carriage to the hospital sections

After pasteurization, the formula bottles are placed in the dedicated carriages and immediately transported to the hospital sections, by the Lactation Service staff. Transport takes place using the lifts in the buildings on the exit side of the clean path of the Lactation Service. Also in this phase, the verification of the staff and the respect of the correct modes of transport is carried out every two weeks, through the verification of the carriages used.

7.5 Storage in the hospital sections

The bottles are stored in specially dedicated refrigerators in the hospital sections, and subsequently heated in a bain-marie. In this phase, the staff of each hospital section checks the storage conditions, by monitoring the temperatures of the refrigerators and checking their sanitary conditions.

7.6 Heating and distribution

The bottles stored at refrigeration temperature are heated in special bain-maries at the time of consumption by the hospital section staff and then distributed. In this phase, it is verified that the staff is using correct distribution procedures.

7.7 Carriages' transport, sanitation, and storage to the Lactation Service after distribution to hospital sections

The carriages return to the Lactation Service through the lift after distribution to the hospital sections. The staff sanitizes the carriages in the dirty carriages storage and washing room and deposits them in their clean deposit. The staff cannot access the Lactarium from this area (clean path) as it is physically divided by a door with a panic bar opening towards the "dirty" corridor.

8. Identification of Critical Control Points (CCP)

The following phases and critical points (CCP) have been identified in the process:

- Receipt of raw materials
- Storage
- Preparation

9. Verification of the HACCP plan

Verification consists of a set of procedures and tests aimed at ensuring that the HACCP plan is adequately followed and put into practice.

The objectives are:

- to assess the adequacy of the critical limits set for each critical control point (CCPs), through scientific and technical procedures and methods;
- to confirm the suitability of the corrective actions established for any deviations that may occur to the CCPs;
- to ensure the effective functioning of the plan prepared for the product/process in question.

10. Review of the self-control plan

The review of the self-control plan consists of a documented and periodic review aimed at ensuring the accuracy and adequacy of the plan. The need for this operation is linked to the countless variations that may affect any of the factors related to the production process, which could negatively affect the safety of the food that derives from this process. The review of the plan is periodic and in any case, the review procedure is activated as soon as changes in:

- raw materials and products;

11. Special Diets Management

According to the Law 123/2005 art. 4 published in the BURC of the Campania Region n°1 of 7 January 2008 (Self-control plan for the preparation of differentiated meals for subjects affected by celiac disease and food intolerances) [4], the preparation of special diets are subjected to a regular self-control procedure.

11.1 Structural requirements and obligations

Special diets preparation takes place in the same areas where other products are processed, and therefore appropriate precautions are taken to prevent special meals contamination:

- adequate environmental cleaning and sanitation;
- staff personal hygiene;
- the special diets preparations take place before standard diets preparation;
- adequate staff training.

11.2 Purchase and storage of raw materials

Foods intended for special medical purposes are used (Legislative Decree 27 January 1992 No. 111) [5]. Their storage takes place in a well-separated and identifiable area in the storage area (dedicated and closed cabinets and containers to be used also in the refrigerator).

- Carriage to the hospital sections
- Storage in the hospital sections
- Carriage transport to the Lactation Service after distribution to hospital sections.

For this purpose, the following inspection and analytical controls have been identified:

- environmental health and hygiene inspections every two weeks;
- microbiological checks: on the entire supply chain every month, on the water used for the production of reconstituted milk every month, on the environment (effectiveness of sanitation procedures) every quarter;
- microclimatic checks every quarter.

- production conditions (premises, equipment and machines, cleaning programs and disinfection) or any information relating to a presumed health risk inherent in the product.

Any changes made to the self-control system are fully incorporated into the documentation and registration system, so that updated and reliable information can be obtained with certainty.

11.3 Areas and equipment

Special diet preparation takes place in a well-identified area of the preparation area, using an easily identifiable work surface, dishes, and utensils. In addition, the temporal differentiation of the preparations is carried out; special diets are prepared before standard diets. These diets, packaged in disposable bottles, are appropriately labeled, and the bottles are closed, to avoid any contamination during transport.

11.4 Staff hygiene

11.4.1 Hand hygiene

Before starting the special diet preparation, the staff put on clean and disposable overcoats and carefully wash their hands.

Hands should be washed thoroughly:

- a) Before starting work
- b) After every break from work
- c) After touching substances other than the product being worked on
- d) After touching the waste
- e) After using own handkerchief
- f) After touching own or other people's skin
- g) After using the toilets

h) After touching dirty packaging, surfaces, or tools

i) After touching raw or dirty food

Wounds or abrasions on the hands, if clean and not infected, must be protected by water-resistant plasters, and it is also necessary to wear latex or blue vinyl [1] gloves to be replaced with the same frequency and with the same criteria by which they wash their hands.

The use of gloves is not recommended as they can decrease the perception of dirt on the hands and if not replaced regularly, increase the risk of food contamination. Furthermore, it is important to remember to replace gloves according to the same criteria established for hand washing.

For the washing operation, it is preferable to use antiseptic solutions based on 70-80 % isopropyl or ethyl alcohol and to use disposable paper for drying.

11.4.2 Staff behavior

Staff in charge of handling foods must adopt adequate hygienic-behavioral measures during processing. In particular, they must keep

their workstation in order, and separate the different processes in time or space, for example by dedicating tools to each category of food, cutting boards, and worktops for exclusive use or sanitizing them at each change of processing. Keep unstable foods subject to controlled temperatures at room temperature no longer than strictly necessary. It is also forbidden to smoke, spit, chew gum, drink, eat while working, taste food with fingers, use toothpicks, and wipe your hands on your lab coat.

11.4.3 Staff health

The staff person who is a sick or healthy carrier of a communicable infectious disease, who has infections, wounds, or infected skin sores, or who suffers from diarrheal forms, must not come into direct or indirect contact with food. In the case of a staff person presenting pathological symptoms, especially affecting the gastrointestinal or respiratory systems, he/she must notify their manager to get away from the work area.

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Conflicts of Interest: The authors declare no conflict of interest.

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