ALABAMA DEPARTMENT OF PUBLIC HEALTH
ADMINISTRATIVE CODE

CHAPTER 420-3-16
PRODUCTION, PROCESSING, HANDLING, OR DISTRIBUTION OF MILK, MILK PRODUCTS AND FROZEN DESSERTS

420-3-16-.10 Sanitization Requirements For Grade "A" Pasteurized Milk, Frozen Dessert, Ultra-Pasteurized, And Aseptically Processed Milk And Milk Products, And Retort Processed After Packaged Low-Acid Milk And/Or Milk Products.

Milk plants shall comply with all items of this section. The *PMO*, with appendices, and the supporting milk plant-specific procedures required herein, shall constitute a milk plant's food safety plan as required by 21 CFR 117.126 to the extent that the procedures address all the hazards identified by the milk plant as applicable for that milk plant. A milk plant shall have a written Hazard Analysis for each kind or group of milk, milk product, and frozen dessert processed. Provided, in the case of milk plants or portions of milk plants that are IMS listed to produce aseptically processed and packaged low-acid milk, milk products, and frozen desserts, and/or retort processed after packaging low-acid milk, milk products, and frozen desserts the APPS or RPPS, respectively, as defined by this rule, shall be exempt from Rule 420-3-16-.10(7); 420-3-16-.10(11-13); 420-3-16-.10(15-16); 420-3-16-.10(19); 420-3-16-.10(22); 420-3-16-.10(24) and shall comply with the applicable portions of 21 CFR Parts 108, 110, and 113. Those Items, contained within the APPS and RPPS, shall be inspected by FDA or a Health Officer, when designated by FDA.

A receiving station shall comply with Rule 420-3-16-.10(1) to 420-3-16-.10(15A-B), inclusive, and Rule 420-3-16-.10(23), 420-3-16-.10(26) and 420-3-16-.10(28), except that the partitioning requirement of Rule 420-3-16-.10(5) shall not apply.

A transfer station shall comply with Rule 420-3-16-.10(1), 420-3-16-.10(4), 420-3-16-.10(6-12), 420-3-16-.10(14), 420-3-16-.10(15A), 420-3-16-.10(23), 420-3-16-.10(26) and 420-3-16-.10(28) and as climatic and operating conditions require the applicable provisions of Rule 420-3-16-.10(2-3). Provided, that in every case, overhead protection shall be provided.

Facilities for the cleaning and sanitizing of milk tank trucks shall comply with Rule 420-3-16-.10(1), 420-3-16-.10(4), 420-3-16-.10(6-12), 420-3-16-.10(14), 420-3-16-.10(15A-B), 420-3-16-.10(26), and 420-3-16-.10(28) and as climatic and operating conditions require, the applicable provisions of Rule 420-3-16-.10(2-3). Provided, that in every case, overhead protection shall be provided.

In the case of milk plants, receiving stations, and transfer stations which have HACCP Systems regulated under Appendix K., the HACCP System shall address the public health concerns described in this section in a manner that provides protection equivalent to the requirements in this section.

Milk plants that have HACCP Systems, which are regulated under the NCIMS voluntary HACCP Program, shall comply with all of the requirements of Rule 420-3-16-.10(16). Pasteurization, Aseptic Processing and Packaging, and Retort Processed after Packaging of this rule and pasteurization shall be managed as a critical control point (CCP) as described in Appendix H, VIII. Milk and Milk Product Continuous-Flow (HTST and HHST) Pasteurization-CCP Model HACCP Plan Summary; and Milk and Milk Product Vat (Batch) Pasteurization-CCP Model HACCP Plan Summary.

(1) **Floors Construction**

(a) The floors of all rooms in which milk, milk products, or frozen desserts are processed, handled or stored or in which milk containers, equipment, and utensils are washed, shall be constructed of concrete or other equally impervious and easily cleaned material, and shall be smooth, properly sloped, provided with trapped drains, and kept in good repair; provided cold-storage rooms used for storing milk and milk products need not be provided with floor drains when the floors are sloped to drain to one (1) or more exits; provided further, that storage rooms for storing dry ingredients, packaged dry ingredients, packaged dry milk or milk products, and packaging materials need not be provided with drains and the floors may be constructed of tightly joined wood.

(b) Public Health Reason - Floors constructed of concrete or other similarly impervious material can be kept clean more easily than floors constructed of wood or other pervious or easily disintegrating material. They will not absorb organic matter and are, therefore, more apt to be kept clean and free of odors. Properly sloped floors facilitate flushing and help to avoid undesirable conditions. Trapping of drains prevents sewer gas from entering the plant.

(c) Administrative Procedures - This item is deemed to be satisfied when:

1. The floors of all rooms in which milk is handled, processed, or stored or in which milk containers, utensils, and/or equipment are washed, are constructed of good quality concrete or equally impervious tile or brick laid closely with impervious joint material or metal surfacing with impervious joints, or other material which is the equivalent of good quality concrete. The floors of storage rooms for dry ingredients and/or packaging material may be constructed of tightly joined wood.

2. The floor surface is smooth and sloped so that there are no pools of standing water after flushing and the joints between the floor and the walls are impervious.

3. The floors are provided with trapped drains. Cold-storage rooms used for storing milk and milk products need not be provided with floor drains when the floors are sloped to drain to one or more exits. Storage rooms for dry ingredients, dry packaged milk and/or milk products, aseptically processed and packaged low-acid milk and/or milk products and/or packaging materials, and retort processed after packaged low-acid milk and/or milk products and/or packaging materials are not required to be provided with drains.

Note: Refer to Rule 420-3-16-.10(11) for requirements for floors of drying chambers.

(2) **Walls and Ceilings Construction**

(a) Walls and ceilings of rooms in which milk, milk products, or frozen desserts are handled, processed, packaged, or stored or in which milk containers, utensils, and equipment are washed shall have a smooth, washable, light-colored surface in good repair.

(b) Public Health Reason - Painted or otherwise properly finished walls and ceilings are more easily kept clean and are, therefore, more apt to be kept clean. A light-colored paint or finish aids in the even distribution of light and the detection of unclean conditions.

(c) Administrative Procedures - This item is deemed to be satisfied when:

1. Walls and ceilings are finished with smooth, washable, light-colored tile, smooth surface concrete, cement plaster, or other equivalent materials with washable, light-colored surfaces.

2. Walls, partitions, windows, and ceilings are kept in good repair and refinished as often as the finish wears off or becomes discolored

Note: Rule 420-3-16-.10(11) for requirements for walls for drying chambers. Storage rooms used for the storage of packaged dry milk and/or milk products, aseptically processed and packaged low-acid milk and/or milk products, and retort processed after packaged low-acid milk and/or milk products are exempt from the ceiling requirements of this Item.

(3) **Doors and Windows**

(a) Effective means shall be provided to prevent the access of insects and rodents. All openings to the outside shall have solid doors or glazed windows which shall be closed during dusty weather.

(b) Public Health Reason - Freedom from insects in the milk or frozen dessert plant reduces the likelihood of contamination of milk or milk products. For information on disease transmission by flies see Rule 420-3-16.09(7).

(c) Administrative Procedures - This item is deemed to be satisfied when:

1. All openings to the outer air are effectively protected by:

(i) Screening; or

(ii) Effective electric screen panels; or

(iii) Fans or air curtains which provide sufficient air velocity so as to prevent the entrance of insects; or

(iv) Properly constructed flaps where it is impractical to use self-closing doors or air curtains; or

(v) Any effective combination of (i), (ii), (iii) or (iv) or by any other method which prevents the entrance of insects.

2. All outer doors are tight and self-closing. Screen doors shall open outward.

3. All outer openings are rodent proofed to the extent necessary to prevent the entry of rodents.

Note: The evidence of insects and/or rodents in the plant shall be considered under Rule 420-3-16-.10(9).

(4) **Lighting and Ventilation**

(a) All rooms in which milk, milk products, or frozen desserts are handled, processed, or stored and/or in which milk containers, equipment, and utensils are washed shall be well-lighted and well-ventilated.

(b) Public Health Reason - Ample light promotes cleanliness. Proper ventilation reduces odors and prevents condensation upon interior surfaces.

(c) Administrative Procedures - This item is deemed to be satisfied when:

1. Adequate light sources are provided (natural, artificial, or a combination of both) which furnish at least twenty (20) foot-candles (220 lux) of light in all working areas. This shall apply to all rooms where milk or milk products are handled, processed, packaged, or stored or where utensils, containers, and equipment are washed. Dry storage and cold storage rooms shall be provided with at least five (5) foot-candles (55 lux) of light.

2. Ventilation in all rooms is sufficient to keep them reasonably free of odors and excessive condensation on equipment, walls, and ceilings.

3. Pressurized ventilating systems, if used, have a filtered air intake.

4. For milk plants that condense and/or dry milk or milk products, ventilating systems in packaging rooms, where used, are separate systems and where possible have the ducts installed in a vertical position.

(5) **Separate Rooms**

(a) There shall be separate rooms for:

1. The pasteurizing, processing, cooling, reconstitution, condensing, drying, and packaging of milk, milk products, and frozen desserts.

2. Packaging of dry milk or milk products.

3. The cleaning of milk cans, containers, bottles, cases, dry milk, or milk product containers.

4. Cleaning and sanitizing facilities for milk tank trucks in plants receiving milk or whey in such tanks.

5. Receiving cans of milk, milk products, and frozen dessert products in plants receiving such cans.

6. The fabrication of containers and closures for milk and/or milk products, except for aseptically processed and packaged low-acid milk and/or milk products and/or retort processed after packaging low-acid milk and/or milk products in which the containers and closures are fabricated within the APPS or RPPS, respectively.

(i) Rooms in which milk, milk products, and frozen dessert products are handled, processed, stored,

condensed, dried, and packaged or in which milk or frozen dessert containers, utensils, and equipment are washed or stored, shall not open directly into any stable or any room for domestic purposes. All rooms shall be of sufficient size for their intended purposes.

(ii) Designated areas or rooms shall be provided for the receiving, handling, and storage of returned packaged milk, milk products, and frozen desserts.

(b) Public Health Reason - If the washing and sanitization of containers are conducted in the same room in which the pasteurizing, processing, cooling, condensing, drying, or packaging or bottling is done, there is opportunity for the pasteurized product to become contaminated. For this reason, separate rooms are required as indicated. The unloading of cans of raw milk directly into the pasteurizing room is apt to increase the prevalence of insects therein, as well as, to render it to public.

(c) Administrative Procedures - This item is deemed to be satisfied when:

1. Pasteurizing, processing, reconstitution, cooling, condensing, drying, and packaging of milk and milk products are conducted in a single room(s), but not in the same room(s) used for the cleaning of milk cans, portable storage bins, bottles, and cases or the unloading and/or cleaning and sanitizing of milk tank trucks, provided that these rooms may be separated by solid partitioning doors that are kept closed. Provided further, that cooling, plate or tubular, may be done in the room where milk tank trucks are unloaded and/or cleaned and sanitized. Separation/clarification of raw milk may be done in an enclosed room where milk tank trucks are unloaded and/or cleaned and sanitized.

Note: Packaging of dry milk or milk products shall be conducted in a separate room.

2. All returned packaged milk, milk products, and frozen desserts which have physically left the premises of the processing plant shall be received, handled, and stored in separate areas or rooms isolated from the Grade "A" and frozen dessert dairy operations. Such separate areas or rooms shall be clearly defined and marked for such use.

3. All bulk milk and milk product storage tanks are vented into a room used for pasteurization, processing, cooling, or packaging operations or into a storage tank gallery room, provided that vents located elsewhere which

are adequately equipped with air filters so as to preclude the contamination of the milk, milk product, or frozen dessert products shall be considered satisfactory.

4. Solid doors installed in required partitions are self-closing.

5. Facilities for the cleaning and sanitizing of milk tank trucks are properly equipped for manual and/or mechanical operations. When such facilities are not provided on the plant premises, these operations shall be performed at a receiving station, transfer station, or separate tank cleaning facility (refer to Appendix B).

6. Rooms in which milk, milk products, or frozen dessert products are handled, processed, or stored or in which milk containers, utensils, and equipment are washed or stored, do not open directly into any stable or any room used for domestic purposes.

7. All rooms shall be of sufficient size for their intended purposes.

8. Cottage cheese vats shall be located in a separate room, maintained free from flies and other vermin, and kept in a clean condition.

(6) **Toilet-Sewage Disposal Facilities**

(a) Every milk and frozen dessert plant shall be provided with toilet facilities conforming to the Rules of the Alabama State Board of Health. Toilet rooms shall not open directly into any room in which milk, frozen desserts, and milk products are processed. Toilet rooms shall be completely enclosed and shall have tight-fitting, self-closing doors. Dressing rooms, toilet rooms, and fixtures shall be kept in a clean condition, in good repair and shall be well ventilated and well lighted. Sewage and other liquid wastes shall be disposed of in a sanitary manner.

(b) Public Health Reason

1. Human excreta are potentially dangerous and must be disposed of in a sanitary manner. The organisms causing typhoid fever, para-typhoid fever, and dysentery may be present in the body discharges of active cases or carriers. Sanitary toilet facilities are necessary to protect the milk, milk products, or frozen dessert products, equipment, containers, and utensils from fecal contamination which may be carried by flies, other insects, hands, or clothing. When the toilet facilities of a satisfactory type are kept clean and in good repair, the opportunities for the spread of contamination by the

above means are minimized. The provision of an intervening room or vestibule between the toilet room and any room in which milk, milk products, or frozen desserts are processed makes it less likely that contaminated flies will enter these rooms. It will also minimize the spread of odors.

2. The wastes resulting from the cleaning and rinsing of containers, equipment, utensils, and floors from flush toilets and from washing facilities should be properly disposed of so as not to contaminate the milk and frozen dessert containers, utensils, or equipment, or to create a nuisance or a public health hazard.

(c) Administrative Procedures - This item is deemed to be satisfied when:

1. The milk or frozen dessert plant is provided with toilet facilities conforming to the Rules of the State Board of Health.

2. Toilet rooms do not open directly into any room in which milk and/or milk products are processed, condensed, or dried.

3. Toilet rooms are completely enclosed and have tight-fitting, self-closing doors.

4. Dressing rooms, toilet rooms, and fixtures are kept in a clean condition, in good repair, and are well-ventilated and well-lighted.

5. Toilet tissue and easily cleanable covered waste receptacles are provided in toilet rooms.

6. All plumbing is installed to meet the applicable provisions of the state or local plumbing code.

7. Sewage and other liquid wastes are disposed of in a sanitary manner.

8. Non-water-carried sewage disposal facilities are not used.

(7) **Water Supply**

(a) Water for milk and frozen dessert plant purposes shall be from a supply properly located, protected, and operated and be easily accessible, adequate, and of a safe, sanitary quality.

(b) Public Health Reason - The water supply should be accessible in order to encourage its use in cleaning operations; and it should be adequate so that cleaning and

rinsing may be thorough; and it should be of safe, sanitary quality in order to avoid the contamination of milk, frozen dessert, containers, utensils, and equipment.

(c) Administrative Procedures - This item is deemed to be satisfied when:

1. Water for milk and frozen dessert plant purposes is from an adequate supply, properly located, protected, and operated. It shall be easily accessible and of a safe, sanitary quality.

2. The water supply is approved as safe by the Health Officer and, in the case of individual water systems, complies with at least the specification outlined in Appendix D and the bacteriological standards outlined in Appendix G.

3. There is no cross-connection between the safe water supply and any unsafe or questionable water supply or any source of pollution through which the safe water supply might become contaminated. A connection between the water supply piping and a make-up tank (such as for cooling or condensing), unless protected by an air gap or effective backflow preventor, constitutes a violation of this requirement. An approved air gap is defined as the unobstructed vertical distance through the free atmosphere of at least twice the diameter of the largest incoming water supply pipe or faucet to the flood level of the vessel or receptacle. The distance of the air gap is to be measured from the bottom of the potable inlet supply pipe or faucet to the top of the effective overflow, (i.e., flood level rim or internal overflow of the vessel). In no case, may the effective air gap be less than 2.54 centimeter (one [1] inch).

4. Condensing water for milk or milk product evaporators and water used to produce vacuum and/or to condense vapors in vacuum heat processing equipment is from a source complying with 2 above, provided when approved by the Health Officer, water from sources not complying with 2 above may be used when the evaporator or vacuum heat equipment is constructed and operated to preclude contamination of such equipment or its contents by condensing water or by water used to produce vacuum. Means of preventing such contamination are:

(i) Use of a surface-type condenser in which the condensing water is physically separated from the vapors and compensated, or

(ii) Use of reliable safeguards to prevent the overflow of condensing water from the condenser into

the evaporator. Such safeguards include a barometric leg extending at least thirty-five (35) feet vertically from the invert of the outgoing condensing water line to the free level at which the leg discharges or a safety shut-off valve, located on the water feed line to the condenser, automatically actuated by a control which will shut off the in-flowing water when the water level rises above a predetermined point in the condenser. This valve may be actuated by water, air, or electricity and shall be designed so that failure of the primary motivating power will automatically stop the flow of water into the condenser.

5. Condensing water for milk or milk product evaporators complying with 2 above and water reclaimed from milk or milk products, may be reused when all necessary means of protection are afforded and it complies with the procedures outlined in Appendix D, V.

6. New individual water supplies and water supply systems, which have been repaired or otherwise become contaminated, are disinfected before being placed in use (refer to Appendix D). The supply shall be made free of the disinfectant by pumping to waste before any sample for bacteriological testing shall be collected.

7. Samples for bacteriological testing of individual water supplies are taken upon the initial approval of the physical structure, each six (6) months thereafter, and when any repair or alteration of the water supply system has been made. Samples shall be taken by the Health Officer and examination shall be conducted in an official laboratory. To determine if water samples have been taken at the frequency established in this item, the interval shall include the designated six (6) month period plus the remaining days of the month in which the sample is due.

8. Current records of water test results are retained on file with the Health Officer or as the Health Officer directs.

9. Water supply outlets are provided immediately available to the cottage cheese vats. The hose for transport of water for washing cottage cheese curd shall be arranged in such a way as to preclude the possibility of the hose touching the floor or the product.

10. A potable water supply, which meets the criteria of this rule, may be connected to the product feed line of a steam vacuum evaporator, provided that the water supply

is protected at the point of connection by an approved backflow prevention device.

11. Water supply piping connected to raw or pasteurized milk, milk product, or frozen dessert product lines or vessels shall be protected with an effective backflow preventer.

Note: Refer to Rule 420-3-16-.15(c), Administrative Procedures, for additional requirements involving the protection of milk and milk products.

(8) **Handwashing Facilities**

(a) Convenient handwashing facilities shall be provided in toilet rooms, receiving rooms, or tank truck unloading areas and including hot and cold and/or warm running water, soap, and individual sanitation towels or other approved hand drying devices. Handwashing facilities shall be kept clean and in good repair. The use of a common towel is prohibited. No employees shall resume work after using the toilet room without first washing his hands. Handwashing facilities shall be kept clean.

(b) Public Health Reason - Proper use of handwashing facilities is essential to personal cleanliness, and reduces the likelihood of contamination of milk, milk products, or frozen desserts.
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(c) Administrative Procedures - This item is deemed to be satisfied when:

1. Convenient handwashing facilities are provided, including hot and cold and/or warm running water, soap, and individual sanitary towels, or other approved hand-drying devices.

2. Handwashing facilities are provided in all toilets and in all rooms in which milk plant and frozen dessert plant operations are conducted.

3. Handwashing facilities are kept in a clean condition and in good repair.

4. Steam-water mixing valves and vats for washing bottles, cans, and similar equipment are not used as handwashing facilities.

(9) **Milk and Frozen Dessert Plant Cleanliness**

(a) All rooms in which milk, milk products, and frozen desserts are handled, processed, or stored and/or in which containers, utensils, and/or equipment are washed or stored, shall be kept clean, neat, and free of evidence of insects and rodents. Only equipment directly related to processing operations or to handling of containers, utensils, and equipment shall be permitted in the pasteurizing, processing, cooling, condensing, drying, packaging, and bulk milk, milk product, or frozen dessert product storage rooms.

(b) Public Health Reason - Clean floors, free of litter, clean walls, ceilings, and all other areas of the milk and frozen dessert plant are conducive to clean milk and frozen dessert handling operations. Cleanliness and freedom from insects and rodents reduces the likelihood of contamination of the milk, milk product, or frozen dessert products. Excess or unused equipment, or equipment not directly related to the plant operations, can be detrimental to the cleanliness of the plant.

(c) Administrative Procedures - This item is deemed to be satisfied when:

1. Only equipment directly related to processing operations or the handling of containers, utensils, and equipment is permitted in the pasteurizing, processing, cooling, condensing, drying, packaging, and bulk milk, or bulk milk, or bulk frozen dessert product storage rooms.

2. All piping, floors, walls, ceilings, fans, shelves, tables, and the non-product contact surfaces of other facilities and equipment are clean.

3. No trash, solid waste, or waste dry product is stored within the plant except in covered containers. Waste containers at the packaging machine or bottle washer may be uncovered during operation of such equipment.

4. All rooms in which milk, milk products, or frozen desserts are handled, processed or stored, and/or in which containers, utensils, and equipment are washed or stored, are kept clean, neat, and free of evidence of insects and rodents.

(10) **Sanitary Piping**

(a) All sanitary piping, fittings, and connections which are exposed to milk, milk products, frozen desserts, or from which liquids may drip, drain, or be drawn into milk, milk products, and frozen dessert products shall consist of smooth, impervious, corrosion resistant, nontoxic, easily cleanable material which is approved for milk product-contact surfaces. All piping shall be in good repair. Pasteurized milk, milk

products, and frozen dessert products shall be conducted from one piece of equipment to another only through sanitary piping.

(b) Public Health Reason

Milk and frozen dessert piping and fittings are sometimes so designed as to be difficult to clean; or they may be constructed of metal which corrodes easily. In either case, it is unlikely that they will be kept clean. Sanitary milk piping is a term which applies to properly designed and properly constructed piping. The purpose of the third sentence is to prevent exposure of the pasteurized product to contamination.

(c) Administrative Procedures - This item is deemed to be satisfied when:

1. All sanitary piping, fittings, and connections which are exposed to milk, milk products, or frozen dessert products from which liquids may drip, drain, or be drawn into milk or frozen dessert products, consist of smooth, impervious, corrosion-resistant, nontoxic, and easily cleanable material.

2. All sanitary piping, connections and fittings consist of:

(i) Stainless steel of the AISI 300 series; or

(ii) Equally corrosion-resistant metal which is nontoxic and nonabsorbent; or

(iii) Heat-resistant glass; or

(iv) Plastic, rubber, and rubberlike materials which are relatively inert, resistant to scratching, scoring, decomposition, crazing, chipping, and distortion under normal use conditions; which are nontoxic, fat resistant, relatively nonabsorbent; which do not impart flavor or odor to the products; and which maintain their original properties under repeated use conditions, may be used for gaskets, sealing applications and for short, flexible takedown jumpers or connections where flexibility is required for essential or functional reasons.

3. Sanitary piping, fittings, and connections are designed to permit easy cleaning, kept in good repair, and free of breaks or corrosion and contain no dead ends of piping in which milk may collect.

4. All interior surfaces of demountable piping, including valves, fittings, and connections are designed,

constructed, and installed to permit inspection and drainage.

5. All cleaned-in-place (CIP) milk and frozen dessert pipelines and return-solution lines are rigid, self-draining, and so supported to maintain uniform slope and alignment. Return solution lines shall be constructed of material meeting the specifications of 2 above. If gaskets are used, they shall be self-positioning, of material meeting the specifications outlined in 2(iv) above; and designed, finished, and applied to form a smooth, flush interior surface. If gaskets are not used, all fittings shall have self-positioning faces designed to form a smooth, flush interior surface. All interior surfaces of welded joints in pipelines shall be smooth and free from pits, cracks, or inclusions. In the case of welded lines, all welds shall be inspected by the use of a boroscope or other appropriate available inspection device as they are made; and such welds shall be approved by the Health Officer. Each cleaning circuit shall have access points for inspection in addition to the entrances and exits. These may be valves, removable sections, fittings, or other means of combinations that are adequate for inspection of the interior of the line. These access points shall be located at sufficient intervals to determine the general condition of the interior surfaces of the pipeline. Detailed plans for welded pipeline systems shall be submitted to the Health Officer for written approval prior to installation. No alteration or addition shall be made to any welded milk pipeline system without prior written approval from the Health Officer.

6. Pasteurized milk, milk products, and frozen dessert products are conducted from one piece of equipment to another only through sanitary milk piping provided cottage cheese, cheese dressings, or cheese ingredients may be transported by other methods which protect the product from contamination.

7. For milk plants and frozen dessert plants that dry milk, milk products, or frozen dessert products, because of the high pressure required to obtain proper dispersal of the product in the drying chamber, the pipeline between the high-pressure pump and the dryer nozzle may be connected with pressure-tight threaded fittings or may be welded.

(11) **Construction and Repair of Containers and Equipment**

(a) All multi-use containers and equipment with which milk, milk products, and frozen dessert products come into contact shall be of smooth, impervious, corrosion-resistant, nontoxic

material; shall be constructed for ease of cleaning; and shall be kept in good repair. All single-service containers, closures, gaskets, and other articles with which milk, milk products, and frozen desserts come in contact shall be nontoxic and shall have been manufactured, packaged, transported, and handled in a sanitary manner. Articles intended for single-service use shall not be reused.

(b) Public Health Reason

1. When equipment is not constructed and located so that it can be cleaned easily and which is not kept in good repair, it is unlikely that it will be properly cleaned.

2. Single-service articles which have not been manufactured and handled in a sanitary manner may contaminate the milk.

(c) Administrative Procedures - This item is deemed to be satisfied when:

1. All multi-use containers and equipment with which milk, milk products, and frozen dessert products come into contact are of smooth, impervious, corrosion-resistant, and nontoxic material.

2. All milk and frozen dessert contact surfaces of multi-use containers and equipment consist of:

(i) Stainless steel of the AISI 300 series; or

(ii) Equally corrosion-resistant metal which is non-toxic and nonabsorbent; or

(iii) Heat-resistant glass; or

(iv) Plastic or rubber and rubberlike materials which are relatively inert, resistant to scratching, scoring, decomposition, crazing, chipping, and distortion under normal use conditions; which are non-toxic, fat resistant, relatively non-absorbent, and do not impart flavor or odor to the product; and which maintain their original properties under repeated use conditions.

3. All joints in containers, equipment, and utensils are flush and finished as smooth as adjoining surfaces or if the surface is vitreous, it must be continuous. Tile floors are not acceptable in dryers. Joints on equipment coming in contact with dry milk or milk products only or used for hot air piping may be sealed by other acceptable means. Where a rotating shaft is inserted through a surface with which milk, milk products, or frozen

desserts come into contact, the joint between the moving and stationary surfaces shall be close-fitting. Grease and oil from gears, bearings, and cables shall be kept out of the milk, milk products, and frozen dessert products. Where a thermometer or temperature sensing element is inserted through a surface with which milk, milk products, or frozen desserts come into contact, a pressure-tight seal shall be provided ahead of all threads and crevices.

4. All openings in covers of tanks, vats, separators, etc., are protected by raised edges, or otherwise, to prevent the entrance of surface drainage. Condensation-diverting aprons shall be provided as close to the tank or vat as possible on all pipes, thermometers, or temperature sensing elements, and other equipment extending into a tank, bowl, vat, or similar equipment unless a water-tight joint is provided.

5. All surfaces with which milk, milk products, and frozen dessert products come into contact, except pneumatic ducts and cyclonic or air separator collectors, are easily accessible or demountable for manual cleaning or are designed for CIP cleaning; provided, flexible plastic or rubber tanker loading and unloading hoses with screw-type hose clamps shall be considered in compliance, if an appropriate screwdriver or tool is readily available for disassembly. All product-contact surfaces shall be readily accessible for inspection and shall be self-draining.

6. There are no threads used in contact with milk, milk products, and frozen dessert products, except where needed for functional and safety reasons, such as in clarifiers, pumps, and separators. Such thread shall be of a sanitary type, except those used on high-pressure lines between the high pressure pump and dryer nozzle.

7 All multi-use containers and other equipment have rounded corners, are in good repair, and free from breaks, crevices, and corrosion. Milk cans shall have umbrella-type covers.

8. Strainers, if used, are of perforated metal design and so constructed as to utilize single-service strainer media. Multiple-use woven material shall not be used for straining milk; provided, when required for functional reasons inherent to the production of certain milk products, such as buttermilk, whey, dry whey, and dry milk products, woven material may be used where it is impractical to use perforated metal. However, woven material parts shall be mechanically cleaned by such

methods that thoroughly clean the woven material and do not contaminate the product.

9. Sifters for dry milk products are so constructed as to utilize single-service or multi-service use strainer media conforming with:

(i) Plastic materials listed in 2(iv) above; or

(ii) Woven stainless steel wire conforming to 2(i) above; or

(iii) Cotton, linen, silk, or synthetic fibers which are non-toxic, relatively insoluble, easily cleanable, and do not impart a flavor to the product.

(iv) Tailings shall be continuously discharged from sifters through dust-tight connections to an enclosed container and shall not be used for human consumption.

10. All single-service containers, closures, gaskets, and other articles which milk, milk products, or frozen dessert products come in contact are nontoxic.

11. The manufacture, packing, transportation, and handling of single-service containers, closures, caps, gaskets, and similar articles comply with the requirements of Appendix J; provided, all paper, plastics, foil, adhesives, and other components of containers used in the packaging of milk and/or milk products that have been condensed and/or dried shall be free from deleterious substances and comply with the requirements of the *FFD&CA*.

12. Inspections and tests shall be made by the Health Officer or any agency authorized by them.

Note: The option for "Inspections and tests" as cited in 12 above, shall only be made by a TPC authorized under the ICP.

13. Provided that all paper, plastics, foil, adhesives, and other components of containers and closures used in the packaging of milk, milk products, and frozen dessert products that have been aseptically processed and packaged or retort processed after packaging are governed under the applicable provisions of 21 CFR Parts 110 and 113 and shall not be subject to this Item.

Note: 3-A Sanitary Standards and Accepted Practices for dairy equipment are developed by 3-A SSI. 3-A SSI is comprised of equipment fabricators, processors, and

regulatory sanitarians, which include state milk regulatory officials, USDA Agricultural Marketing Service Dairy Programs, the USPHS/FDA CFSAN/MST, academic representatives, and others.

14. Equipment manufactured in conformity with 3-A Sanitary Standards and Accepted Practices complies with the sanitary design and construction standards of this rule. For equipment not displaying the 3-A Symbol, the 3-A Sanitary Standards and Accepted Practices may be used by Health Officers as guidance in determining compliance with this rule.

(12) **Cleaning and Sanitizing of Containers and Equipment**

(a) The product-contact surfaces of all multi-use containers, utensils, and equipment used in the transportation, processing, condensing, drying, packaging, handling, and storage of milk, milk products, or frozen desserts shall be effectively cleaned after each usage and shall be sanitized before each use; provided, piping, equipment, and containers used to process, conduct, or package aseptically processed milk and milk products beyond the final heat treatment process shall be sterilized before any aseptically processed milk or milk product is packaged and shall be re-sterilized whenever any unsterile product has contaminated it.

(b) Public Health Reason - Milk, milk products, and frozen dessert products cannot be kept clean and safe if permitted to come into contact with containers, utensils and equipment which have not been properly cleaned and sanitized.

(c) Administrative Procedures - This item is deemed to be satisfied when:

1.All multi-use containers and utensils are thoroughly cleaned after each use and all equipment is thoroughly cleaned at least once each day used, unless the Health Officer has reviewed and accepted information, in consultation with FDA, supporting the cleaning of multi-use containers and utensils at frequencies extending beyond one (1) day or seventy-two (72) hours in the case of storage tanks or forty-four (44) hours in the case of evaporators, which are continuously operated. Supporting information shall be submitted to and approved by the Health Officer prior to initiating the qualification period if required. Finished product produced during an extended run shall meet all applicable requirements of Rule 420-3-16-.08. Any significant equipment or processing changes shall be communicated to the Health Officer, and may result in a re-verification of the extended run proposal, if it is determined that the

change could potentially affect the safety of the finished milk and/or milk product(s).

2. The supporting information may include but is not limited to:

(i) Statement of proposal, including desired cleaning frequency.

(ii) Product and equipment description.

(iii) Intended use and consumers.

(iv) Distribution and storage temperatures of product.

(v) Diagram of process of interest.

(vi) Process parameters, including temperature and times.

(vii) Hazard evaluation and safety assessment.

(viii) Review of equipment for sanitary design.

(xi) When indicated by a hazard evaluation and safety assessment, a plan for initial qualification shall be developed to address identified critical process parameters.

3. Otherwise, storage tanks shall be cleaned when emptied and shall be emptied at least every seventy-two (72) hours. Records shall be available to verify that milk storage in these tanks does not exceed seventy-two (72) hours. These records shall be available for at least the previous three (3) months or from the time of the last regulatory inspection, whichever is longer. In the case of pasteurized storage tanks, which are CIP cleaned at intervals of less than seventy-two (72) hours, the CIP cleaning records required under Item 2b shall be considered adequate. Storage tanks, which are used to store raw milk and/or milk products or heat-treated milk products longer than twenty-four (24) hours and silo tanks used for the storage of raw milk and/or milk products or heat-treated milk products, shall be equipped with a seven (7) day temperature-recording device complying with the specifications of Appendix H, IV. Electronic records that comply with the applicable provisions of Appendix H, IV, and V, with or without hard copy, may be used in place of the seven (7) day temperature-recording records. Otherwise provided, evaporators shall be cleaned at the end of a continuous operation, not to exceed forty-four (44) hours, and

records shall be available to verify that the operation time does not exceed forty-four (44) hours.

4. Drying equipment, cloth-collector systems, packaging equipment, and multi-use dry milk products and dry whey storage containers are cleaned at intervals and by methods recommended by the manufacturer and approved by the Health Officer. Such methods may include cleaning without water by use of vacuum cleaners, brushes, or scrapers. After cleaning, such equipment is sanitized by a method approved by the Health Officer. Cloth collector systems and all dry product-contact surfaces downstream from the dryer shall be sanitized or purged at intervals and by methods recommended by the manufacturer and approved by the Health Officer. Storage bins used to transport dry milk or milk products shall be dry cleaned after each usage and washed and sanitized at regular intervals.

Note: Appendix F contains additional information on dry cleaning of drying equipment, packaging equipment, and dry milk product and dry whey storage containers.

5. All milk tank trucks that transport Grade "A" milk and/or milk products shall be washed and sanitized at a permitted milk plant, receiving station, transfer station, or milk tank truck cleaning facility. The milk tank truck shall be cleaned and sanitized prior to its first use. When the time elapsed after cleaning and sanitizing and before its first use, exceeds ninety-six (96) hours, the tank shall be re-sanitized.

Note: Appendix B contains additional information on the cleaning and sanitizing requirements for milk tank trucks.

6. Whenever a milk tank truck has been cleaned and sanitized, as required by the Health Officer, it shall bear a tag or a record shall be made showing the date, time, place, and signature or initials of the employee or contract operator doing the work, unless the milk tank truck delivers to only one (1) receiving facility where responsibility for cleaning and sanitizing can be definitely established without tagging. The tag shall be removed at the location where the milk tank truck is next washed and sanitized and kept on file for fifteen (15) days as directed by the Health Officer.

7. Pipelines and equipment designed for mechanical cleaning meet the following requirements.

(i) An effective cleaning and sanitizing regimen for each separate cleaning circuit shall be followed.

(ii) A temperature recording device, complying with the specifications in Appendix H, IV, or a recording device which provides sufficient information to adequately evaluate the cleaning and sanitizing regimen and which is approved by the Health Officer, shall be installed in the return solution or other appropriate areas to record the temperature and time which the line or equipment is exposed to cleaning and sanitizing solutions. Optionally, time may be identified in military time (24 hour clock). Electronic records that comply with the applicable provisions of Appendix H, IV, and V, with or without hard copy, may be used in place of the cleaning records described above. For purposes of this rule, recording devices which produce records not meeting the specifications of Appendix H, IV may be acceptable if:

I. The temperature-recording device provides a continuous record of the monitoring of the cleaning cycle time and temperature, cleaning solution velocity or cleaning pump operation, and the presence or strength of cleaning chemicals for each cleaning cycle.

II. The record shows a typical pattern of each circuit cleaned, so that changes in the cleaning regimen may be readily detected.

III. Electronic storage of required cleaning records, with or without hard copy printouts may be acceptable; provided, the electronically generated records are readily available for review by the Health Officer. Electronic records shall meet the criteria of this rule and Appendix H, V. Except that, electronic storage of required cleaning records, with or without hard copy, shall be acceptable; provided, the computer and computer generated records are readily available for review by the Health Officer and meet the criteria of this rule and 21 CFR Part 11.

(iii) Temperature recording charts shall be identified, dated, and retained for three (3) months or until the next regulatory inspection, whichever is longer.

(iv) During each official inspection, the Health Officer shall examine and initial temperature recording charts to verify the time of exposure to solutions and their temperatures.

8. Plants in which containers are washed manually are equipped with a two (2) compartment wash-and-rinse vat for this purpose. Such plants shall also provide a steam cabinet or individual steam-jet plate with hood for sanitizing of cleaned containers or if sanitizing is done with chemicals, a third treatment vat.

9. In plants utilizing automatic bottle washers, such washers must provide for bactericidal treatment by means of steam, hot water, or chemical treatment. Soaker-type bottle washers, in which bactericidal treatment depends upon the causticity of the washing solution, the caustic strength for a given soaking time and temperature shall be as specified in the following table listing combinations of causticity, time, and temperature of equal bactericidal value, for the soaker tank of soaker-type bottle washers:

TABLE 2

COMBINATIONS OF CAUSTICITY, TIME, AND TEMPERATURE OF EQUAL BACTERICIDAL VALUE, FOR SOAKER TANK OF SOAKER-TYPE BOTTLE WASHERS

(Based on NSDA Specifications for Beverage Bottles)

Temperature, Degrees

Time in Minutes	F	170	160	150	140	130	120	110
	C	77	71	66	60	54	49	43

Concentration of NaO H, Percent

3	0.57	0.86	1.28	1.91	2.86	4.27	6.39
5	0.43	0.64	0.96	1.43	2.16	3.22	4.80
7	0.36	0.53	0.80	1.19	1.78	1.66	3.98

Note: The National Soft Drink Association (NSDA), Washington, D.C. 20036 alkali test, the NSDA caustic test, or other suitable test may be used to determine the strength of the soaker solution. The caustic strength shall be tested monthly by the Health Officer.

10. When caustic is so used, subsequent final rinsing of the bottles shall be with water which has been treated with heat or chemicals to assure freedom from viable pathogenic or otherwise harmful organisms, to prevent recontamination of the treated bottles during the rinsing operation.

11. All multi-use containers, equipment, and utensils are sanitized before use, employing one or a combination of the methods prescribed under Rule 420-3-16-.09(11). Additionally, for milk and frozen dessert plants that

condense or dry milk products the following methods are acceptable or any other method, which has been demonstrated to be equally efficient:

(i) Exposure to an enclosed jet of stream for not less than one (1) minute.

(ii) Exposure to hot air at a temperature of at least 83°C (180°F) for at least twenty (20) minutes as measured by an acceptable indicating thermometer located in the coldest zone.

12. Assembled equipment shall be sanitized prior to each day's run, unless the FDA and the Health Officer have reviewed and accepted information supporting the sanitizing of multi-use containers, utensils, and equipment at frequencies extending beyond one (1) day. Tests to determine the efficiency of sanitization should be made by the Health Officer at intervals sufficient to satisfy the Health Officer that the sanitization process is effective.

13. For milk plants that dry milk, milk products, or frozen dessert products, higher temperatures and longer periods may be necessary for the sanitization of high-pressure lines. It has been demonstrated that alkaline cleaners at 72°C (160°F) for thirty (30) minutes, followed by an acid cleaner for thirty (30) minutes at the same temperature, produce satisfactory results. Studies have indicated that effective sanitization of the dryer may be accomplished by the following procedure:

(i) Operate the spray nozzles with water at a temperature and rates at least as high as those employed during the drying operation.

(ii) Adjust airflow to give at least 0.5 inch (water) pressure in the drying chamber.

(iii) Continue the operation for twenty (20) minutes while a temperature of not less than 85°C (185°F) is being registered at the discharge from the dryer.

14. Portions of the drying system not reached by this treatment or dryers in which this procedure is not practical shall be treated by one of the methods prescribed above, or by other methods of demonstrated effectiveness.

15. The residual bacteria count of multi-use containers and closures shall be conducted as outlined in Appendix J. The residual bacterial count of multi-use containers used for packaging pasteurized milk and/or milk products shall not exceed one (1) colony per milliliter (1/mL) of

capacity, when the rinse test is used, or fifty (50) colonies per fifty (50) square centimeters (cm2) one (1) colony per square centimeter) of product-contact surface, when the swab test is used, in three (3) out of four (4) samples taken at random on a given day. Coliform organisms shall be undetectable in all multi-use containers.

16. The residual bacteria count of single-service containers and closures, used for packaging pasteurized milk and/or milk products shall not exceed fifty (50) colonies per container, or in the case of dry product packaging, shall not exceed one (1) colony per milliliter (1/mL) of capacity when the rinse test is used, except that in containers less than 100 mL the count shall not exceed ten (10) colonies or fifty (50) colonies per fifty (50) cm2 (one [1] colony per square centimeter) of product-contact surface, when the swab test is used, in three (3) out of four (4) samples taken at random on a given day. Coliform organisms shall be undetectable in all single-service containers and/or closures.

17. When single-service containers and/or closures are fabricated in another plant that conforms to the Standards of Appendix J and the Health Officer has information that they do comply, the Health Officer may accept the containers and/or closures as being in conformance without additional testing. If there is reason to believe that containers and/or closures do not conform to the bacteriological standards, additional testing may be required. If containers and/or closures are fabricated in the milk plant, the Health Officer shall collect, during any consecutive six (6) months, at least four (4) sample sets of containers with applied closures, as defined in Appendix J from each manufacturing line, as defined in Appendix J, in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days, and analyze the sample sets at an Official Commercial or Industry Laboratory, approved by the Milk Laboratory Control Agency specifically for the examinations required under Appendix J.

18. Plants which utilize multi-use plastic containers for pasteurized milk, milk products, and frozen desserts shall comply with the following criteria:

(i) The plastic material from which the containers are molded shall be of safe material.

(ii) The plastic material shall comply with the material specifications of Rule 420-3-16-.10(11).

(iii) All containers shall be identified as to plant of manufacture, date of manufacture, and type and class of plastic material used. This information may be by code, provided the code is revealed to the Health Officer.

(iv) A device shall be installed in the filling line capable of detecting in each container before it is filled, volatile organic contaminants in amounts that are of public health significance. Such device must be constructed so that it may be sealed by the Health Officer to prevent the changing of its sensitivity functioning level. Models using an air-injection system and with a testing device built into the detection equipment do not have to be sealed. To assure proper functioning of the system, the operator needs to be able to adjust the sensitivity. However, those models utilizing an external testing device must be sealed. Any container detected by the device as being unsatisfactory must be automatically made unusable to prevent refilling. In addition, the device must be interconnected so that the system will not operate unless the detecting device is in proper operating condition, provided any other system so designed and operated will provide equal assurance of freedom from contamination and recognized by the FDA to be equally efficient may be accepted by the Health Officer. When other systems are used in place of a device for the detection of volatile organic contaminants, the following criteria has been developed to determine what constitutes equal assurance:

(v) A soaker-type washer shall be used for cleaning and sanitizing the containers and shall conform with the following criteria:

I. If caustic is used, the caustic strength for a given washing time and temperature shall be as specified in Table 2 of this item; or

II. If a cleaning compound, other than caustic is used, the compound shall be a mild or moderately alkaline, granular composition formulated from a blend of sodium phosphate, and anionic synthetic detergents and conform to the following:

III. The used solution shall have at least a 3 percent concentration with a pH of at least 11.9 and an alkalinity expressed as sodium oxide of at least 2.5 percent.

IV. There shall be at least a two (2) minute soak time in the soaker tank.

V. The temperature of the soaker tank shall be at least 69°C (155°F); and
the final rinse subsequent to the soaking tank shall be with a sanitizing solution.

VI. The soaker-type washer system shall be so designed and operated that unless the time, temperature, and concentration, as specified for the soaker solutions, are met, the containers cannot be discharged from the washer. The mechanism for control of the time, temperature, and concentration of the use solution shall be sealed.

VII. A standard must be available for the use of the Health Officer for testing the proper sensitivity functioning levels of the detection device.

VIII. A thorough inspection procedure shall be in effect to remove any containers which show stress cracks, splitting, pitting, discoloration, or cloudiness, as well as any unremoved soil. This shall be carried out with adequate light and be much more thorough than the customary cursory inspection given to glass bottles.

IX. The containers shall comply with the applicable construction requirements of Rule 420-3-16-.10(11). The closure for the container shall be single-service. Screw-type closures shall not be used.

X. The container shall not impart into the product pesticide residual levels or other chemical contaminants in excess of those considered acceptable under the FFDCA, as amended and regulations issued there under.

XI. The phrase "Use only for food" shall appear on all containers.

19. The following requirements are for NCIMS listed milk plants choosing to use single-service glass bottles for the packaging of Grade “A” milk and/or milk products:

(i) Single-service glass containers shall be manufactured from non-toxic materials, packaged, and shipped in a manner that protects them from contamination, (i.e., shrink-wrapped in plastic or

other methods acceptable to the Health Officer). All containers shall be identified (coding is acceptable) as to the plant of manufacture. Closures for the containers shall be single-service, designed to protect the pouring lip of the container and from an IMS listed fabricator.

(ii) These containers shall be inspected prior to filling to determine general condition, damage, and/or the presence of foreign materials, broken glass, and other contaminates, etc.

(iii) Single-service glass containers shall be sanitized immediately prior to filling. Sanitizing solutions shall be removed from the container prior to filling. Inverted draining, sterile air evacuation, or other effective methods acceptable to the Health Officer may accomplish this.

(iv) As determined by the Health Officer, single-service glass containers that are received at the processing plant in an unclean and/or unprotected state shall be properly cleaned and sanitized immediately prior to packaging. This cleaning and sanitizing operation shall be conducted in a room separate from case washing operations and rooms used for the pasteurization, processing, cooling, and packaging of milk and milk products. Equipment and procedures used for the cleaning of single-service glass bottles shall meet all the requirements of this Item 5 including recommended sanitization efficiency tests by the Health Officer.

(v) Single-service glass containers shall be labeled with wording to designate “single-service use only.”

(13) **Storage of Cleaned Containers and Equipment**

(a) After cleaning, all multi-use milk product containers, utensils, and equipment shall be transported and stored to assure complete drainage and shall be protected from contamination before use.

(b) Public Health Reason - If containers and equipment are not protected from contamination, the value of sanitization may be partly or entirely nullified.

(c) Administrative Procedures - This item is deemed to be satisfied when:

1. All multi-use containers, equipment, and utensils, after cleaning, are transported and/or stored on metal racks or racks made of impervious food grade material, in

clean cases, elevated above the floor. Containers shall be stored inverted on racks or in cases constructed of relatively nonabsorbent, corrosion-resistant, nontoxic materials, or otherwise protected from contamination.

2. Floors are not flushed or washed when crates of clean bottles are stacked on them.

(14) **Storage of Single-Service Containers, Utensils, and Materials**

(a) Single-service closure, closure stock, parchment paper containers, gaskets, liners, bags, and other single-service articles for use in contact with milk, milk products, and frozen desserts shall be purchased and stored in sanitary tubes, wrappings, or cartons; shall be kept therein in a clean, dry place until used; and shall be handled in a sanitary manner.

(b) Public Health Reason - Soiled or contaminated closures, parchment paper, gaskets, and single-service containers nullify the benefits of the safeguards prescribed throughout these rules. Packing the closures in tubes which remain unbroken until they are placed in the bottling machine is the best method of assuring closure cleanliness.

(c) Administrative Procedures - This item is deemed to be satisfied when:

1. Single-service closures, closure stock, parchment paper, containers, gaskets, liners, bags, and other single-service articles for use in contact with milk, milk products, and frozen desserts are purchased and stored in sanitary tubes, wrappings, or cartons; are kept in a clean, dry place until used; and are handled in a sanitary manner.

2. Paperboard shipping containers used to enclose plastic bags or unfilled containers are used only once unless other methods are employed to protect the containers from contamination.

3. Tubes or cartons are not refilled with spilled caps, gaskets, or parchment papers.

4. Cartons or boxes from which contents have been partially removed are kept closed.

5. Suitable cabinets are provided for storage of tubes after removal from the large outer box and for storage of opened cartons, unless other satisfactory means are employed to protect the caps, closures, or containers.

(15) **Protection from Contamination**

(a) Milk and frozen dessert plant operations, equipment, and facilities shall be located and conducted to prevent any contamination of milk, milk products, or frozen desserts, ingredients, equipment, containers, and utensils. All milk, milk products, or frozen dessert products or ingredients which have been spilled, overflowed, or leaked shall be discarded. The processing or handling of products other than milk and milk products in the pasteurization plant shall be performed to preclude the contamination of such milk, milk products, and frozen desserts. The storage, handling, and use of poisonous or toxic materials shall be performed to preclude the contamination of milk, milk products, and frozen desserts or ingredients of such milk, milk products, and frozen desserts or the product-contact surfaces of all equipment, containers, or utensils. Milk plant operations that handle nondairy food allergens shall have a written food allergen control plan to protect milk, milk products, and frozen dessert products from allergen cross-contract, including during storage and use, and to ensure proper declaration of allergens on product labeling.

(b) Public Health Reason - Because of the nature of milk, milk products, and frozen desserts and their susceptibility to contamination by bacteria, chemicals, and other adulterants, as well as the potential for allergen cross-contact of such products in certain facilities, every effort should be made to provide adequate protection for the milk, milk products, and frozen desserts at all times. Public health officials have long recognized that raw milk contains microorganisms of public health concern and it is important to understand that these microorganisms may be found in the milk plant environment if measures are not taken to minimize the risk of contamination by these microorganisms. Contamination of milk from the environment can result in milkborne illness. Misuse of pesticides and other harmful chemicals can provide opportunities for contamination of the milk, milk product, or frozen dessert or equipment with which the milk, milk product, or frozen dessert comes in contact.

(c) Administrative Procedures - This item is deemed to be satisfied when:

1. Equipment and operations are so located within the plant as to prevent overcrowding and contamination of cleaned and sanitized containers, equipment, and utensils by splash, condensation, or manual contact.

2. Packaged milk, milk products, and frozen desserts which have physically left the premise or the processing plant are not repasteurized for Grade “A” or grade manufacturing use. The Health Officer may, on a specific individual request, authorize reprocessing of packaged milk, milk products, and frozen desserts; provided, all other aspects of this item, including proper storage

temperature and container integrity are complied with; provided, that the re-pasteurization of milk, milk products, and frozen desserts shipped in milk transport tankers which have been pasteurized at another Grade "A" or manufacturing grade plant and have been handled in a sanitary manner and maintained at 7°C (45°F) or less is permitted. Equipment, designated areas, or rooms utilized for storage, processing, and handling of returned packaged milk, milk products, and frozen desserts are maintained, operated, cleaned, and sanitized so as to preclude contamination of Grade "A" milk, milk products, frozen dessert products, equipment, and the operations.

Note: The option for the authorizing of the reprocessing of packaged milk and/or milk products on an individual request, as cited in 2 above, shall not be applicable to a TPC authorized under the ICP.

3. All product-contact surfaces of containers, equipment, and utensils are covered or otherwise protected to prevent the access of insects, dust, condensation, and other contamination. All openings, including valves and piping attached to milk and milk product storage tanks and milk tank trucks, pumps, or vats, etc., shall be capped or otherwise properly protected. While unloading at a receiving station, transfer station, or pasteurization plant, one of the following conditions shall be met:

(i) If the area is completely enclosed (walls and ceiling, with doors closed) during the unloading process and the dust-cover or dome and the manhole cover is opened slightly and held in this position by the metal clamps used to close the cover, then a filter is not required. However, if the dust-cover and/or manhole cover(s) are opened in excess of that provided by the metal clamps or the covers have been removed, then a suitable filter is required for the manhole.

(ii) If the area is not completely enclosed or doors of the unloading area are open during unloading, a suitable filter is required for the manhole or air inlet vent and suitable protection must be provided over the filter material either by design of the filter holding apparatus or a roof or ceiling over the area. When weather and environmental conditions permit, manhole openings and covers of milk tank trucks may be opened outdoors for the short period of time necessary for the collection of samples for animal drug residue screening. Direct connections from milk tank truck to milk tank truck must be made from valve to valve or through the manhole lid;

provided, all connections are made ferrule-to-ferrule and adequate protection is provided for the air vent.

(iii) Receiving and dump vats shall be completely covered, except during washing and sanitizing, and when milk is being dumped. Where strainers are used, the cover for the vat opening shall be designed to cover the opening with the strainer in place.

4. Ingredients added to milk, milk products, and frozen desserts are handled in such a manner as to avoid contamination.

5. Whenever air under pressure is used for the agitation or movement of milk, or is directed at a milk-contact surface, it is free of oil, dust, rust, excessive moisture, extraneous materials, and odor, and shall otherwise comply with the applicable standards of Appendix H. Air intakes for drying equipment shall be located so as to minimize the amount of atmospheric contamination and shall be equipped with suitable single-service filters, multi-use filters, or continuous air filter systems (refer to Appendix H). The use of steam containing toxic substances is expressly prohibited. Whenever steam is used in contact with milk, milk products, or frozen desserts it shall be of culinary quality and shall comply with the applicable standards of Appendix H.

6. Air exhausts from the dryer systems are covered when dryers are not in operation.

7. Standardization is done before the pasteurization process is started, unless pasteurized milk or milk products are used for standardization. Such pasteurized milk products shall be protected against contamination. In no case shall pasteurized milk or milk products be standardized with unpasteurized milk unless the standardized product is subsequently pasteurized. Reconstituted or recombined milk and milk products shall be pasteurized after reconstitution or recombining of all ingredients. Standardization of Grade “A” milk and milk products with other than Grade “A” milk and milk products is prohibited. These rules permit standardization as a process of adjusting the milkfat of milk in a milk plant by the addition or removal of cream or non-fat milk.

8. All multi-use cases used to encase packaged milk, milk product, or frozen dessert containers are cleaned prior to their use.

9. All ingredients and non-product-contact materials used in the preparation or packaging of milk, milk products,

and frozen desserts are stored in a clean place and are so handled as to prevent their contamination.

10. Pasteurized milk and milk products are not strained or filtered, except through a perforated metal strainer; provided, pasteurized milk and milk products that are concentrated (condensed) in membrane processing systems may be filtered; provided, a single service in-line filter that is sanitized after assembly may be allowed if it is a part of the membrane processing system.

11. Only those poisonous or toxic materials, including, but not limited to, insecticides, rodenticides, detergents, sanitizers, caustics, acids, related cleaning compounds, and medicinal agents necessary for the maintenance of the dairy or frozen dessert plant are present in the dairy and frozen dessert plant.

12. Those poisonous or toxic materials that are necessary are not stored in any room where milk, milk products, or frozen desserts are received, processed, pasteurized, condensed, dried, or stored or where equipment, containers, or utensils are washed or where single-service containers, closures, bags, or caps are stored.

13. Those poisonous or toxic materials that are necessary are stored in a separate area of the plant in prominently and distinctly labeled containers; provided, this does not preclude the convenient availability of detergents or sanitizers to areas where equipment, containers, and utensils are washed and sanitized.

14. Only insecticides and rodenticides approved by the Health Officer and/or registered with the EPA shall be used for insect and rodent control. Such insecticides and rodenticides shall be used only in accordance with the manufacturer's label directions and shall be prevented from contaminating milk, milk products, frozen dessert products, containers, equipment, and utensils.

15. During processing, pipelines and equipment used to contain or conduct milk, milk products, and frozen desserts shall be effectively separated from tanks or circuits containing cleaning and/or sanitizing solutions. In the case of separating non-Grade “A” and Grade “A” milk or milk products, a water rinse after processing non-Grade “A” and prior to Grade “A” is adequate separation; provided, both processed as Grade “A” and raw and pasteurized milk or milk products are kept physically separated.

16. Grade "A" raw milk or milk products and non-Grade "A" raw products, dairy or non-dairy, shall be separated by one (1) valve.

17. Grade "A" pasteurized milk or milk products and non-Grade "A" pasteurized products, dairy or non-dairy, shall be separated by one (1) valve.

18. Provided, during the actual flushing of raw milk or milk product lines and vessels with water, there shall be a sufficient separation between water piping and unpasteurized milk or milk products or lines used to conduct unpasteurized milk or milk products, to prevent the accidental addition of water.

19. Water piping and raw milk and milk product lines and vessels may be separated by one (1) fail-safe valve that upon loss of air or power shall move to a position that will close or block the water lines from milk or milk product lines or vessels. Water piping conducting water which has undergone an equivalent process to pasteurization as described in Rule 420-3-16 (15) and pasteurized milk and milk product lines or vessels may also be separated by one (1) fail-safe valve. In addition, a sanitary check-valve or a sanitary valve arrangement(s) that is equally effective shall be located between the fail-safe valve and the milk product line(s) and/or vessel(s). Sanitary piping shall be used downstream from the sanitary check-valve. Provisions shall be made for cleaning this sanitary piping.

Note: Refer to Rule 420-3-16-.10(7), Administrative Procedures page 74, for additional requirements involving the protection of the water system.

20. When two (2) grades of milk or milk products are received in the same milk plant in dual receiving equipment, a swing type dump grill is not permitted. When two (2) grades of milk or milk products are received in the milk plant by milk tank trucks, the following options may be used:

(i) Separate receiving equipment and unloading pumps shall be provided; or

(ii) The receiving equipment and pump shall be subjected to a water rinse, as provided in Administrative Procedures 15 above, prior to use with Grade "A" milk or milk product; or

(iii) The non-Grade "A" milk or milk product shall be received last and the equipment washed and sanitized prior to receiving Grade "A" milk or milk products.

21. All milk, milk products, and frozen desserts which have overflowed, leaked, have been spilled, or improperly handled are discarded. Milk, milk products, and frozen desserts drained from processing equipment at the end of a run, collected from a defoamer system, and milk solids rinsed from equipment, containers, or pipelines shall be re-pasteurized only if such milk, milk products, and frozen desserts are handled in a sanitary manner and maintained at 7°C (45°F) or less. When the handling and/or refrigeration of such milk, milk products, and frozen desserts are not in compliance with this requirement, they shall be discarded. Milk, milk products, and frozen desserts from damaged, punctured, or otherwise contaminated containers or product from out of code containers shall not be re-pasteurized for use.

22. Means are provided to prevent contamination of milk containers, utensils, and equipment by drippings, spillage, and splash from overhead piping, platforms, or mezzanines.

23. The processing of foods and/or drinks other than Grade "A" milk and milk products are performed to preclude the contamination of such milk, milk products, and frozen desserts.

24. During processing, pipelines and equipment used to contain or conduct milk, milk products, and frozen dessert products shall be effectively separated from tanks/silos and/or circuits containing cleaning and/or sanitizing solutions. This can be accomplished by:

(i) Physically disconnecting all connection points between tanks/silos and/or circuits containing cleaning and/or sanitizing solutions from pipelines and equipment used to contain or conduct milk and/or milk products; or

(ii) Separation of all connection points between such circuits by at least two (2) automatically controlled valves with a drainable opening to the atmosphere between the valves; or by a single-bodied double seat mixproof valve, with a drainable opening to the atmosphere between the seats, if:

(I) the drainable opening to the atmosphere (vent) is equal to the largest pipeline connected to the mixproof valve or one (1) of the following exceptions:

a. If the cross sectional area of the vent opening is less than that of the largest pipe diameter for the double seat valve, the

maximum pressure in the space between the two (2) valve seats for the double seat valve shall be equivalent to or less than the maximum pressure in the space between the two (2) blocking seats of two (2) automatically controlled compression type valves (three [3]-way valve to the drain and a two [2]-way valve separating product lines from cleaning and/or sanitizing solution lines); or

b. In low pressure gravity drain applications, (i.e., cheese curd transfer lines from cheese process vats where the product line is the same size or larger than the cleaning and/or sanitizing solution line), the vent may be the size of the solution line and the valves or valve seats are not required to be position detectable. In order to accept this variation, the valve(s) shall fail to the blocked position upon loss of air or power, and there shall not be any pumps capable of pushing milk and/or milk product, cleaning solutions, and/or sanitizing solutions into this valve arrangement.

(II) Both valves and valve seats, in the case of single-bodied double seat valves, are position detectable and capable of providing an electronic signal when not properly seated in the blocked position (refer to Appendix H, I-pg. H-1).

(III) These valves or valve seats, in the case of single-bodied double seat valves, are part of an automatic fail-safe system that shall prevent the contamination of milk, milk products, and frozen dessert products with cleaning and/or sanitizing solutions. Automatic fail-safe systems shall be unique to each particular installation, but are normally based on the premise that both blocking valve seats are properly seated in the blocked position before the CIP cleaning system can be activated for the cleaning circuit containing this valve arrangement, except as provided in (VI) below.

(IV) The system shall not have any manual overrides.

(V) Controls for the fail-safe system are secured as directed by the Health Officer in order to prevent unauthorized changes.

(VI) The vent is not cleaned until milk and/or milk products have been removed or isolated, except in the case of a properly designed and operated single-bodied double seat valve, in which case, the vent may be cleaned while milk and/or milk products are present in one (1) of the valve housings. A properly designed and operated single-bodied double-seat valve shall incorporate the following:

I. There shall not be any impingement of cleaning liquid on the opposite valve seat gasket during seat lifting, even in the case of damaged or missing gaskets.

II. The pressure in the critical seat area of the valve vent cavity, even in the case of damaged or missing gaskets, shall be demonstrated to be atmospheric or less at all times.

III. During a seat-lift operation, the position of the seat opposite to the seat being lifted shall be monitored by a position detection device that is interlocked with the cleaning pump or source of the CIP cleaning solution pressure such that if this opposite seat is determined to be other than fully closed, the cleaning pump or source of the CIP cleaning solution pressure shall be immediately de-energized.

IV. The single-bodied double seat valve vent cavity cleaning option shall have an Automated Fail-Safe Control System and the Control System shall comply with applicable provisions of Appendix H, VI.

(VII) Variations from the above specifications may be individually evaluated and found to also be acceptable if the level of protection is not compromised.

(iii) In the case of higher-heat-shorter-time (HHST) pasteurized milk and milk products that are processed and the equipment cleaned and/or chemically sanitized above the atmospheric boiling point of the milk or milk product or cleaning and/or sanitizing solutions, the required separation between pipe lines and equipment used to contain or conduct milk and milk products and tanks or circuits containing cleaning and/or chemical sanitizing solutions may be accomplished using an alarmed steam block(s), located

between the milk and milk product or cleaning and/or chemical sanitizing solutions if:

(I) The steam block is equipped with a visible steam trace that exits at the bottom of the steam block;

(II) The steam trace is equipped with a temperature sensor that is capable of differentiating between those temperatures that indicate steam exiting the steam trace has not been exposed to liquid in the steam block and temperatures that will occur when liquid is present in the steam block;

(III) This steam trace shall be physically isolated from other steam lines or traces such that the temperature sensor measures the steam temperature only from that single trace;

(IV) The temperature sensor is integrated with automatic controls, such that when there is milk or milk products on one (1) side of the steam block and cleaning and/or chemical sanitizing solutions on the other side of the steam block, and the temperature sensor in the steam trace detects a temperature that indicates that liquid, rather than steam, is present in the steam trace, the cleaning pump shall be de-energized, and when needed to prevent solution pressure on the steam block, the cleaning and/or chemical sanitizing solution are automatically drained away from the steam block. Except that in systems where the cleaning and/or sanitizing solution is circulated by the timing pump, that pump may continue to operate during an alarmed condition; provided, a legal flow-diversion device (FDD) is used to divert the cleaning and/or chemical sanitizing solution flow away from the steam block.

(V) During times when a steam block(s) is used as described in this section to provide separation between pipe lines and equipment used to contain or conduct milk and milk products and tanks or circuits containing cleaning and/or chemical sanitizing solutions, there shall be no time delays or other means that delay an immediate automatic response to liquid exiting the steam trace;

(VI) Although the automatic control system is not required to comply with Appendix H, VI, there shall be means provided to test and verify the

accuracy of the sensor and the operation of the control system.

(VII) In order to facilitate testing, the temperature set point that will activate the automatic controls described in this section shall be identified for each steam block used for this purpose. Means shall be provided to verify that lowering the temperature below this set point will activate the control system when a steam block(s) is used, as described in this section, to provide separation between pipe lines and equipment used to contain or conduct milk and milk products and tanks or circuits containing cleaning and/or chemical sanitizing solutions.

Note: The valve arrangement(s) described in this section shall not be used to separate raw products, dairy, non-dairy, or water, from pasteurized milk or milk products; provided, nothing in this section shall be construed as barring any other means to separate milk and milk product from cleaning/sanitizing solution in systems which have been recognized by the FDA to be equally effective and which are approved by the Health Officer.

25. Except as permitted in Rule 420-3-16-.10(16), there shall be no physical connection between unpasteurized products, dairy, non-dairy, or water, and pasteurized milk or milk products. Pasteurized non-dairy products not completely separated from pasteurized milk and milk products shall be pasteurized in properly designed and operated equipment at times and temperatures which meet at least the minimum times and temperatures provided for in the definition of pasteurization.

In the case of water, it shall:

(i) Meet at least the minimum times and temperatures provided for in the definition of pasteurization in equipment that may not meet Rule 420-3-16-.10(16); or

(ii) Meet the requirements found in Appendix H, Rule 420-3-16-.10(16); or

(iii) Have undergone an equivalent process found acceptable by FDA and the Health Officer; or

(iv) Have undergone a hazard evaluation and safety assessment of the specific water supply and application involved and has undergone an additional treatment to destroy or remove bacteria acceptable to

the Health Officer, in consultation with the FDA, to ensure the water will not compromise the safety of the milk or milk product. Supporting information shall be submitted to and approved by the Health Officer. The supporting information may include, but is not limited to the following:

(I) Statement of proposal.

(II) Intended use.

(III) Review of equipment to be used in the process.

(IV) Diagram of the process of interest.

(V) Documentation that the source water shall meet or exceed the EPA Safe Drinking Water Bacteriological Standards. Safety Assessment comparison of samples from the facility's water source, pasteurized water, and proposed equivalent water. Water samples shall be collected daily for two (2) weeks following approval of the initial installation and every six (6) months thereafter.

(VI) Protocol for the continued monitoring of criteria and procedures; provided, that daily tests shall be conducted for one (1) week following any repairs or alteration to the system.

a. In the event of a water control authority issued boil water order or other emergency that renders the water supply to be a public health concern, the established approved equivalency protocol shall be evaluated to determine that it will continue to produce water equivalent to pasteurized water. In addition, a safety assessment shall be made of the milk, milk products, and frozen dessert products that may have been affected during the time that the water utilized may not have been equivalent to pasteurized water.

b. This section does not require separate raw and pasteurized CIP cleaning systems.

26. Pasteurized re-circulation lines, divert lines, and leak-detect lines connecting to the constant-level tank shall be designed so that there is an air gap between the termination of these pipelines and the raw milk or milk

product overflow level. This air gap shall be equivalent to at least two (2) times the diameter of the largest of these pipelines. For purposes of this section, an overflow is defined as the flood rim of the constant-level tank or any unrestricted opening below the flood rim of the constant-level tank which is large enough that it is at least equivalent to two (2) times the diameter of the largest of these pipelines.

27. All milk and/or milk products that have overflowed, leaked, been spilled, or improperly handled are discarded. Milk and/or milk products drained from processing equipment at the end of a run, collected from a defoamer system, and milk or milk product solids rinsed from equipment, containers, or pipelines shall be repasteurized only if such milk or milk products are handled in a sanitary manner and maintained at 7°C (45°F) or less. When the handling and/or cooling of such milk and/or milk products are not in compliance with this requirement, they shall be discarded. Milk, milk products, and frozen dessert products from damaged, punctured, or otherwise contaminated containers or product from out-of-code containers shall not be repasteurized for Grade "A" use.

28. Means are provided to prevent contamination of milk and/or milk products, containers, utensils and equipment by drippings, spillage, and splash from overhead piping, platforms, or mezzanines.

29. The processing of foods and/or drinks other than Grade "A" milk, milk products, and/or frozen dessert products are performed to preclude the contamination of such milk, milk products, and frozen dessert products.

30. No product is handled in the milk or frozen dessert plants that may create a public health hazard. Permission to handle products other than those defined in Rule 420-3-16-.02 or to conduct operations in equipment or rooms, other than those for which they are designated, should be provisional and subject to revocation if found objectionable.

31. In no case shall pasteurized milk, milk products, and frozen dessert products be standardized with unpasteurized milk or milk products, unless the standardized milk or milk product is subsequently pasteurized.

32. Reconstituted or recombined milk and milk products shall be pasteurized after reconstitution or recombining of all ingredients.

33. Raw milk or milk product-to-water-to-pasteurized milk or milk product plate or double/triple tube type heat exchangers may be used for heat-exchange purposes other than legal pasteurization, when constructed, installed, and operated in accordance with the following:

(i) Plate or double/triple tube type heat exchangers, as described above, shall be constructed, installed, and operated so that pasteurized milk or milk product in the plate or double/triple tube type heat exchanger will automatically be under greater pressure than the heat-transfer water in the plate or double/triple tube type heat exchanger at all times.

(ii) The pasteurized milk or milk product between the outlet of the last flow promoting device and the entrance to the plate or double/triple tube type heat exchanger shall rise to a vertical elevation of 30.5 centimeters (twelve [12] inches) above the highest heat-transfer water level, downstream from the water supply tank, and shall be open to the atmosphere at this or a higher elevation.

(iii) The pasteurized milk or milk product between its outlet from the plate or double/triple tube type heat exchanger and the nearest point downstream open to the atmosphere shall rise to a vertical elevation of 30.5 centimeters (twelve [12] inches) above the highest heat-transfer water level, downstream from the water supply tank, and shall be open to the atmosphere at this or a higher elevation.

(iv) The overflow of the top rim of the water supply tank shall always be lower than the lowest heat-transfer water level in the plate or double/triple tube type heat exchanger.

(v) A pump(s) or flow-promoting device(s), which can affect the proper pressure relationships within the plate or double/triple tube type heat exchanger, shall not be located between the pasteurized milk or milk product outlet from the plate or double/triple tube type heat exchanger and the nearest downstream point open to the atmosphere.

(vi) A pump(s) shall not be located between the heat-transfer water inlet to the plate or double/triple tube type heat exchanger and the water supply tank, unless it is designed and installed to operate only when pasteurized milk or milk product is flowing through the pasteurized milk or milk product side of the plate or double/triple tube type heat exchanger and when the pressure of the pasteurized milk or milk

product is higher than the maximum pressure produced by the pump(s). This may be accomplished by wiring the heat-transfer water pump(s) so that it cannot operate unless:

(I) Pasteurized milk or milk product is flowing through the pasteurized milk or milk product side of the plate or double/triple tube type heat exchanger.

(II) The pasteurized milk or milk product pressure exceeds, by at least 6.9 kPa (1 psi), the maximum pressure developed by the heat-transfer water pump. A pressure differential controller shall be installed with a sensor located at the heat-transfer water inlet to the plate or double/triple tube type heat exchanger and the pasteurized milk or milk product outlet of the plate or double/triple tube type heat exchanger. The differential set point of this pressure differential controller shall be tested by the Health Officer upon installation; at least once every three (3) months thereafter; whenever the regulatory seal has been broken; and following any repair or replacement. Accuracy shall be determined by utilizing testing procedures as outlined in Appendix I, Test 9.2.1 to assure that the pressure differential controller probes are accurately calibrated. Also, the applicable procedures cited in Appendix I, Test 9.2.2 shall be utilized to assure that the pressure differential controller is accurately calibrated and will de-energize the heat-transfer water pump at the required differential pressure set point.

(vii) All heat-transfer water in the plate or double/triple tube type heat exchanger shall automatically drain freely back to the water supply tank or to the floor when the heat transfer water pump(s) are shut down and the heat-transfer water connection(s) at the plate or double/triple tube type heat exchanger is disconnected.

34. Food Allergen Control - A milk plant operation that handles nondairy food allergens shall implement a written food allergen control plan that includes procedures, practices, and processes to control food allergens. Food allergen controls shall include those procedures, practices, and processes employed for:

(i) Ensuring protection of food from allergen cross-contact, including during storage and use.

(ii) Labeling the finished food, including ensuring that the finished food is not misbranded under Section 403(w) of the FFD&CA with an undeclared food allergen.

(iii) Raw materials and ingredients that are food allergens, and rework that contains food allergens, shall be identified and held in a manner that prevents cross-contact.

35. Environmental Monitoring - A milk plant shall have a written environmental monitoring program that is implemented and supported by records for milk, milk products, and frozen desserts exposed to the environment when the milk, milk products, and frozen desserts do not subsequently receive a treatment that would significantly minimize the pathogen. The environmental monitoring program shall, at a minimum:

(i) Be supported by scientific information.

(ii) Include written procedures and records.

(iii) Identify environmental monitoring locations and the number of sample sites to be tested during routine environmental monitoring.

(iv) Identify the timing and frequency for collecting and testing samples.

(v) Identify the environmental pathogen or appropriate indicator microorganism for which to test.

(vi) Identify the test(s) conducted, including the analytical method used, and the test result.

(vii) Identify the laboratory conducting the testing.

(viii) Include corrective action procedures for environmental monitoring test results.

36. Supplier Control Program - A milk plant or frozen dessert plant shall have a supplier control program for raw materials and ingredients that is implemented and supported by records to control food safety hazards. The supplier control program shall, at a minimum;

(i) Document that all milk and/or milk product ingredients are obtained from an IMS listed source or, when an IMS source does not exist that the supplier has, at a minimum, a functional risk-based program with appropriate controls to significantly

minimize hazards for all milk, milk product, and frozen dessert ingredients obtained from non-IMS listed sources utilized in the milk plant's Grade "A" milk and/or milk products.

(ii) Document that a supplier of non-milk and/or milk, milk product, and frozen desserts product ingredients has a functional and written food safety program that includes allergen management, if utilized in the milk plant's Grade "A" milk and/or milk products.

(16) **Pasteurization, Aseptic Processing and Packaging and Retort Processed After Packaging**

(a) Pasteurization shall be performed as defined in Rule 420-3-16-.02 and 420-3-16-.10(16). Aseptic processing and packaging and retort processed after packaging shall be performed
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in accordance with the applicable requirements of 21 CFR Parts 108, 110, and 113 (refer to Appendix L).

1. In all cases, except for the specific exemptions provided for in Administrative Procedures 3, pasteurization of raw milk or milk product shall be performed before the raw milk, milk product, or frozen dessert product enters the reverse osmosis (RO), ultra-filtration (UF), evaporator, or condensing equipment and shall be performed in the milk plant where the processing is done. All condensed milk, milk products, and frozen dessert products transported to a milk plant or frozen dessert plant for drying shall be re-pasteurized at the milk plant or frozen dessert plant at which it is dried. If condensed whey containing at least 40 percent total solids has been partially crystallized by cooling, it may be transported to a separate milk plant for drying without re-pasteurization, provided the following conditions are complied with:

2. The condensed, partially crystallized whey is cooled and maintained at 7°C (45°F) or less.

3. Milk tank trucks dedicated to hauling pasteurized product shall be used to transport the condensed, partially crystallized whey and shall be washed and sanitized immediately prior to filling and then sealed after filling until unloading.

4. Separate unloading pumps and pipelines shall be provided and used only for the unloading of the condensed, partially crystallized whey. Such pumps and

pipelines shall be cleaned and sanitized as a separate cleaning circuit.

(b) Public Health Reason

1. The public health value of pasteurization is unanimously agreed upon by health officials. Long experience conclusively shows its value in the prevention of diseases which may be transmitted through milk. Pasteurization is the only practical commercial measure which, if properly applied to all milk, will destroy all milk-borne disease organisms. Examination of lactating animals and milk handlers, while desirable and of great value can be done only at intervals and, therefore, it is possible for pathogenic bacteria to enter the milk for varying periods before the disease condition is discovered. Disease bacteria may also enter milk accidentally from other sources such as flies, contaminated water, utensils, etc. It has been demonstrated that the time-temperature combinations specified by these rules, if applied to every particle of milk, will devitalize all milk-borne pathogens. Compilations of outbreak of milk-borne disease by the U.S. Public Health Service (USPHS) and FDA over many years indicate that the risk of contracting disease from raw milk is approximately fifty (50) times as great as from milk labeled "pasteurized."

2. A note of caution is in order. Although pasteurization devitalizes the organisms, it does not destroy the toxins that may be formed in milk and/or milk products when certain staphylococci are present (as from udder infections), and when the milk, milk products, and/or frozen dessert product are not properly refrigerated before pasteurization. Such toxins may cause severe illness. Aseptic processing and packaging and retort processed after packaging have also been conclusively demonstrated to be effective in preventing outbreaks from milk borne pathogens.

3. Numerous studies and observations clearly prove that the food value of milk is not significantly impaired by pasteurization.

(c) Administrative Procedures - The pasteurization portion of this item is deemed to be satisfied when:

1. Every particle of milk, milk product, or frozen dessert is heated in properly designed and operated equipment to one of the temperatures specified in the following table and held continuously at or above that temperature for at least the time specified:

Table 3. Pasteurization Temperature vs.

Batch (Vat) Pasteurization	
Temperature	**Time**
63°C (145°F)*	30 Minutes
Continuous Flow (HTST and HHST) Pasteurization	
Temperature	**Time**
72°C (161°F)*	15 Seconds
89°C (191°F)	1.0 Seconds
90°C (194°F)	0.5 Seconds
94°C (201°F)	0.1 Seconds
96°C (204°F)	0.05 Seconds
100°C (212°F)	0.01 Seconds

*If the fat content of the milk product is 10 percent or greater, or a total solids of 18 percent or greater or if it contains added sweeteners, the specified temperature shall be increased by 5˚F (3˚C); provided, that eggnog and frozen dessert mix shall be heated to at least the following temperature and time specifications:

Table 3. Pasteurization Temperature vs.	
Batch (Vat) Pasteurization	
Temperature	**Time**
69°C (155°F)*	30 Minutes
Continuous Flow (HTST) Pasteurization	
Temperature	**Time**
80°C (175°F)*	25 Seconds
83°C (180°F)	15 Seconds

2. Provided, nothing shall be construed as barring any other pasteurization process for milk, milk products, and/or frozen dessert products which has been recognized by the FDA as provided in FFD&CA to be equally efficient and which is approved by the State Health Officer.

3. All milk and milk products, (i.e., milk solids, whey, nonfat dry milk, condensed milk, cream, skim milk, etc.), eggs, egg products, cocoa, cocoa products, emulsifiers, stabilizers, vitamins, and liquid sweeteners shall be added prior to pasteurization; provided, ingredients which may be added after pasteurization are those flavoring ingredients and other ingredients which have been found to be safe and suitable and which include:

(i) Ingredients permitted by the CFR standards of identity when considering a standardized milk or milk product.

(ii) Fresh fruits and vegetables added to cultured milk and milk products; provided, the resultant equilibrium pH level (4.6 or below when measured at 24˚C (75˚F) of the finished product is reached

without undue delay and is maintained during the shelf life of the product.

(iii) Ingredients subjected to prior heating or other technology, which has been demonstrated to the FDA to be sufficient to destroy or remove pathogenic microorganisms.

(iv) Ingredients having an Aw of 0.85 or less.

(v) Ingredients having a high acid content (pH level of 4.6 or below when measured at 24°C (75°F) or high alkalinity (pH level greater than 11 when measured at 24°C [75°F]).

(vi) Roasted nuts.

(vii) Dry sugars and salts.

(viii) Flavor extracts having a high alcohol content.

(ix) Safe and suitable bacterial cultures and enzymes.

(x) Ingredients which have been found to be safe and suitable by the FDA.

All such additions shall be made in a sanitary manner which prevents the contamination of the added ingredient or the milk or milk product.

4. All milk and milk products shall be pasteurized, prior to the entrance into RO, UF, evaporator, or condensing equipment, and shall be performed in the milk plant where the processing is done, except that:

(i) If the product is whey, pasteurization is not required, provided:

(I) The product is acid whey (pH less than 4.7); or

(II) It is processed in RO or UF equipment at temperatures at or below 7°(C) (45°F).

(ii) If the product is raw milk for pasteurization, the product may be concentrated by the use of RO or UF membrane filtration without pasteurization prior to the entrance into the equipment; provided, the following sampling, testing, design, installation, and operational criteria are met:

(I) Prior to processing, all raw milk supplies are sampled and tested for antibiotic residues in accordance with the provisions of Appendix N.

(II) The RO or UF filtration system is designed and operated to assure that milk or milk product temperature is maintained at or below 18.3°C (65°F) throughout the process; provided, the product temperature may rise above 18.3°C (65°F) for a period of not more than fifteen (15) minutes, further provided, should the product temperature rise above 21.1°C (70°F), the product shall be either immediately diverted to the system's balance tank until the product is again below 18.3°C (65°F) or diverted to exit the system entirely. Diverted product that has exited the system shall be either discarded, immediately cooled to below 7°C (45°F), or immediately pasteurized.

(III) The RO or UF system shall be equipped with temperature monitoring and recording devices that comply with the applicable specifications outlined in Appendix H. At a minimum, milk or milk product temperature shall be monitored and recorded prior to entering the system, prior to entering each stage of the modules in series that contains cooling, and the retentate stream prior to any final cooler and upon exiting the system.

(IV) If the RO or UF system is not designed, installed, and operated in accordance with the above noted criteria, the raw milk or milk product shall be pasteurized prior to entering the RO or UF system.

5. Milk and/or milk products for pasteurization may be processed by micro-filtration (MF) systems prior to pasteurization for the sole purpose of the removal of micro-organisms; provided,

(i) Prior to processing, all raw milk supplies are sampled and tested for antibiotic residues in accordance with the provisions of Appendix N.

(ii) If there is a continuous, circulating retentate loop with a feed and bleed system, the following design, installation and operational criteria shall be complied with:

(I) The MF system is designed and operated to assure that milk or milk product temperature in the circulating retentate loop is maintained at

or below 18.3°C (65°F), or at or above 51.7°C (125°F) throughout the process; provided, the product temperature may rise above 18.3°C (65°F) or fall below 51.7°C (125°F) for a period of not more than fifteen (15) minutes; further provided, should the product temperature rise above 21.1°C (70°F) or fall below 48.9°C (120°F), the product shall be either immediately diverted to the system's balance tank until the product is again below 18.3°C (65°F) or above 51.7°C (125°F), or be diverted to exit the system entirely. Diverted product that has exited the system shall be either discarded, immediately cooled to below 7°C (45°F), or immediately pasteurized.

(II) The MF system shall be equipped with temperature monitoring and recording devices that comply with the applicable specifications outlined in Appendix H. At a minimum, milk or milk product temperature shall be monitored and recorded prior to entering the MF system and within the circulating retentate loop of each module just prior to the circulation pump.

(III) The permeate from the MF system is either immediately cooled to below 7°C (45°F), or immediately pasteurized.

6. All condensed milk and milk products transported to a milk plant for drying shall be repasteurized at the milk plant where it is dried.

7. If condensed whey containing at least 40 percent total solids has been partially crystallized by cooling, it may be transported to a separate milk plant for drying without re-pasteurization; provided, the following conditions are complied with:

(i) The condensed, partially crystallized whey is cooled and maintained at 7°C (45°F) or less.

(ii) Milk tank trucks used to transport the condensed, partially crystallized whey shall be washed and sanitized immediately prior to filling and are sealed after filling until unloading.

(iii) Separate unloading pumps and pipelines shall be provided and used only for the unloading of the condensed, partially crystallized whey. Such pumps and pipelines shall be cleaned and sanitized as a separate cleaning circuit.

8. The design and the operation of pasteurization equipment and all appurtenances thereto shall comply with the applicable specifications and operational procedures of sub-items (I), (II), (III), (IV), and (V) as follows:

(17) **Batch Pasteurization**

(1) All indicating and recording thermometers used in connection with the batch pasteurization of milk, milk products, or frozen desserts shall comply with the applicable specifications set forth in Appendix H. (Specifications for test thermometers and other test equipment appear in Appendix I).

(2) Public Health Reason

(a) Unless the temperature-control instruments and devices used on pasteurization equipment are accurate within known limits, there can be no assurance that the proper pasteurization temperature is being applied. Pasteurization must be performed in equipment which is properly designed and operated, and which ensures that every particle of milk, milk products, or frozen desserts will be held continuously at the proper temperature for the specified period of time.

(b) Recording thermometers are the only known means for furnishing the Health Officer with a record of the time and temperature of pasteurization. Experience has shown that recording thermometers due to their mechanical complexity are not entirely reliable. Therefore, mercury indicating thermometers or equivalent, which are much more reliable are needed to provide a check on the recording thermometers and assurance that proper temperatures are being applied.

(c) The recording thermometer shows the temperature of the product immediately surrounding its bulb, but cannot indicate the temperature of the product in other portions of the holder. Similarly, it shows the holding time in manual-discharge vats but not in automatic-discharge systems. The pasteurizer must, therefore, be so designed and so operated and, where necessary; provided, with such automatic controls as to assure that every portion of the milk, milk product, or frozen dessert product will be subjected to the proper temperature for the required length of time.

(d) Unless the inlet and outlet valves and connections to vats properly designed and operated, cold pockets of product may be held in the outlet valve or pipe-line; raw product may leak into the vat or pocket during the filling, holding, or emptying time; and raw or

incompletely pasteurized product may leak into the outlet line during the filling, heating, or holding period.

(e) Tests have shown that when foam is present on product in vats or pockets during pasteurization, the temperature of the foam may be well below the pasteurization temperature. In such cases, pathogenic organisms that may be in the foam will not be killed. Experience indicates that some foam is present at some time in all vats, particularly at certain seasons. Furthermore, in filling vats, product frequently is splashed on the surfaces and fixtures above the product level as well as on the underside of the vat cover. Droplets of this splash may drop back into the body of the product, and since they may not have been at pasteurization temperature for the required time, they may contain living pathogenic organisms. Heating the air above the product, above pasteurization temperature, remedies these conditions. When air heating is not provided, its need may frequently be demonstrated by swabbing product from the upper vat walls, and from the underside of the cover, at the end of the holding period, and running phosphatase tests on the swab samples.

(f) Many plant operators have reported that the use of airspace heaters, especially with partly filled vats with uninsulated lids, makes it easier to maintain the product at a uniform and sufficiently high temperature. It also helps to prevent the growth of thermophilic organisms and promotes easier cleaning.

(g) Obviously, if the design and construction of pasteurization vat and pocket covers do not prevent leakage, condensation, and the entrance of water and dust, the product may become contaminated with material containing disease bacteria. Keeping the covers closed during operation will decrease the chance of dust, flies, sputum droplets, drip, and splash entering the product.

(3) Administrative Procedures - This item is deemed be satisfied when:

(a) Time and Temperature Controls for Batch Pasteurizers

1. Temperature Difference - The pasteurizer shall be so designed that the simultaneous temperature difference between the milk, milk product, or frozen dessert mix at the center and the coldest milk, milk product, or frozen dessert mix in the vat will not exceed 1°F (0.5°C) at any time during the holding period. The vat shall be provided with adequate agitation, operating throughout the holding period. No batch of milk, milk product, or frozen dessert mix

shall be pasteurized unless it covers a sufficient area of the agitator to ensure adequate agitation.

2. Location and Required Readings of Indicating and Recording Thermometers - Each batch pasteurizer shall be equipped with both an indicating and a recording thermometer. The thermometers shall read not less than the required pasteurization temperature throughout the required holding period. The plant operator shall check the temperature shown by the recording thermometer against the temperature shown by the indicating thermometer at the start of the holding period; this comparison shall be noted on the recording thermometer chart. The recording thermometer shall not read higher than the indicating thermometer. No batch of milk, milk products, or frozen dessert mix shall be pasteurized unless it is sufficient to cover the bulbs of both the indicating and the recording thermometers.

3. Assurance of Minimum Holding Periods - Batch pasteurizers shall be so operated that every particle of milk, milk product, or frozen dessert mix will be held at not less than the minimum pasteurization temperature continuously for at least thirty (30) minutes. When milk, milk products, or frozen dessert mix are raised to pasteurization temperature in the vat, and cooling is begun in the vat, simultaneously with or before the opening of the outlet valve, the recorder chart shall show at least thirty (30) minutes at not less than minimum pasteurization temperature. When milk, milk products, or frozen dessert mix are preheated to pasteurization temperature before entering the vat, the recorder chart shall show a holding period of at least thirty (30) minutes at not less than the minimum pasteurization temperature plus the time of filling from the level of the recorder bulb. When cooling is begun in the holder after the opening of the outlet valve, or is done entirely outside the holder, the recording chart shall show at least thirty (30) minutes at not less than the minimum pasteurization temperature plus the time of emptying to the level of the recording thermometer bulb. When the recorder time interval on the recorder chart at the pasteurization temperatures includes filling and/or emptying time, such intervals shall be indicated on the recorder chart by the operator, by removing the recording thermometer bulb from the product for a sufficient time to depress the pen or by turning cold water into the vat jacket at the end of the holding period or by inscribing the holding time on the chart. The filling time and the emptying time for

each holder so operated shall be determined by the Health Officer, initially, and after any change which may affect these times. No product shall be added to the holder after the start of the holding period.

(b) Airspace Heating

1. Means shall be provided and used in batch pasteurizers to keep the atmosphere above the milk, milk products, and frozen dessert mix at a temperature not less than 5°F (3°C) higher than the minimum required temperature of pasteurization during the holding period (see Appendix H).

2. Each batch pasteurizer shall be equipped with an airspace thermometer. The surface of the milk, milk product, or frozen dessert mix shall be at least one (1) inch (25 millimeters) below the bottom of the thermometer bulb when the vat is in operation.

3. The temperature shown by the airspace thermometer shall be recorded on the recording thermometer chart each time the pasteurizer is in operation. The chart shall show and shall indicate the start of the holding period and the end of the holding period at a given time or reference point as indicated or the recording chart.

(c) Inlet and Outlet Valves and Connections - The following definitions shall apply to inlet and outlet valves and connections:

1. "Valve stop" shall mean a guide which permits turning the valve plug to, but not beyond, the fully closed position.

2. "90 stop" shall mean a stop so designed as to prevent turning the plug more than 90°.

3. "120 stop" shall mean a stop which prevents turning the plug more than 120°.

4. "180 stop" shall mean a stop which prevents turning the plug more than 180°, but which permits two fully closed positions, each diametrically opposite the other.

5. "Valve with an irreversible plug" shall mean one in which the plug cannot be reversed in the shell.

6. "Single-quadrant stop" shall mean a 90° stop in a valve with an irreversible plug.

7. "The fully open position" shall mean that position of the valve seat which permits the maximum flow into or out of the pasteurizer.

8. "The closed position" shall mean any position of the valve seat which stops the flow of milk, milk product, or frozen dessert mix into or out of the pasteurizer.

9. "The fully closed position" shall mean that closed position of the valve seat which requires the maximum movement of the valve to reach the fully open position.

10. "The just closed position" shall mean that closed position of a plug-type valve in which the flow into or out of the holder is barely stopped or any closed position within 0.078 inch thereof as measured along the maximum circumference of the valve seat.

11. "Leakage" shall mean the entrance of unpasteurized milk, milk product, or frozen dessert mix into a batch pasteurizer during the holding or emptying period or the entrance of unpasteurized product into any pasteurized product line at any time.

12. "Leak-protector valve" shall mean a valve provided with a leak-diverting device, which, when the valve is in any closed position, will prevent leakage of product past the valve or in the case of batch pasteurizers filled or emptied by suction or compressed air, will prevent leakage of product past the valve or the leakage of product due to the leakage of air past the suction valve or the compressed air valve, as the case may be.

13. "Closed-coupled valve" shall mean a valve, the seat of which is either flush with the inner wall of the pasteurizer or so closely coupled that no product in the valve inlet is more than 1°F (0.5°C) colder than the product at the center of the pasteurizer at any time during the holding period. A closed-coupled valve which is not truly flushed shall be considered as satisfying this requirement when:

(i) The vat outlet is so flared that the smallest diameter of the large end of the flare is not less than the diameter of the outlet line, plus the depth of the flare.

(ii) The greatest distance from the valve seat to the small end of the flare is not greater than the diameter of the outlet line.

(iii) In the case of batch pasteurizers, the outlet and the agitator are so placed as to ensure that product currents will be swept into the outlet.

(d) Design and Installation of Valves and Connections - All valves and connections shall comply with the following requirements:

1. Valves and pipeline connections shall meet the requirements of Rule 420-3-16-.10(10).

2. All pipelines and fittings shall be so constructed and so located that leakage will not occur. Dependence shall not be placed on soldered joints to prevent leakage.

3. To prevent clogging and to promote drainage, all leak-protection grooves shall be at least 0.187 inch (5 millimeters) wide and at least 0.094 inch (2.3 millimeters) deep at the center. Mating grooves shall provide these dimensions throughout their combined length whenever the valve is in, or approximately in, the fully closed position. All single-leak grooves and all mating leak grooves when mated, shall extend throughout the entire depth of the seat so as to divert leakage occurring at all points throughout the depth of the seat and so as to prevent air bindings. Washers or other parts shall not obstruct leak-protector grooves.

4. A stop shall be provided on all plug-type outlet valves and on all plug-type inlet valves in order to guide the operator in closing the valve so that unpasteurized product may not inadvertently be permitted to enter the outlet line or the holder, respectively. The stop shall be so designed that the plug will be irreversible when the plug is provided with any grooves or their equivalent unless duplicate, diametrically opposite grooves are also provided. In the case of two-way, plug-type valves (i.e., those having only one inlet and one outlet), a 180° stop or any combination of stops permitting two fully closed positions, may be substituted for a 90° stop; provided, there are no air-relief grooves in the plug and that all leak grooves are located symmetrically with respect to the valve inlet. Stops shall be so designed that the operator cannot turn

the valve beyond the stop position either by raising the plug or by any other means.

5. Outlet valves, in addition to the requirements listed above, shall be so designed as to prevent the accumulation of unpasteurized product in the product passages of the valve when the valve is in any closed position.

6. All outlets from vat pasteurizers shall be equipped with close-coupled leak-protector valves or be otherwise similarly protected during filling, holding, and emptying periods.

7. All leak-protector grooved outlet valves shall be installed in the proper position to ensure the function of the leak-protector groves and the drainage of the leak-detector valve.

8. All outlet valves shall be kept fully closed during filling, heating, and holding periods.

9. Close-coupled vat pasteurizer outlet valve bodies and plugs shall be made of stainless steel or of other materials that have heat transfer properties at least equal to stainless steel.

10. All inlet pipelines are disconnected during the holding and emptying periods, and all outlet pipelines are disconnected during the filling and holding periods.

11. Recording Charts - All recording thermometer charts shall comply with all the applicable requirements of Rule 420-3-16-.10(21)(a).

(18) **High Temperature, Short-Time (HTST) Continuous-Flow Pasteurization**

(a) Public Health Reason - See Public Health Reason under Rule 420-3-16-.10(16) and 420-3-16-.10(17).

(b) Administrative Procedures - This item deemed to be satisfied when:

1. Indicating Thermometers and Recorder/Controller Instruments - All indicating thermometers and recorder/ controller instruments and devices used in connection with the high-temperature, short-time continuous-flow pasteurization of milk, milk products, or frozen dessert mix shall comply with the applicable specifications, set forth in Appendix H.

(c) Automatic Milk Controller - Each high-temperature, short-time continuous-flow (HTST) pasteurization system shall be equipped with an automatic milk-flow control of the diversion type which complies with the following definition, specifications, and performance requirements:

(d) Automatic Milk or Milk Product-Flow Controls - The term "automatic milk or milk product flow control" shall mean those safety devices which control the flow of product in relation to the temperature of the product or heating medium and/or pressure, vacuum, or other auxiliary equipment. Milk-flow controls shall not be considered as part of the temperature control equipment. Milk-flow controls shall be of the flow-diversion type, which automatically cause the diversion of the product in response to a sublegal pasteurization temperature. At sublegal temperatures, flow-diversion devices return the product to the raw product side of the heating systems continuously until legal pasteurization temperatures are obtained; at which time, the device restores forward flow through the pasteurizer.

(e) Flow-Diversion Devices (FDDs) - All FDDs used in continuous pasteurizers shall comply with the following or equally satisfactory specifications:

1. Forward flow of subtemperature product due to the omission or looseness of the connecting clip, shall be prevented by making the valve and its actuating mechanism integral; or where there is a connecting device, by making it impossible to assemble the valve and its actuating mechanism, except in such manner that it will function properly; or where there is a connecting device which may be omitted or shaken loose by providing for pushing instead of pulling, the valve to the diverted position; or by providing that the pump will shut down when the product is below the pasteurization temperature and the valve is not in the fully-diverted position; or by any other equally satisfactory means. For the detection of the FDD and valve seat positions, refer to Appendix H, I, position detection devices of this rule.

2. When a packing gland is used to prevent leakage around the actuating stem, it shall be impossible to tighten the stem packing nut to such an extent as to prevent the valve from assuming the fully-diverted position.

3. A leak escape shall be installed on the forward-flow side of the valve seat. However, when back pressure is exerted on the forward-flow side of the valve seat, while the product flow is being diverted, the leak-escape should lie between two valve seats or between two portions of the same seat, one upstream and one downstream from the leak-escape. The leak-escape shall be

designed and installed to discharge all leakage to the outside or to the constant-level tank through a line separate from the diversion line; provided, when leakage is discharged to the constant-level tank, a sight glass shall be installed in the leak-escape line to provide a visual means of leak detection.

4. The closure of the forward-flow seat shall be sufficiently tight so that leakage past it will not exceed the capacity of the leak escape-device, as evidenced when the forward-flow line is disconnected; and, in order that proper seating may not be disturbed, the length of the connecting rod shall not be adjustable by the user.

5. The FDD shall be so designed and installed that failure of the primary motivating power shall automatically divert the flow of product.

6. The FDD shall be located downstream from the holder. The flow-control sensor shall be located in the product line not more than eighteen (18) inches = forty-six (46) centimeters upstream from the flow-control device.

7. In the case of higher-heat, shorter-time (HHST) pasteurizing systems utilizing the temperatures of 191°F (89°C) and above and holding times of one second and less, the FDD may be located downstream from the regenerator and/or cooler section; provided, when the FDD is located downstream from the regenerator and/or cooler section, the FDD shall be automatically prevented from assuming the forward-flow position until all product-contact surfaces between the holding tube and FDD have been held at or above the required pasteurization temperature continuously and simultaneously for at least the required pasteurization time as defined in Rule 420-3-16-.02(68).

8. The pipeline from the diversion port of the FDD shall be self-draining, and shall be free of restrictions or valves, unless such restrictions are noticeable and valves are so designed that stoppage of the diversion line cannot occur. In the case of continuous flow pasteurization systems, which have the FDD located downstream from the regenerator and/or cooler and are inter-wired or are computer controlled to thoroughly clean the system, including the divert pipeline before the re-starting of production, a cooling section, which is not self-draining, may be present in the divert pipeline.

9. When it is used, the pipeline from the leak detector port of the FDD shall be self-draining and shall be free of restrictions or valves.

10. For the timing pump, a one (1) second maximum "off" time delay is allowed to maintain the flow-promoting device in the "on" position through the travel time of the FDD.

11. If the area between the divert and leak-detect valve seats is not self-draining when the FDD is in the diverted position, a delay of at least one (1) second and not more than five (5) seconds is required between the movement of the divert and leak-detect valves when the FDD assumes the forward-flow position. Except that, the delay may be longer than five (5) seconds if: the timing system is a magnetic flow meter based timing system; or if the holding time in diverted-flow through an unrestricted divert valve line is longer than the required pasteurization time as specified in the definition of Pasteurization of this rule; and except that, no time delay is required in pasteurization systems in which the FDD is located downstream from the pasteurized regenerator and in which all forward-flow product-contact surfaces of the FDD are sanitized, or sterilized during the normal start-up process.

12. In the case of HHST pasteurizing systems utilizing temperatures and holding times to meet the definition of ultra-pasteurization (UP) of this rule, the FDD may be located downstream of the regenerator and/or cooler section. Said FDD may alternatively be a system of the "Steam-Block Type" as described in Appendix H. This FDD system shall allow for the flow of water and/or milk, milk product, or frozen dessert to the constant-level tank through appropriate valves and coolers during sterilization and when diverted.

(f) Milk-Flow Controller Instrumentation - The following requirements shall be met with respect to the instrumentation of the milk-flow controller:

1. The thermal-limit controller shall be set and sealed so that forward-flow of product cannot start unless the temperature at the controller sensor is above the required pasteurization temperature as defined in Rule 420-3-16-.02(68) for the milk, milk product, and frozen dessert, and the process used nor continue during descending temperatures when the temperature is below the required pasteurization temperature. The seal shall be applied by the Health Officer after testing, and shall not be removed without immediately notifying the Health Officer. The system shall be so designed that no product

can be by-passed around the controller sensor which shall not be removed from its proper position during the pasteurization process. The cut-in and cut-out milk temperatures, as shown by the indicating thermometer, shall be determined at the beginning of each day's operation and entered upon the recorder chart daily by the plant operator.

2. In the case of HHST pasteurization systems utilizing the temperatures of 191°F (89°C) and above, and holding times of one (1) second or less, with the FFD located downstream from the regenerator and/or cooler section, additional temperature controllers and timers shall be interwired with the thermal-limit-controller; and the control system shall be set and sealed so that forward-flow of product cannot start until all product-contact surfaces between the holding tube and FFD have been held at or above the required pasteurization temperature, continuously and simultaneously for at least the required pasteurization time as defined in Rule 420-3-16-.02(68). The control system shall also be set and sealed so that forward-flow cannot continue when the temperature of the product in the holding tube is below the required pasteurization temperature.

3. Provided, for systems used for the processing of milk, milk products and frozen desserts labeled as ultra-pasteurized (UP), it is not necessary to set and seal the thermal-limit-controller at or above 138°C (280°F). Also, provided, these systems shall meet all the public health control requirements for HHST systems, and that the recorder-controller chart shows that the UP milk, milk product, and frozen dessert has been processed at a minimum temperature of 138°C (280°F), and has been verified by the Health Officer to have a calculated holding time of at least two (2) seconds. The seal, if required, shall be applied by the Health Officer after the equipment has been tested, and shall not be removed without immediately notifying the Health Officer. The seal shall be applied by the Health Officer after test and shall not be removed without immediately notifying the Health Officer. The system shall be so designed that no product can be bypassed around the control sensors, which shall not be removed from their proper position during the pasteurization process. For these HHST systems, daily measurement by the operator of the cut-in and cut-out temperatures is not required.

4. Manual switches for the control of pumps, homogenizers, or other devices which produce flow through the holder shall be wired so that the circuit is completed only when the product is above the required pasteurization temperature as defined in Rule 420-3-16-.

02(68) for the milk product and the process used, or when the diversion device is in the fully-diverted position.

(g) Holding Tube

1. Holding tubes shall be designed to provide for the holding of every particle of milk or milk product for at least the time required in Rule 420-3-16-.02(68) for the milk or milk product and the process used.

2. The holding tube shall be so designed that the simultaneous temperature difference between the hottest and coldest product in any cross section of flow at any time during the holding period will not be greater than 1°F (0.5°C). This requirement may be assumed to have been satisfied without testing in tubular holders of seven (7) inches (17.8 centimeters) or smaller diameter which are free of any fitting through which the product may not be thoroughly swept.

3. No device shall be permitted for short circuiting a portion of the holder to compensate for changes in rate of product flow. Holding tubes shall be installed so that sections of pipe cannot be left out, resulting in a shortened holding time.

4. The holding tube shall be arranged to have a continuously upward slope in the direction of flow of not less than 0.25 inch (2.1 centimeters) per foot.

5. Supports for holding tubes shall be provided to maintain all parts of holding tubes in a fixed position, free from any lateral or vertical movement.

6. The holding tube shall be so designed that no portion between the inlet and the flow-control temperature sensor is heated.

(h) The following items apply to HHST systems:

1. The holding time for the HHST processes must be determined from the pumping rate rather than by the salt conductivity test because of the short holding tube. The holding tube length must be such that the fastest flowing particle of any product will not traverse the holding tube in less than the required holding time. Since laminar flow (the fastest flowing particle travels twice as fast as the average flowing particle) can occur in the holding tube during pasteurization of high-viscosity products, holding tube lengths are calculated as twice the length required to hold the average flow for the time standard.

2. With the direct steam heating processes, the holding time is reduced because the product volume increases as the steam condenses to water during heating in the injector. This surplus water is evaporated as the pasteurized product is cooled in the vacuum chamber. For example, with a 120°F (66°C) increase by steam injection which is probably the maximum temperature rise that will be used, a volume increase of 12 percent will occur in the holding tube. The measurement of the average flow rate at the discharge of the pasteurizer does not reflect this volume increase in the holding tube. However, this volume increase (i.e., holding time decrease) must be considered in the calculations.

3. For those HHST systems capable of operating with less than 518 kPa (75 psig) pressure in the holding tube, a pressure limit indicator/pressure switch shall be interwired so that the FDD will move to the divert position if the milk, milk product, and frozen dessert pressure falls below a prescribed value. For operating temperatures between 89°C (191°F) and 100°C (212°F) the instrument shall be set at 69 kPa (10 psi). To prevent vaporization in the holding tube, which may substantially reduce residence times, HHST systems operating above 100°C (212°F), the instrument shall be set at 69 kPa (10 psi) above the boiling pressure of the product, at its maximum temperature in the holding tube.

4. With the steam injection process, a differential pressure limit indicator across the injector is needed to keep the heated milk or milk product in the liquid phase and to ensure adequate isolation of the injection chamber. The instrument shall have a differential pressure switch so that the FDD will move to the divert position, if the pressure drop across the injector falls below 69 kPa (10 psi).

(i) Indicating and Recording Thermometers

1. An indicating thermometer shall be located as near as practicable to the temperature sensor of the recorder/ controller, but may be located a short distance upstream from the latter where product between the two thermometers does not differ significantly in temperature.

2. The temperature shown by the recorder/controller shall be checked daily by the plant operator against the temperature shown by the indicating thermometer. Readings shall be recorded on the chart. The recorder/controller shall be adjusted to read no higher than the indicating thermometer.

3. The recorder/controller charts shall comply with the applicable provisions of Rule 420-3-16-.10(21)(a).

(j) Flow-Promoting Devices

1. The pump or pumps and other equipment which may produce flow through the holder shall be located upstream from the holder; provided, that pumps and other flow-promoting devices shall be located downstream from the holder if means are provided to eliminate negative pressure between the holder and the inlet to such equipment. When vacuum equipment is located downstream from the holder, an effective vacuum breaker, plus an automatic means of preventing a negative pressure in the line between the FDD and the vacuum chamber shall be acceptable.

2. The speed of pumps or other flow-promoting devices governing the rate of flow through the holder shall be so controlled as to ensure the holding of every particle of product for at least the time required as defined in Rule 420-3-16-.02(68) for the milk or milk product and the process used. In all cases, the motor shall be connected to the metering pump by means of gears, pulleys, or a variable-speed drive, with the gear box, the pully box, or the setting of the variable speed protected in such a manner that the holding time cannot be shortened without detection by the Health Officer. This shall be accomplished by the application of suitable seal(s) after tests by the Health Officer and such seal shall not be broken without immediately notifying the Health Officer. The provision shall apply to all homogenizers used as timing pumps. Variable speed drives used in connection with the metering pump shall be so constructed that wearing or stretching of the belt results in a slow-down, rather than a speed-up, of the pump. The metering or timing pump shall be of the positive displacement type or shall comply with the specifications for magnetic flow meter systems as outlined in Appendix H. Timing pumps and homogenizers, when used as a timing pump, shall not have by-pass lines connected from their outlet pipelines to their inlet pipelines during processing if an additional flow-promoting or vacuum producing device is located within the system. When a homogenizer is used in conjunction with a timing pump, it shall be either:

(i) Of larger capacity than the timing pump. In which case an unrestricted, open, recirculation line shall be used to connect the outlet pipeline from the homogenizer to its inlet line. The recirculation line must be of at least the same or larger diameter than the inlet pipeline feeding product to the homogenizer. A check valve, allowing flow from the

outlet line to the inlet line, may be used in the re-circulating line provided it is of the type which provides a cross-sectional area at least as large as the recirculating line.

(ii) Of smaller capacity than the timing pump. In which case a relief line and valve shall be used. Such relief line shall be located after the timing pump and before the inlet to the homogenizer and shall return product to the balance tank or to the outlet of the balance tank upstream of any booster pump or other flow-promoting device.

5. For those systems which do not homogenize all products and wish to utilize a by-pass line to by-pass the homogenizer while processing such product, the by-pass line must be connected with valves which are so designed that both lines cannot be open at the same time. This may be accomplished with three (3)- way plug valves with properly designed and operating pins or other automatic, fail-safe valves which accomplish the same objective.

6. The holding time shall be taken to mean the flow time of the fastest particle of milk, at or above the required pasteurization temperature as defined in Rule 420-3-16-. 02(68), for the milk or milk product and the process used, throughout the holder section (i.e., that portion of the system that is outside of the influence of the heating medium, slopes continuously upward in the downstream direction, and is located upstream from the FDD). Tests for holding time shall be made when all equipment and devices are operated and adjusted to provide for maximum flow. When a homogenizer is located upstream from the holder, the holding time shall be determined with the homogenizer in operation with no pressure on the homogenizer valves. For those systems which do not homogenize all products and utilize by-pass lines as outlined in (i) above, the holding time shall be tested in both flow patterns and the fastest time used. The holding time shall be tested during both forward and diverted flow. If it is necessary to lengthen the holding time during diverted flow, an identifiable restriction may be placed in the vertical portion of the diversion pipeline. When vacuum equipment is located downstream from the holder, the holding time shall be tested with the metering pump operating at maximum flow, and the vacuum equipment adjusted to provide for the maximum vacuum. The holding time shall be tested in both forward and diverted flow by the Health Officer initially; semi-annually thereafter; after any alteration or replacement that may affect the holding time; and whenever the seal of the speed setting has been broken.

(k) Heating by Direct Addition of Steam - Steam injection is an inherently unstable process; accordingly, when steam in injected into a fluid, condensation of the steam may not be completed inside the injector unless the proper design criteria are used. Lack of complete condensation inside the injector would cause temperature variations in the holding tube that could lead to some product particles being processed below pasteurization temperature. When culinary steam is introduced directly into milk or milk products, as the means of terminal heating to achieve pasteurization temperature, the steam injector shall be designed, installed, and operated to comply with the following or equally satisfactory specifications:

1. The product and steam flows must be isolated from pressure fluctuations inside the injection chamber. One method of isolation is to insert supplementary orifices on the product inlet and the heated product outlet of each injector. The two (2) supplementary orifices must be sized for at least a 10 psi (69kPa) product pressure drop across the injector during a simulation of normal operations. Excessive vibrations, pressure fluctuations, or erratic noise levels indicate an unstable steam injection system and a need to check the isolation of the injection chamber.

2. The product pressure in the holding tube must be of sufficient magnitude to condense the steam and keep the heated product in the liquid phase. If this pressure is too low, the resultant vaporization in the holding tube will substantially reduce residence times. A minimum product pressure in the holding tube of 10 psi (.69 kPa) for operating temperatures from 191°F (89°C) through 212°F (100°C) is satisfactory. For units which have operating temperatures above 212°F (100°C) the pressure of the product in the holding tube must be at least 10 psi (.703 KPI) above the boiling pressure of the product at its maximum temperature in the holding tube.

3. The process should be as free as possible of non-condensable gases that may evolve from the product or be carried in the steam supply. Any two-phase flow caused by the non-condensable gases would displace the product in the holding tube, resulting in reduced residence times. In addition, these gases in the steam supply may also markedly alter the condensation mechanism at the point of injection. Accordingly, the steam boiler shall be supplied with a deaerator. The deaerator will aid in keeping the product in the holding tube as free as possible of non-condensable gases.

(l) Prevention of Product Adulteration with Added Water

1. When culinary steam is introduced directly into the milk or milk product, downstream from the FDD, means shall be provided to preclude the addition of steam to the milk or milk product, unless the FDD is in the forward-flow position. This provision may be satisfied by the use of an automatic steam control valve with a temperature sensor located downstream from the steam inlet, or by the use of an automatic solenoid valve installed in the steam line and so wired through the FDD controls, so that steam cannot flow unless the FDD is in the forward-flow position.

2. When culinary steam is introduced directly into the milk or milk product, automatic means (i.e., stand-alone and/or programmable logic controller [PLC]-based ratio control system) shall be provided to maintain a proper temperature differential between incoming and outgoing milk or milk product to preclude dilution with water.

3. Where a water feed line is connected to a vacuum condenser and the vacuum condenser is not separated from the vacuum chamber by a physical barrier, means shall be provided to preclude the backup and overflow of water from the vacuum condenser to the vacuum chamber. This provision may be satisfied by the use of a safety shut-off valve, located on the water feed line to the vacuum condenser, automatically actuated by a control which will shut off the in-flowing water if, for example, the condensate pump stops and the water level rises above a predetermined point in the vacuum condenser. This valve may be actuated by water, air, or electricity, and shall be so designed that failure of the primary motivating power will automatically stop the flow of water into the vacuum condenser.

(m) Aseptic Processing Systems

1. Public Health Reason - Aseptically processed milk and milk products are being packaged in hermetically sealed containers and stored for long periods of time under non-refrigerated conditions. These conditions are favorable to the growth of many types of bacteria (pathogenic, toxin producing, and spoilage types). Because of this, every precaution must be taken to ensure that all viable organisms and their spores are destroyed by the chosen heat process for the particular milk or milk product and that the subsequent handling, packaging, and storage processes do not provide an opportunity for recontamination of the product. The selected process must conform to the acceptable requirements for low acid canned foods.

2. Administrative Procedures - The aseptic processing portion of this item is deemed to be satisfied when the design and operation of aseptic processing systems comply with the applicable specifications and operational procedures of sub-items C, D, and E as follows; provided, nothing shall be construed as barring any other aseptic processing system which have been recognized by the FDA to be equally effective and which is approved by the Health Officer.

(n) Indicating Thermometers and Recorder/Controller Instruments: All indicating thermometers, recorder/controller instrument devices used in connection with aseptic processing systems used for the aseptic processing of milk or milk products shall comply with the applicable specifications set forth in Appendix H.

(o) Aseptic Processing Equipment

1. Temperature Indicating Device - Each aseptic processing system shall be equipped with at least one mercury-in-glass thermometer or an equivalent temperature-indicating device.

2. Temperature Recorded/Controller - An accurate temperature recorded/controller shall be installed in the product at the holding-tube outlet and before the inlet to the cooler or regenerator. The following requirements shall be met with respect to the instrumentation of the temperature recorded/controller:

(i) The temperature recorded/controller shall be set and sealed so that during product processing the forward flow of product cannot start unless the temperature at the controller sensor is above the required temperature for the product and the process used, nor continue during descending temperatures when the temperature is below the required temperature. The seal shall be applied by the Health Officer after testing, and shall not be removed without immediately notifying the Health Officer. The system shall be so designed that no product can be bypassed around the controller sensor which shall not be removed from its proper position during the processing of aseptic milk and milk products.

(ii) Additional temperature controllers and timers shall be interwired with the thermal limit controller, and the control system shall be set and sealed so that forward flow of product cannot start until all product-contact surfaces between the holding tube and flow-diversion device have been held at or above the required sterilization temperature,

continuously and simultaneously for at least the required sterilization time. The control system shall also be set and sealed so that forward flow cannot continue when the temperature of the product in the holding tube is below the required temperature. The seal shall be applied by the Health Officer after test, and shall not be removed without immediately notifying the Health Officer. The system shall be so designed that no product can be bypassed around the control sensors, which shall not be removed from their proper position during the processing of aseptic milk and milk products.

(iii) Manual switches for the control of pumps, homogenizers, or other devices which produce flow through the holder, shall be wired so that the circuit is completed only when the milk is above the required temperature for the product and the process used, or when the diversion device is in the fully-diverted position.

(p) Metering Pump

1. A metering pump shall be located upstream from holding tube and shall be operated to maintain the required metering pump by means of a common drive shaft or by means of gears, pulleys, or a variable-speed drive with the gear box, the pulley box, or the setting of the variable speed protected in such a manner that the hold time cannot be shortened without detection by the Health Officer. This shall be accomplished by the application of a suitable seal(s) after tests by the Health Officer and such seal shall not be broken without immediately notifying the Health Officer. The provision shall apply to all homogenizers used as timing pumps. Variable speed drives used in connection with the metering pump shall be so constructed that wearing or stretching of the belt results in a slowdown, rather than a speedup of the pump. The metering or timing pump shall be of the positive displacement type or shall comply with the specifications for magnetic flow meter systems.

2. The holding time shall be taken to mean the flow time of the fastest particle of product throughout the holder section (i.e., that portion of the system that is outside of the influence of the heating medium, slopes continuously upward in the down-stream direction, and is located upstream from the FDD). Tests for holding time shall be made when all equipment and devices are operated and adjusted to provide for maximum flow. When a homogenizer is located upstream from the holder, the holding time shall be determined with the homogenizer in operation with no pressure on the homogenizer valves. For

those systems which do not homogenize all milk or milk products and utilize by-pass lines as outlined in (j)2(i) above, the holding time shall be tested in both flow patterns and the fastest time used. The holding time shall be tested during both forward and diverted-flow. If it is necessary to lengthen the holding time during diverted-flow, an identifiable restriction may be placed in the vertical portion of the diversion pipeline. When vacuum equipment is located downstream from the holding tube, the holding time shall be tested with the timing pump operating at maximum flow and the vacuum equipment adjusted to provide for the maximum vacuum. The holding time shall be tested by the Health Officer initially, semi-annually thereafter, after any alteration or replacement that may affect the holding time, and whenever the seal of the speed setting has been broken.

(q) Product Holding Tube

1. The product holding tube shall be designed to give continuous holding of every particle of product for at least the minimum holding time specified in the scheduled process. The holding tube shall be designed so that no portion of the tube between the product inlet and the product outlet can be heated, and it must be sloped upward at least 0.25 (2.1 cm/m) inch per foot. Supports for tubes shall be provided to maintain all parts of holding tubes in a fixed position, free from any lateral or vertical movement.

2. No device shall be permitted for short circuiting a portion of the holder to compensate for changes in rate of production flow. Holding tubes shall be installed so that sections of pipe cannot be left out, resulting in a shortened holding time. The holding time for the processes must be determined from the pumping rate rather than by the salt conductivity test.

3. The holding tube length must be such that the fastest flowing particle of any product will not traverse the holding tube in less than the required holding time.

Note: Since laminar flow (the fastest flowing particle travels twice as fast as the average flowing particle) can occur in the holding tube during aseptic processing of high-viscosity products, holding tube lengths are calculated as twice the length required to hold the average flow for the time standard. With the steam injection process, the holding time is reduced because the product volume increases as the steam condenses to water during heating in the injector. This surplus water is evaporated as the aseptically processed product is cooled in the vacuum chamber. For example, with a 120°F

(66°C) increase by steam injection, which is probably the maximum temperature rise that will be used, a volume increase of 12 percent will occur in the holding tube. The measurement of the average flow rate at the discharge of the aseptic processor does not reflect this volume increase in the holding tube. However, this volume increase (i.e., holding time decrease) must be considered in the calculations.

4. With the steam injection process, a pressure limit indicator is needed in the holding tube to keep the heated product in the liquid phase. The instrument must have a pressure switch so that the FDD will move to the divert position if the product pressure falls below a prescribed value. The pressure switch must be set at a pressure 10 psi (.703 kPa) above the boiling pressure of the product at its maximum temperature in the holding tube.

5. With the steam injection process, a differential pressure limit indicator across the injector is needed to ensure adequate isolation of the injection chamber. The instrument must have a differential pressure switch so that the FDD will move to the divert position if the pressure drop across the injector falls below 10 psi (. 703 kPa).

6. Heating by Direct Addition of Steam - Injection is an inherently unstable process; accordingly, when steam is injected into a fluid, condensation of the steam may not be completed inside the injector unless the proper design criteria are used. Lack of complete condensation inside the injector would cause temperature variations in the holding tube that could lead to some product particles being processed below filed process temperature. When culinary steam is introduced directly into milk or milk products as the means of terminal heating to achieve aseptic processing temperature, the steam injector shall be designed, installed, and operated to comply with the following or equally satisfactory specifications.

7. The product and steam flows must be isolated from pressure fluctuations inside the injection chamber. One method of isolation is to insert supplementary orifices on the product inlet and the heated product outlet of each injector. The two supplementary orifices must be sized for at least a 10 psi (.703 kPa) product pressure drop across the injector during a simulation of normal operations. Excessive vibrations, pressure fluctuations, or erratic noise levels indicate an unstable steam injection system and a need to check the isolation of the injection chamber.

8. The product pressure in the holding tube must be of sufficient magnitude to condense the steam and keep the heated product in the liquid phase. If this pressure is too low, the resultant vaporization in the holding tube will substantially reduce residence times. For units which have operating temperatures above 212°F (100°C), the pressure of the product in the holding tube must be at least 10 psi (.703 kPa) above the boiling pressure of the product at its maximum temperature in the holding tube.

9. The process should be as free as possible of non-condensable gases that may evolve from the product or be carried in the steam supply. Any two-phase flow caused by the non-condensable gases would displace the product in the holding tube, resulting in reduced residence times. In addition, these gases in the steam supply may also markedly alter the condensation mechanism at the point of injection. Accordingly, the steam boiler shall be supplied with a deaerator. The deaerator will aid in keeping the product in the holding tube as free as possible on non-condensable gases.

(r) Prevention of Product Adulteration with Added Water

1. When culinary steam is introduced directly into the milk or milk product downstream from the FDD, means shall be provided to preclude the addition of steam to the milk or milk product unless the FDD is in the forward-flow position. This provision may be satisfied by the use of an automatic steam control valve with a temperature sensor located downstream from the steam inlet, or by the use of an automatic solenoid valve installed in the steam line and so wired through.

2. Where a water feed line is connected to a vacuum condenser and the vacuum condenser is not separated from the vacuum chamber by a physical barrier, means shall be provided to preclude the back-up and overflow of water from the vacuum condenser to the vacuum chamber. This provision may be satisfied by the use of a safety shutoff valve located on the water feed line to the vacuum condenser, automatically actuated by a control which will shut off the inflowing water, if, for example, the condensate pump stops and the water level rises above a predetermined point in the vacuum condenser. This valve may be actuated by water, air, or electricity, and shall be so designed that failure of the primary motivating power will automatically stop the flow of water into the vacuum condenser.

(s) FDD - All FDDs used in continuous aseptic process systems shall comply with the following or equally satisfactory specifications:

1. Forward flow of sub-temperature product due to the omission of looseness of the connecting clip shall be prevented by making the valve and its actuating mechanism integral; or, where there is a connecting device, by making it impossible to assemble the valve and its actuating mechanism, except in such manner that it will function properly; or, where there is a connecting device which may be omitted or shaken loose by providing for pushing, instead of pulling, the valve to the diverted position; or by providing that the pump will shut down when the product is below the aseptic processing temperature and the valve is not in the fully-diverted position; or by any other equally satisfactory means.

2. When a packing gland is used to prevent leakage around the actuating stem, it shall be impossible to tighten the stem packing nut to such an extent as to prevent the valve from assuming the fully-diverted position.

3. A leak escape shall be installed on the forward-flow side of the valve seat. However, when back pressure is exerted on the forward-flow side of the valve seat, while the product flow is being diverted, the leak escape should lie between two portions of the same seat, one upstream and the other downstream from the leak escape. The leak escape shall be designed and installed to discharge all leakage to the outside, or to the constant-level tank through a line separate from the diversion line; provided, when leakage is discharged to the constant-level tank, a sight glass shall be installed in the leak escape line to provide a visual means of leak detection.

4. The closure of the forward-flow seat shall be sufficiently tight so that leakage past it will not exceed the capacity of the leak escape device, as evidenced when the forward-flow line is disconnected; and, in order that proper seating may not be disturbed, the length of the connecting rod shall not be adjustable by the user.
5. The FDD shall be so designed and installed that failure of the primary motivating power shall automatically divert the flow of milk.

6. The FDD shall be located down-stream from the regenerator and/or cooler section. The FDD shall be automatically prevented from assuming the forward-flow position until all product-contact surfaces between the holding tube and FDD have been held at or above the

required sterilization temperature continuously and simultaneously for at least the required sterilization time.

7. The pipeline from the diversion port of the FDD shall be self-draining, and shall be free of restrictions or valves, unless such restrictions or valves are so designed that stoppage of the diversion line cannot occur.

8. When it is used, the pipeline from the leak detector port of the FDD shall be self-draining, and shall be free of restrictions or valves.

(t) Pasteurizers and Aseptically Processing Systems Employing Regenerative Heating

1. Public Health Reason - To prevent contamination of the pasteurized product in regenerators, the raw product must always be under less pressure than the pasteurized product or the heat-transfer medium. In the case of milk-to-milk regenerators or milk regenerators, this requirement is necessary to prevent contamination of the pasteurized product by the raw product if flaws should develop in the metal or in the joints separating the two kinds of product.

2. Administrative Procedure - This item is deemed to be satisfied when:

(19) **Milk-To-Milk Product-To-Milk or Milk Product Regenerative Heating**

(1) Pasteurizers employing milk-to-milk regenerative heating with both sides closed to the atmosphere shall comply with the following or equally satisfactory specifications:

(a) Regenerators shall be constructed, installed, and operated so that pasteurized or aseptic product in the regenerator will automatically be under greater pressure than raw product in the regenerator at all times.

(b) The pasteurized product, between its outlet from the regenerator and the nearest point downstream open to the atmosphere, shall rise to a vertical elevation of 12 (30.5cm) inches above the highest raw product level downstream from the constant-level tank and shall be open to the atmosphere at this or a higher elevation.

(c) The overflow of the top rim of the constant-level raw product tank shall always be lower than the lowest product level in the regenerator.

(d) No pump or flow-promoting device which can affect the proper pressure relationships within the regenerator shall be located between the pasteurized or aseptic product outlet from the regenerator and the nearest downstream point open to the atmosphere.

(e) No pump shall be located between the raw product inlet to the regenerator and the constant-level tank, unless it is designed and installed to operate only when product is flowing through the pasteurized product side of the regenerator, and when the pressure of the pasteurized milk product is higher than the maximum pressure produced by the pump. This may be accomplished by wiring the booster pump so that it cannot operate unless:

1. The metering pump is in operation.

2. The FDD is in forward-flow position.

3. The pasteurized product pressure exceeds, by at least 6.9 kPa (1 psi) the maximum pressure developed by the booster pump. Pressure gauges shall be installed at the raw product inlet to the regenerator and the pasteurized product outlet of the regenerator or the outlet of the cooler. The accuracy of required pressure gauges shall be checked by the Health Officer on installation, quarterly thereafter, and following repair or adjustment.

(i) The motor, casing, and impeller of the booster pump shall be identified, and such records thereof maintained as directed by the Health Officer. All electric wiring interconnections should be in permanent conduit (except that rubber covered cable may be used for final connections) with no electrical connections to defeat the purpose of any provisions of these rules.

(ii) All raw products in the regenerators will automatically drain freely back into the constant-level raw product tank or to the floor when the raw product pump(s) are shut down and the raw product outlet from the regenerator is disconnected.

(iii) When vacuum equipment is located downstream from the FDD, means shall be provided to prevent the lowering of the pasteurized or milk product level in the regenerator during periods of diverted-flow or shutdown. An effective vacuum breaker, plus an automatic means of preventing a

negative pressure, shall be installed in the line between the vacuum chamber and the pasteurized product inlet to the regenerator.

4. In the case of HHST pasteurization systems utilizing the temperatures of 191°F (89°C) and above, and holding times of one (1) second or less, with the FDD located downstream from the regenerator and/or cooler section, the requirement that the pasteurized product from the outlet of the regenerator or cooler shall rise to a vertical elevation of twelve (12) inches above the highest raw product level downstream from the constant-level tank and shall be open to the atmosphere at this or a higher elevation, may be eliminated--provided a differential pressure controller is used to monitor the highest pressure in the raw product side of the regenerator and the lowest pressure in the pasteurized side of the regenerator, and the controller is interlocked with the FFD and is set and sealed so that whenever improper pressures occur in the regenerator, forward flow of product is automatically prevented and will not start again until all product-contact surfaces between the holding tube and FFD have been held at or above the required pasteurization temperature, continuously and simultaneously for at least the required pasteurization time as defined in Rule 420-3-16-.02(68).

5. When culinary steam is introduced directly into milk or milk products as the means of terminal heating to achieve pasteurization temperature, and vacuum equipment is located downstream from the holding tube, the requirement that a vacuum breaker be installed at the inlet to the pasteurized or aseptic side of the regenerator may be eliminated; provided, that the differential pressure controller is installed and wired to control the FDD as described in (iii) above.

6. When the differential pressure controller is installed and wired to control the FDD as described in (i) above, the raw product booster pump may be permitted to run at all times; provided, the metering pump is in operation.

(20) **Milk or Milk Product-To-Water-To-Milk or Milk Product Regenerative Heating**

OPTION I: Milk-to-water-to-milk regenerators with both the product and the heat-transfer water in the raw product section closed to the atmosphere shall comply with the following or equally satisfactory specifications:

(a) Regenerators of this type shall be so designed, installed, and operated that the heat-transfer-medium side of the regenerator in the raw product section will automatically be under greater pressure than the raw side at all times.

(b) The heat-transfer water shall be safe water and the heat-transfer water shall be in a covered tank which is open to the atmosphere at an elevation higher by at least twelve (12) inches (30.5 cm) than any raw product level downstream from the constant-level tank. The heat-transfer water between its outlet from the regenerator and the nearest point downstream open to the atmosphere shall rise to a vertical elevation of at least twelve (12) inches (30.5 cm) above any raw product in the system and shall be open to the atmosphere at this or a higher elevation.

(c) The heat-transfer water circuit shall be full of water at the beginning of the run, and all loss of water from the circuit shall be automatically and immediately replenished whenever raw product is present in the regenerator.

(d) The overflow of the top rim of the constant-level raw product tank shall always be lower than the lowest product level in the raw product section of the regenerator. The regenerator shall be designed and installed so that all raw product shall drain freely back to the upstream supply tank when the raw product pumps are shut down and the raw product line is disconnected from the regenerator outlet.

(e) No pump shall be located between the raw product inlet to the regenerator and the raw product supply tank, unless it is designed and installed to operate only when water is flowing through the heat-transfer section of the regenerator, and when the pressure of the heat-transfer water is higher than the pressure of the raw product. This may be accomplished by wiring the booster pump so that it cannot operate unless:

1. The heat-transfer water pump is in operation.

2. Pressure gauges shall be installed at the raw product inlet and the heat-transfer water outlet of the regenerator. The heat-transfer water pressure exceeds, by at least 6.9 kPa (1 psi), the raw milk or milk product pressure in the regenerator. A differential pressure controller shall be installed at the raw milk or milk product inlet and the heat-transfer water outlet of the regenerator. The raw milk or milk product booster pump shall be wired so that it cannot operate unless the differential pressure is met. The accuracy of the required differential pressure controller shall be checked by the Health Officer on installation; quarterly thereafter; and following repair or replacement.

OPTION II: Milk or milk product-to-water-to-milk or milk product regenerators may also be constructed, installed, and operated such that the pasteurized milk or milk product in the regenerator will be under greater pressure than the heat-transfer-medium in the pasteurized milk or milk product side of the regenerator:

(a) A differential pressure recorder-controller shall be used to monitor pressures of the pasteurized product and the heat-transfer medium. One pressure sensor shall be installed at the pasteurized milk or milk product outlet of the regenerator and the other pressure sensor shall be installed at the heat-transfer-medium inlet of the aseptic product side of the regenerator. This recorder-controller shall divert the FDD whenever the lowest pressure of pasteurized milk or milk product in the regenerator fails to exceed the highest pressure of heat-transfer-medium in the aseptic product side of the regenerator by at least one (1) psi (6.9 kPa). Forward flow of product shall be automatically prevented until all product-contact surfaces between the holding tube and the FDD have been held at or above the required pasteurization sterilization temperature continuously and simultaneously for at least the pasteurization time.

(b) The heat-transfer-medium pump shall be wired so that it cannot operate unless the metering pump is in operation.

Note: See Appendix H for further discussion concerning methods of achieving the required pressure relationships within the regenerator.

(21) **Pasteurization Records**

(a) Pasteurization Records - All temperature and flow rate pasteurization recording charts or alternative records, acceptable to the FDA, in place of charts shall be preserved for a period of three (3) months. The use of such charts shall not exceed the time limit for which they are designed. Overlapping of recorded data shall be a violation of this Item. The following information shall be entered on the charts or other records acceptable to FDA in place of charts as applicable:

1. Batch Pasteurizers.

(i) Date.

(ii) Number or location of recorder when more than one is used.

(iii) A continuous record of the product temperature.

(iv) Extent of holding period, including filling and emptying times when required.

(v) Reading of the airspace thermometer, at the start of the holding period and at the end of the holding period, at a given time or reference point as indicated on the chart; provided, if the airspace thermometer is a digital combination airspace/ recording thermometer which provides a continuous recording of the airspace temperature and has been calibrated by the Health Officer in accordance with Appendix I, Test 4, the recording of the airspace temperature on the chart shall only be required at the start of the holding period.

(vi) Reading of indicating thermometer at the start of the holding period, at a given time or reference point as indicated on the chart.

(vii) Quarterly, the initials of the Health Officer opposite the required readings of the indicating thermometer and airspace thermometer. Refer to Rule 420-3-16-.10(16)(C)2.(i).

(viii) Quarterly, the time accuracy of the recording thermometer as determined by the Health Officer (refer to Appendix I, Test 3).

(ix) Amount and name of pasteurized milk or milk product represented by each batch or run on the chart.

(x) Record of unusual occurrences.

(xi) Signature or initials of operator.

(xii) Name of milk plant.

(b) High-Temperature Short-Time (HTST) and HHST Pasteurizers, Short-Time Pasteurizers-Recording thermometer charts shall contain all the information specified in 1 above, except for (iv) and (v) above, in addition, shall include the following:

1. A record of the time during which the FDD is in the forward-flow position.

2. The cut-in and cut-out product temperatures recorded daily by the operator at the beginning of the run (HTST only) and initialed quarterly by the Regulatory Agency; and (III) and (vi) from above shall also be recorded immediately after a chart has been changed.

Note: The recorded temperature shown on the controller chart shall be used to determine that the required temperature for milk products containing higher fat and/ or sweeteners has been achieved.

3. Continuous-Flow Pasteurization Systems with Magnetic Flow Meter Based Timing Systems: Flow rate recording charts shall be capable of continuously recording flow at the flow alarm set point and at least 19 liters (5 gallons) per minute higher than the high flow alarm setting. Flow rate recording charts shall contain all the information specified in subitem (a). above except (iii), (iv), (v), (vi), and (vii), and, in addition, shall include the following:

(i) A continuous record of the status of the high and low-flow/loss of signal alarms.

(ii) A continuous record of the flow rate.

4. Electronic Data Collection, Storage, and Reporting: Electronic collection, storage, and reporting of required pasteurization records, with or without hard copy printouts, may be acceptable, provided the electronically generated records are readily available at the milk plant for review by the Health Officer and meet the criteria of this section and Appendix H, V.

5. HTST and HHST Pasteurizers - Recording charts shall contain all the information specified in (a) from above except for (iv) and (v), and reference to airspace thermometers, and in addition shall include the following:

(i) A record of the time during which the FDD is in the forward-flow position.

(ii) The cut-in and cut-out milk or milk product temperatures, recorded daily by the operator, at the beginning of the run (HTST only), and initialed quarterly by the Health Officer, or in the case of milk plants regulated under the NCIMS voluntary HACCP Program, a qualified industry person acceptable to the Health Officer; and (ii), (iii), and (vi) from above and shall also be recorded immediately after a chart has been changed.

(iii) Not later than one working day after the actual process, and before shipment or release for distribution, a representative of plant management who is qualified by suitable training or experience shall review all processing and production records for completeness to ensure that the product received the scheduled process. The records, including the recording thermometer chart(s), shall be signed or initialed and dated by the reviewer.

(22) **Equipment Tests and Examination**

(a) The Health Officer shall perform the indicated tests on the following instruments and devices identified in Table 4 initially upon installation; at least once each three (3) months thereafter, including the remaining days of the month in which the equipment tests are due; whenever any alteration or replacement is made which may affect the proper operation of the instrument or device; or whenever a regulatory seal has been broken. Provided, that the pasteurization holding time tests shall be conducted at least once each six (6) months thereafter, including the remaining days of the month in which the equipment test is due.

Note: A TPC authorized under the ICP may utilize appropriately trained and TPC authorized in-country regulatory personnel to comply with (22) above.

(b) On an emergency basis, pasteurization equipment may be tested and temporarily sealed by a milk plant employee provided the following conditions are met:

1. The individual applying the seal(s) shall be employed by the milk plant in which the seal(s) was removed.

2. The individual has satisfactorily completed training acceptable to the Health Officer on test controls for pasteurization equipment.

3. The individual has demonstrated the ability to satisfactorily conduct all pasteurization control tests in the presence of a regulatory official within the past year.

4. The individual shall be in possession of authorization from the Health Officer to perform these pasteurization equipment tests.

5. The individual shall immediately notify the Health Officer of the time of the shutdown that would necessitate the breaking and removal of the regulatory seal(s). Permission to test and reseal the equipment shall be obtained for each specific incident. The individual shall also notify the Health Officer of the identity of the pasteurization equipment controls affected, the cause, if known, of the pasteurization equipment failure, the repairs made, and the results of the pasteurization equipment testing. Test results for the pasteurization equipment testing shall be recorded on a similar document for all milk plants (refer to the reference in Appendix M for an example). The individual shall provide to the Health Officer the identity and volume of milk and/or milk products processed during the period that the temporary seal(s) was applied.

6. If regulatory pasteurization equipment testing reveals that the pasteurization equipment or controls are not in compliance with the provisions of this rule, all milk and/or milk products that were processed during this period may be recalled by the Health Officer.

7. The Health Officer or a properly trained regulatory official commissioned by the responsible Health Officer of each participating non-U.S. country or political subdivision thereof shall remove the temporary seal(s), retest the pasteurization equipment, and apply the regulatory seal(s) within ten (10) working days of the notification by the milk plant.

8. Grade "A" milk and/or milk products shall not be processed after ten (10) working days of the notification by the milk plant without the affected pasteurization equipment being tested and sealed by the Health Officer or a properly trained regulatory official, commissioned by the responsible Health Officer of each participating non-U.S. country or political subdivision thereof.

(c) In the case of milk plants with HACCP Plans regulated under the NCIMS voluntary HACCP Program, pasteurization equipment may be tested and sealed by industry personnel acceptable to the Health Officer, if the following conditions are met:

1. Test results for the pasteurization equipment testing shall be recorded on a similar document for all milk plants (refer to the reference in Appendix M for an example).

2. Industry personnel conducting the pasteurization equipment testing shall be adequately trained and shall be able to demonstrate an acceptable understanding and ability to conduct these pasteurization equipment tests to the Health Officer.

(i) Industry personnel shall physically demonstrate to the Health Officer that they understand and can perform the required pasteurization equipment tests according to the requirements of this rule.

(ii) The Health Officer shall accept a field practical exercise, a written exam, formal classroom training, on-the-job training, or any combination of these except that, if industry personnel do not physically demonstrate the appropriate capability to perform the pasteurization equipment tests to the satisfaction of the Health Officer, they are not acceptable for conducting such pasteurization equipment tests.

(iii) Continued training such as, but not limited to, on-the-job training with supervision or an acceptable pasteurizer training course shall be completed before they reapply for pasteurizer equipment testing approval.

(I) Pasteurization equipment tests shall be conducted at a frequency not less than the requirements of this rule. Industry personnel shall have responsibility for the performance of all required pasteurization equipment tests. At least each six (6) months, the Health Officer shall physically supervise these pasteurization equipment tests. Regulatory supervised pasteurization equipment tests shall include the semi-annual HTST and HHST pasteurization equipment tests, if applicable. These six (6) month pasteurization equipment tests shall be performed at a time that is mutually convenient to all parties. Because these pasteurization equipment tests are required to support a CCP, the industry is responsible for conducting these pasteurization equipment tests even in the absence of the regulatory official.

(II) Upon initial installation or extensive modification of any pasteurization equipment, pasteurization equipment tests shall be physically supervised or conducted by the Health Officer.

(III) Sealing guidance for pasteurization equipment by industry is as follows:

a. All pasteurization equipment that is required to be sealed within this rule shall also be sealed under the HACCP System. The sealing shall be done by a trained, qualified individual who is acceptable to the milk plant and the Health Officer.

b. The Health Officer may verify any pasteurization equipment sealing and evaluate (accept or reject) the skills and knowledge of the individual performing the sealing.

c. During an audit, the auditor may conduct any or all of the pasteurization equipment tests. The auditor shall, through a combination of the physical examination of the pasteurization equipment and a records review, satisfy themselves that the

pasteurization equipment is properly installed and operated.

Table 4. Equipment Tests - Batch Pasteurizers and HTST and HHST Pasteurization Systems (Refer to		
1.	Vat, HTST and HHST indicating and airspace thermometers	Temperature accuracy
2.	Vat, HTST and HHST recording thermometer	Temperature accuracy
3.	Vat, HTST and HHST recording thermometer	Time accuracy
4.	Vat, HTST and HHST indicating and recording thermometer	Recording vs. Indicating thermometer
5.1	HTST and HHST FDD	Leakage pass FDD
5.2	HTST and HHST FDD	FDD freedom of movement
5.3	HTST and HHST FDD	Device assembly (single stem)
5.4	HTST and HHST FDD	Device assembly (dual stem)
5.5	HTST FDD	Manual diversion
5.6	HTST and HHST FDD	Response time
5.7	HTST and HHST FDD	Time delay (inspect)
5.8	HTST and HHST FDD	Time delay (CIP)
5.9	HTST FDD	Time delay (leak-detect flush)
6.	Vat leak-protector valve(s)	Leakage
7.	HTST indicating thermometers	Response time
8.	HTST recording thermometers	Response time
9.1	HTST pressure switches	Regenerator pressures
9.2.1	HTST and HHST differential pressure controllers	Calibration
9.2.2	HTST differential pressure controllers	Regenerator pressure
9.2.3	HTST* and HHST differential pressure controllers	Regenerator pressure
9.3.1	HTST booster pump/FDD	Inter-wiring check
9.3.2	HTST booster pump/timing pump	Inter-wiring check
10.1	HTST FDD	Temperature cut-in/ cut-out
10.2	HTST* and HHST FDD divert system (indirect heat)	Temperature cut-in/ cut-out
10.3	HTST* and HHST FDD divert system (direct heat)	Temperature cut-in/ cut-out
11.1		Holding time

	HTST holding tubes/timing pumps (except magnetic flow meter based timing systems (MFMBTS))	
11.2.a	HTST holding tubes/ MFMBTS	Holding time
11.2.b	HTST and HHST MFMBTS	Flow alarm
11.2.c	HTST and HHST MFMBTS	Loss of signal/low flow
11.2.d	HTST MFMBTS	Flow rate cut-in/cut-out
11.2.e	HTST MFMBTS	Time delay
11.2.f	All MFMBTS	High flow alarm response time
11.3	HHST holding tubes indirect heat	Holding time
11.4	HHST holding tubes direct injection heat	Holding time
11.5	HHST holding tubes direct infusion heat	Holding time
12.1	HTST* and HHST indirect heating	Sequence logic
12.2	HTST* and HHST direct heating	Sequence logic
13.	HHST	Pressure in the holding tube
14.	HTST* and HHST using direct injection heating	Pressure differential across injector
15.	HTST and HHST (all electronic controls)	Electro-Magnetic Interference

For HTST systems with the FDD located downstream of the regenerator and/or cooler section.

(23) **Cooling of Milk, Milk Products, and Frozen Desserts**

(a) All raw milk, milk products, and frozen dessert mix shall be maintained at 7°C (45°F) or less until processed. All whey and whey products for condensing and/or drying shall be maintained at a temperature of 7°C (45°F) or less; or 57°C (135°F) or greater until processed, except that acid-type whey with a titratable acidity of 0.40% or above, or a pH of 4.6 or below, is exempted from these temperature requirements.

(b) For a milk or milk product flavoring slurry that contains milk and/or milk products and is not to be injected within a HTST pasteurization system as a part of a liquid ingredient injection system as outlined in Appendix H, the tanks and/or vessels used to blend and hold the slurry shall be completely emptied and cleaned after each four (4) hours of operation or less, unless the slurry is stored at a temperature of 7°C (45°F) or less, or at a temperature of 66°C (150°F) or greater and maintained thereat.

(c) All pasteurized milk and milk products, except the following, are cooled immediately in approved equipment prior to filling or packaging to a temperature of 7°C (45°F) or less, unless drying is commenced immediately after condensing:

1. Those to be cultured.

2. Cultured sour cream at all milkfat levels with a pH of 4.70 or below*.

3. Acidified sour cream at all milkfat levels with a pH of 4.60 or below*.

4. All yogurt products at all milkfat levels with an initial pH of 4.80 or below* at filling.

5. Cultured buttermilk at all milkfat levels with a pH of 4.60 or below*.

6. Cultured cottage cheese at all milkfat levels with a pH of 5.2 or below*.

(i) Filled at 63°C (145°F) or above* for containers of four (4) ounces (118 ml) or larger, or

(ii) Filled at 69°C (155°F) or above* for containers of 2.9 ounces (85.6 ml), and

(iii) The additional applicable critical factors*, as cited below, shall also be utilized for either hot fill temperature to determine the acceptability of filling at these temperatures, or

(iv) The addition of potassium sorbate at a minimum concentration of 0.06% and filled at 13°C (55°F) or less*, or

(v) The addition of one (1) of the specified microbial inhibitors and/or preservatives, at the specified concentration as addressed in M-a-97, and filled at 13°C (55°F) or less*; and

7. All condensed whey and whey products shall be cooled during the crystallization proess to 10°C (50°F) or less within seventy-two (72) hours of condensing, including the filling and emptying time, unless filling occurs above 57°C (135°F), in which case, the seventy-two (72) hour time period begins when cooling is started.

*Critical factors including, but not limited to, pH, filling temperature, cooling times and temperatures, and potassium sorbate concentration or specified microbial inhibitors and/or preservatives, at the specified

concentration as addressed in M-a-97, if applicable, shall be monitored and documented by the processing facility for verification by the Health Officer. pH limit with a pH variance of + 0.05 units to account for reproducibility and inaccuracies in pH measurements. Formulation or processing changes that affect critical factors shall be communicated to the Health Officer.

Note: Microbial inhibitors and/or preservatives and/or all of their individual components shall have GRAS status; and pathogen inhibition shall be supported by documented challenge study results that are acceptable to the Health Officer and FDA.

8. All pasteurized milk and milk products, except the following, shall be stored at a temperature of 7°C (45°F) or less and maintained thereat following filling or until further processed.

(i) Cultured sour cream at all milkfat levels with a pH of 4.70 or below* and cooled to 7°C (45°F) or less within one hundred sixty eight (168) hours of filling**.

(ii) Acidified sour cream at all milkfat levels with a pH of 4.60 or below* and cooled to 7°C (45°F) or less within one hundred sixty eight (168) hours of filling**.

(iii) All yogurt products at all milkfat levels with an initial pH of 4.80 or below* at filling, with a pH of 4.60 or below within twenty-four (24) hours of filling* and cooled to 7°C (45°F) or less within ninety-six (96) hours of filling**.

(iv) Cultured buttermilk at all milkfat levels with a pH of 4.60 or below* and cooled to 7°C (45°F) or less within twenty-four (24) hours of filling**.

(v) Cultured cottage cheese at all milkfat levels with a pH of 5.2 or below* and:

I. Filled at 63°C (145°F) or above* for containers of four (4) ounces (118 ml) or larger, cooled to 15°C (59°F) or less within ten (10) hours of filling**, and cooled to 7°C (45°F) or less within twenty-four (24) hours of filling**.

II. Filled at 69°C (155°F) or above* for containers of 2.9 ounces (85.6 ml), cooled to 15°C (59°F) or less within ten (10) hours of filling**, and cooled to 7°C (45°F) or less within twenty-four (24) hours of filling**.

III. The addition of potassium sorbate at a minimum concentration of 0.06% and filled at 13°C (55°F) or less*, cooled to 10°C (50°F) or less within twenty-four (24) hours of filling**, and cooled to 7°C (45°F) or less within seventy-two (72) hours of filling**, or

IV. The addition of one (1) of the specified microbial inhibitors and/or preservatives, at the specified concentration as addressed in M-a-97, filled at 13° (55°F) or less*, cooled to 10°C (50°F) or less with twenty-four (24) hours of filling**, and cooled to 7°C (45°F) or less within seventy-two (72) hours of filling**.

*Critical factors including, but not limited to, pH, filling temperature, cooling times and temperatures, and potassium sorbate concentration or specified microbial inhibitors and/or preservatives, at the specified concentration as addressed in M-a-97, if applicable, shall be monitored and documented by the processing facility for verification by the Health Officer. pH limit with a pH variance of + 0.05 units to account for reproducibility and inaccuracies in pH measurements. Formulation or processing changes that affect critical factors shall be communicated to the Health Officer.

Note: Microbial inhibitors and/or preservatives and/or all of their individual components shall have GRAS status; and pathogen inhibition shall be supported by documented challenge study results that are acceptable to the Health Officer and FDA.

**Cooling temperatures monitored at the slowest cooling portion, (i.e., in the middle of the container), of the slowest cooling container, (i.e., in the middle of the pallet).

9. All pasteurized milk and milk products to be condensed and/or dried shall be stored at a temperature of 10°C (50°F) or less and be maintained thereat until further processed. Every refrigerated room or tank in which milk or milk products, whey and whey products, and condensed milk and milk products are stored shall be equipped with an accurate indicating thermometer.

10. On delivery vehicles, the temperature of milk and milk products shall not exceed 7°C (45°F). Aseptically processed and packaged low-acid milk and/or milk products and retort processed after packaged low-acid milk and/or

milk products to be packaged in hermetically sealed containers shall be exempt from the cooling requirements of this item.

11. Electronic Data Collection, Storage and Reporting - The electronic storage of required cleaning records and product storage temperature records, with or without hard copy printouts, shall be acceptable, provided, the electronically generated records are readily available at the milk plant for review by the Health Officer. Electronic records that comply with the applicable provisions of Appendix H, IV, and V, with or without hard copy, may be used in place of the cleaning records.

(d) Public Health Reason - When milk, milk products, and frozen dessert mix are not cooled within a reasonable time after it is received at the pasteurization plant, its bacterial content will be materially increased. The same reasoning applies to cooling the milk, milk products, and frozen desserts after pasteurization, unless drying is commenced immediately after condensing.

(e) Administrative Procedures - This item is deemed to be satisfied when:

1. All raw milk, milk products, and frozen dessert mix shall be maintained at 7°C (45°F) or less until processed, except that acid-type whey with a titratable acidity of 0.40 percent or above, or a pH of 4.6 or below, is exempted from these temperature requirements; provided, all balance or surge tanks (continuous flow with a retention time not to exceed one [1] hour) for raw milk and milk products, pasteurized milk and milk products, and whey and whey products may be maintained at any temperature for up to twenty-four (24) hours.

2. All whey and whey products for condensing and/or drying are maintained at a temperature of 7°C (45°F) or less; or 57°C (135°F) or greater until processed. Storage tanks containing whey and whey product above 7°C (45°F) and below 57°C (135°F) shall be emptied, cleaned, and sanitized after each four (4) hours of use or less.***

3. For a milk or milk product flavoring slurry that contains milk and/or milk products and is not intended to be injected within a HTST pasteurization system as a part of a liquid ingredient injection system as outlined in Appendix H., the tanks and/or vessels used to blend and hold the slurry shall be completely emptied and cleaned after each four (4) hours of operation or less, unless the slurry is stored at a temperature of 7°C (45°F) or less, or at a temperature of 66°C (150°F) or greater and maintained thereat.

4. All pasteurized milk, milk products, and frozen dessert mix, except the following, shall be cooled immediately prior to filling or packaging, in approved equipment, to a temperature of 7°C (45°F) or less, unless drying is commenced immediately after condensing:

(i) Those to be cultured.

(ii) Cultured sour cream at all milkfat levels with a pH of 4.70 or below*.

(iii) Acidified sour cream at all milkfat levels with a pH of 4.60 or below*.

(iv) All yogurt products at all milkfat levels with an initial pH of 4.80 or below* at filling.

(v) Cultured buttermilk at all milkfat levels with a pH of 4.60 or below*.

(vi) Cultured cottage cheese at all milkfat levels with a pH of 5.2 or below*.

I. Filled at 63°C (145°F) or above* for containers of four (4) ounces (118 ml) or larger, or

II. Filled at 69°C (155°F) or above* for containers of 2.9 ounces (85.6 ml), and
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III. The additional applicable critical factors*, as cited below, shall also be utilized for either hot fill temperature to determine the acceptability of filling at these temperatures, or

IV. The addition of potassium sorbate at a minimum concentration of 0.06 percent and filled at 13°C (55°F) or less*, or

V. The addition of one (1) of the specified microbial inhibitors and/or preservatives, at the specified concentration as addressed in M-a-97, and filled at 13°C (55°F) or less*; and

(vii) All condensed whey and whey products shall be cooled during the crystallization process to 10°C (50°F) or less within seventy-two (72) hours of condensing, including the filling and emptying time, unless filling occurs above 57° (135°F), in which

case, the seventy-two (72) hour time period begins when cooling is started.***

*Critical factors including, but not limited to, pH, filling temperature, cooling times and temperatures, and potassium sorbate concentration or specified microbial inhibitors and/or preservatives, at the specified concentration as addressed in M-a-97, if applicable, shall be monitored and documented by the processing facility for verification by the Health Officer. The pH limit with a pH variance of + 0.05 units to account for reproducibility and inaccuracies in pH measurements. Formulation or processing changes that affect critical factors shall be communicated to the Health Officer.

Note: Microbial inhibitors and/or preservatives and/or all of their individual components shall have GRAS status; and their pathogen inhibition shall be supported by documented challenge study results that are acceptable to the Health Officer and the FDA.

5. All pasteurized milk and milk products, except the following, shall be stored at a temperature of 7°C (45°F) or less and be maintained thereat following filling or until further processed:

(a) Cultured sour cream at all milkfat levels with a pH of 4.70 or below* and cooled to 7°C (45°F) or less within one hundred sixty eight (168) hours of filling**.

(b) Acidified sour cream at all milkfat levels with a pH of 4.60 or below* and cooled to 7°C (45°F) or less within one hundred sixty eight (168) hours of filling**.

(c) All yogurt products at all milkfat levels with an initial pH of 4.80 or below* at filling, with a pH of 4.60 or below within twenty-four (24) hours of filling* and cooled to 7°C (45°F) or less within ninety-six (96) hours of filling**.

(d) Cultured buttermilk at all milkfat levels with a pH of 4.60 or below* and cooled to 7°C (45°F) or less within twenty-four (24) hours of filling**.

(e) Cultured cottage cheese at all milkfat levels with a pH of 5.2 or below*.

(i) Filled at 63°C (145°F) or above* for containers of four (4) ounces (118 ml) or larger, cooled to 15°C (59°F) or less within ten (10)

hours of filling**, and cooled to 7°C (45°F) or less within twenty-four (24) hours of filling**, or

(ii) Filled at 69°C (155°F) or above* for containers of 2.9 ounces (85.6 ml), cooled to 15°C (59°F) or less within ten (10) hours of filling**, and cooled to 7°C (45°F) or less within twenty-four (24) hours of filling**, or

(iii) The addition of potassium sorbate at a minimum concentration of 0.06 percent and filled at 13°C (55°F) or less*, cooled to 10°C (50°F) or less within twenty-four (24) hours of filling**, and cooled to 7°C (45°F) or less within seventy-two (72) hours of filling**, or

(iv) The addition of one (1) of the specified microbial inhibitors and/or preservatives, at the specified concentration as addressed in M-a-97, filled at 13°C (55°F) or less*, cooled to 10°C (50°F) or less with twenty-four (24) hours of filling**, and cooled to 7°C (45°F) or less within seventy-two (72) hours of filling**.

(f) All condensed whey and whey products shall be cooled during the crystallization process to 10°C (50°F) or less within seventy-two (72) hours of condensing, including the filling and emptying time, unless filing occurs above 57°C (135°F), in which case, the seventy-two (72) hour time period begins when cooling is started.

*Critical factors including, but not limited to, pH, filling temperature, cooling times, and temperatures, and potassium sorbate concentration or specified microbial inhibitors and/or preservatives, at the specified concentration as addressed in M-a-97, if applicable, shall be monitored and documented by the processing facility for verification by the Health Officer. The pH limit with a pH variance of + 0.05 units to account for reproducibility and inaccuracies in pH measurements. Formulation or processing changes that affect critical factors shall be communicated to the Health Officer

Note: Microbial inhibitors and/or preservatives and/or all of their individual components shall have GRAS status; and pathogen inhibition shall be supported by documented challenge study results that are acceptable to the Health Officer and the FDA.

**Cooling temperatures monitored at the slowest cooling portion (i.e., in the middle of the container) of the slowest cooling container (i.e., in the middle of the pallet).

6. All pasteurized milk and milk products to be condensed and/or dried, shall be stored at a temperature of 10°C (50°F) or less and be maintained thereat until further processed. If storage tanks are used between the condenser and dryer, any such storage tank(s) containing pasteurized milk or milk products stored above 10°C (50°F) and below 57°C (135°F) shall be completely emptied and cleaned after each six (6) hours of operation or less.***

7. Each refrigerated room in which pasteurized milk, milk products, and frozen dessert mix are stored is equipped with an indicating thermometer that complies with the applicable specifications of Appendix H. Such thermometer shall be located in the warmest zone of the refrigerated room.

8. Each storage tank shall be equipped with an indicating thermometer, the sensor of which shall be located to permit the registering of the temperature of the contents when the tank contains no more than 20 percent of its calibrated capacity. Such thermometer shall comply with the applicable specification of Appendix H.

9. On delivery vehicles, the temperature of milk and milk products shall not exceed 7°C (45°F).

10. All surface coolers comply with the following specifications:

(i) The sections of open-surface coolers shall be so installed as to leave a gap of at least 6.4 millimeters (0.25 of an inch) between the header sections to permit easy cleaning.

(ii) Where header ends are not completely enclosed within the cooler covers, condensation or leakage from the headers shall be prevented from entering the milk or milk product by so shaping the exposed header faces above and below all gaps that condensation is directed away from the tubes, and by using deflectors at the bottom of the headers; or by shortening the bottom of the headers; or by shortening the bottom trough; or by some other approved method.

(iii) The location of supports of cooler sections shall prevent condensation and leakage from entering the milk, milk product, or frozen dessert.

(iv) All open-surface coolers shall be provided with tight-fitting shields that protect the milk, milk product, or frozen dessert product from contamination by insects, dust, drip, splash, or manual contact.

11. Recirculated cooling water which is used in plate or tubular coolers and/or heat exchangers, including those systems in which a freezing point depressant is used, is from a safe source and protected from contamination. Such water shall be tested semiannually and shall comply with the bacteriological standards of Appendix G. Samples shall be taken by the Health Officer and examination shall be conducted in an official laboratory. Recirculated cooling water systems which become contaminated through repair work or otherwise shall be properly treated and tested before being returned to use. Freezing point depressants and other chemical additives, when used in recirculating systems, shall be non-toxic under conditions of use. Propylene glycol and all additives shall be either USP Grade, Food Grade, or GRAS. To determine if recirculated cooling water samples have been taken at the frequency established in this item, the interval shall include the designated six (6) month period plus the remaining days of the month in which the sample is due.

12. Recirculated cooling water contained in corrosion resistant, continuous piping, with no joints or welds, which fail to meet applicable American Society of Mechanical Engineers (ASME) or equivalent standards in the non-potable water contact areas, may be considered to be protected from contamination, as required above, when cooled by non-potable water flowing over the exterior of the piping, within open evaporative type cooling tower. In these systems, the recirculated cooling water piping shall be properly maintained and shall be installed so that it is at least two (2) pipe diameters above the flood rim of the cooling tower.

13. Water from an open, evaporative cooling tower may be used to cool water in an intermediate cooling media loop that will subsequently be used to cool product, provided that the water in the intermediate cooling media loop is effectively protected against infiltration and contamination by tower water at all times.

14. If a plate type or double/triple tube type heat exchanger is used to exchange heat between the water from the open tower and the water in the intermediate cooling media loop, it shall be protected by an isolation system to assure that there is no possibility of contamination of the intermediate cooling media loop water by the tower water. The isolation system shall include:

(i) Tower water heat exchangers shall be constructed, installed, and operated so that the intermediate cooling media water in the heat exchanger will

automatically be under greater pressure than the open tower water in the heat exchanger at all times.

(ii) The tower water heat exchanger shall be effectively isolated from the tower water system and the tower water side of the heat exchanger shall drain during shut down.

(iii) The isolation system shall be controlled with a pressure differential controller set to a minimum of 6.9 kPa (1 psi). Pressure sensors shall be installed at the tower water inlet to the heat exchanger and intermediate cooling water outlet of the heat exchanger. The differential pressure controller shall be interwired with the related supply valves and/or pumps to automatically shut down all supply pumps and return valves in the isolation system to a fail-safe position to isolate the heat exchanger from the open tower water system, as would occur in a shut down or power failure.

(iv) The intermediate cooling water shall rise to a vertical elevation of at least 30.5 centimeters (12 inches) above the highest tower water in the tower water heat exchanger isolation system, and shall be open to the atmosphere at this elevation. During a shut down, the intermediate cooling water shall not drain from the tower water heat exchanger.

(v) The isolation system shall meet one (1) of the following:

(I) In a system with tower water supplied directly from the tower water distribution line without a balance tank, or with a balance tank higher than the lowest water level in the tower water heat exchanger (refer to Figures 8, 9, and 10 in Appendix D.).

(II) In this application, the isolation system shall begin at the normally closed tower water supply stop "block" valve and ends at the check-valve in the line returning to the open cooling tower.

(III) Isolation is accomplished by meeting all of the following:

I. Closing the tower water supply valve. This tower water supply valve shall be a normally closed (spring-to-close) valve.

II. Opening a full port vent valve on the supply side of the tower water heat exchanger and a full port drain valve prior to a check-valve in the tower water return line. This drain valve shall be normally open (spring-to-open).

III. The drain valve and any pipes or pumps located between the drain valve and the heat exchanger shall be lower than the lowest liquid level in the heat exchanger.

IV. De-energize any dedicated tower water supply pump, if present, located between the tower water reservoir and the tower water heat exchanger.

V. If a tower water return pump is used, a bypass line may be used to flood the dry pump at start up.

(IV) In a system with the overflow of an atmospheric balance tank lower than the lowest water level in the heat exchanger (refer to Figures 11 and 12 in Appendix D, VII).

(V) In this application, the isolation system shall begin at the tower water balance tank and end at the check-valve in the line returning to the open cooling tower.

(VI) Isolation is accomplished by meeting all of the following:

I. De-energizing the “local tower water supply pump”, if present (refer to Figure 11 in Appendix D, VII).

II. Opening a full port vent valve on the supply side of the tower water heat exchanger.

III. Open a full port drain valve prior to a check-valve in the tower water return line.

IV. This drain valve shall be normally open (spring-to-open).
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V. The drain valve and any pipes or pumps located between it and the heat exchanger

shall be lower than the lowest liquid level in the heat exchanger.

(VII) Variations from the above isolation systems may be individually evaluated and found to also be acceptable by the Health Officer, if the level of protection required by this Administrative Procedure is not compromised.

(VIII) Testing - A means to test the response of this isolation system shall be developed and available at the milk plant. The accuracy of the required differential pressure controller shall be checked by the Health Officer on installation; every six (6) months thereafter; and following repair or replacement.

***__**Note:**__ Nothing shall be construed as barring other time and temperature relationships, which have been recognized by FDA to be equally efficient and which are approved by the Health Officer.

(24) Bottling, Packaging, and Container Filling

(a) Bottling, packaging, and container filling of milk, milk products, and frozen dessert products shall be done at the place of pasteurization in a sanitary manner by approved mechanical equipment.

(b) For milk plants that dry milk products, these dry milk products shall be packaged in new containers which protect the contents from contamination, and after packaging, shall be stored in a sanitary manner.

(c) For milk plants that condense and/or dry milk or milk products, these condensed and dry milk products may be transported in sealed containers in a sanitary manner from one (1) milk plant to another for further processing and/or packaging.

(d) Condensed and dry milk product packaging containers shall be stored in a sanitary manner.

(e) Public Health Reason - Manual bottling, packaging, and container filling is very apt to result in the exposure of the milk, milk product, and frozen dessert products to contamination, which would nullify the effect of pasteurization. The transfer of milk, milk product, and frozen dessert products from the place of pasteurization to another milk plant for bottling, packaging, or container filling may subject the pasteurized milk or milk product to unnecessary risks of contamination. Reuse of packages for dry milk

products is likely to result in contamination of the dry milk products.

(f) Administrative Procedures - This item is deemed to be satisfied when:

1. All milk and milk products, including concentrated (condensed) milk and milk products, are bottled and packaged at the milk plant where final pasteurization is performed. Such bottling and packaging shall be done without undue delay following final pasteurization.

2. All bottling or packaging is done on approved mechanical equipment. The term "approved mechanical equipment" shall not be interpreted to exclude manually operated machinery, but is interpreted to exclude methods in which the bottling and capping devices are not integral within the same system.

3. All pipes, connections, defoaming devices, and similar appurtenances shall comply with Rule 420-3-16-.10-11. Milk and milk products from continuous defoamers are not returned directly to the filler bowl.

4. Bottling or packaging machine supply tanks and bowls are equipped with covers that are constructed to prevent any contamination from reaching the inside of the filler tank or bowl. All covers shall be in place during operation.

5. A drip deflector is installed on each filler valve. Drip deflectors shall be designed and adjusted to divert condensation away from the open container.

6.) Container in-feed conveyors to automatic bottling or packaging machines have overhead shields to protect the bottles or packages from contamination. These shields shall extend from the bottle washer discharge to the bottle feed-star, or in the case of single-service packaging machines, from the forming unit discharge to the filling unit and from the filling unit to the closure unit. Overhead shields shall be required on can in-feed conveyors when the cans are fed to the filler with the covers off.

7. Container coding/dating devices are designed, installed, and operated such that the coding/dating operations are performed in a manner that open containers are not subjected to contamination. Shielding shall be properly designed and installed to preclude the contamination of open containers.

8. Container fabricating materials, such as paper stock, foil, wax, plastic, etc., are handled in a sanitary manner and protected against undue exposure during the package assembly operation.

9. Bottling and packaging machine floats are designed to be adjustable without removing the cover.

10. The filler pipe of all bottling and packaging machines have a diversion apron or other acceptable device, as close to the filler bowl as possible, to prevent condensation from entering the inside of the filler bowl.

11. Filling cylinders on packaging machines are protected from contamination by overhead shields. When lubricants are used on filler pistons, cylinders or other milk or milk product-contact surfaces, the lubricant shall be food-grade and applied in a sanitary manner.

For milk plants that condense and/or dry milk or milk products, the following shall apply:

(i) The filling of condensed and dry milk product containers is done by mechanical equipment. The term "mechanical equipment" shall not be interpreted to exclude manually operated equipment.

(ii) All pipes, connections, and similar appurtenances comply with Rule 420-3-16-.10-11.

(iii) Filling devices are constructed so as to prevent any contamination from reaching the product. Covers of filling devices, if used, shall be in place during operation.

(iv) Packaged dry milk and milk products are stored and arranged so as to be easily accessible for inspection and to permit cleaning of the storage room.

(v) All condensed and dry milk product containers are filled in a sanitary manner by methods which:

(I) Protect the product from airborne contamination.

(II) Prevent manual contact with condensed and dry milk product-contact surfaces.

(III) Minimize manual contact with the product.

(iv) All final containers for dry milk products shall be new and of the single-service type and sufficiently substantial to protect the contents from impairment of quality with respect to sanitation, contamination, and moisture, under customary conditions of handling, transportation, and storage.

(vii) If portable storage bins are used, they comply with the applicable provisions of Rule 420-3-16-.10-11.

(viii) Containers are closed immediately after being filled.

(25) **Capping, Container Closure and Sealing, and Dry Milk Product Storage**

(a) Capping, closing, or sealing of Grade "A" milk and milk product containers shall be done in a sanitary manner by approved mechanical capping, closing, or sealing equipment. The cap or closure shall be designed and applied in such a manner that the pouring lip is protected to at least its largest diameter and, with respect to fluid product containers, removal cannot be made without detection. Frozen dessert containers shall be closed in a sanitary manner approved by the Health Officer.

(b) Public Health Reason - Hand-capping exposes the milk or milk product to contamination. A cover extending over the pouring lip of the container protects it from contamination during subsequent handling and prevents the sucking back into the bottle, by temperature contraction, of any contaminated liquid on the cap, including milk or milk products which have been forced out by temperature expansion and which may have become contaminated. Caps or closures that are applied in such a manner that they cannot be removed without detection help to assure the consumer that the milk and milk products have not been contaminated after packaging.

(c) Administrative Procedures - This item is deemed to be satisfied when:

1. The capping, closing, or sealing of Grade "A" milk and milk product containers is done in a sanitary manner on approved mechanical capping, closing, or sealing equipment. The term "approved mechanical capping, closing, or sealing equipment" shall not exclude manually operated machinery. Hand-capping shall be prohibited. Provided, if suitable mechanical equipment for the capping or closing of specific container(s) of three (3) gallons 12.8 liters or more is not available, other methods which eliminate all possibility of contamination may be approved by the Health Officer.

2. All mechanical capping or closure mechanisms are designed to minimize the need for adjustment during operation.

3. Bottles and packages which have been imperfectly capped or closed are emptied immediately into approved sanitary containers. Such milk, milk products, or frozen desserts shall be protected from contamination, maintained at 45°F (7°C) or less, except dry milk products, and subsequently re-pasteurized or discarded.

4. All caps and closures are designed and applied in such a manner that the pouring lip is protected to at least its largest diameter and, with respect to fluid product containers, removal cannot be made without detection. Single-service containers are so constructed that the product and the pouring and opening areas are protected from contamination during handling, storage, and when the containers are initially opened.

5. All caps and closures are handled in a sanitary manner. The first cap from each tube, the first lap(s) from each roll of cap or cover stock, and the first sheet of parchment or cover paper shall be discarded. The subsequent use of loose caps which are left in the cappers at the end of an operation period after removal from the cap tubes shall be a violation of this paragraph, provided that loose plastic caps and closures supplied by the manufacturer in plastic bags may be returned to storage in a protective wrap if removed from a hopper/descrambler immediately after a production run. Plastic caps and closures remaining in the chute between the hopper and the cupping device shall be discarded. Provided further that if suitable equipment is not available for capping cottage cheese, dry curd cottage cheese, and lowfat cottage cheese, other methods of capping which eliminate possible chance of contamination may be approved by the Health Officer.

6. Closures for cottage cheese, dry curd cottage cheese, and lowfat cottage cheese containers shall extend over the top edges of the container so as to protect the product from contamination during subsequent handling.

7. Provided, that this requirement shall not apply to cottage cheese, dry curd cottage cheese, and lowfat cottage cheese container closures, when such closures are supplied in a totally enclosed package, or wrapped so as to protect the closures.

(26) **Personnel - Cleanliness**

(a) Hands shall be thoroughly washed before commencing plant functions and as often as may be required to remove soil and contamination. No employee shall resume work after visiting the toilet room without thoroughly washing his hands. All persons while engaged in the processing, pasteurization, handling, storage, transportation, or packaging of milk, milk products, frozen desserts, containers, equipment, and utensils shall wear clean outer garments. All persons, while engaged in the processing of milk, milk products, or frozen desserts, shall wear adequate hair coverings and shall not use tobacco.

(b) Public Health Reason - Clean clothing and clean hands (including clean fingernails) reduce the possibility of milk, milk products, frozen desserts, containers, utensils, and equipment from becoming contaminated.

(c) Administrative Procedures - This item is deemed to be satisfied when:

1. Hands are thoroughly washed before commencing plant functions and as often as may be required to remove soil and contamination.

2. Each employee washes his hands following a visit to the toilet room and prior to resuming work.

3. All persons, while engaged in the processing, pasteurization, handling, storage, transportation, or packaging of milk, milk products, frozen desserts, containers, equipment, and utensils wear clean outer garments.

4. The use of tobacco products is prohibited in all rooms in which milk, milk products, and frozen dessert products are handled, processed, or stored, or in which milk, milk products, and frozen dessert products, containers, utensils, and/or equipment are washed. These rooms shall include, but are not limited to, the receiving, processing, packaging, milk, milk product, and frozen dessert product storage, cooling and dry storage ingredients, single-service article storage, and container/utensil wash-up areas. Any person engaged in the processing of milk, milk products, and frozen dessert products wears adequate hair coverings.

5. Specially provided clean rubbers or boot covers, clean coveralls, and white cap, clean cloth or paper, are worn whenever it is necessary to enter the drying chambers. Such articles of clothing are stored in such a manner as to be protected from contamination. Boot covers which have come into contact with areas other than those within the dryer are not considered clean.

(27) **Vehicles**

(a) All vehicles used for transportation of pasteurized milk, milk products, and frozen desserts shall be constructed and operated so that the milk, milk products, and frozen dessert are maintained at 45°F (7°C) or less, and are protected from sun, from freezing, and from contamination. Milk tank cars, milk tank trucks, and frozen dessert transport vehicles, and portable shipping bins shall not be used to transport or contain any substances that may be toxic or harmful to humans.

(b) Public Health Reason - The exposure of milk to the sun will alter the flavor of milk and will tend to increase the temperature, thus increasing the possibility of bacterial growth. Freezing alters the physical and chemical properties of milk. Milk, milk products, and frozen dessert products, as well as empty containers, should be protected against contamination at all times.

(c) Administrative Procedures - This item is deemed to be satisfied when:

1. All vehicles are kept clean.

2. Material which is capable of contaminating milk, milk products, and frozen desserts is not transported with milk, milk products, or frozen desserts.

3. Milk and milk products, except dry milk products, are maintained at 7°C (45°F) or less.

4. The operation of milk tank cars and shipping bins comply with the following provisions:

(i) Milk, milk products, and frozen dessert products shall be conducted to and from tank cars or shipping bins only through sanitary conveying equipment. Such equipment shall be capped or otherwise protected when not in use.

(ii) Inlets and outlets of shipping bins shall be provided with tight-fitting dust caps or covers.

(iii) Facilities shall be provided for the adequate washing and sanitizing of shipping bins, piping, and accessories at all milk plants receiving or shipping milk, milk products, and frozen dessert products in shipping bins.

(iv) Shipping bins shall be cleaned at the receiving milk plant immediately after being emptied. The clean shipping bins shall be sanitized at the shipping milk plant before loading. Milk tank trucks which must

make more than one trip while unloading a tank car need not be cleaned and sanitized after each time they are emptied.

(v) Piping connections and pumps used with shipping bins shall be cleaned and sanitized after each use.

5. The doors of tank cars and covers of shipping bins are sealed with a metal seal immediately after loading. The seal shall remain unbroken until the contents are delivered to the consignee. Contents of the tank car or shipping bin shall be labeled as prescribed in Section 4 by means of a tag attached to the tank car or shipping bin.

6. Vehicles have fully enclosed bodies with well-fitted, solid doors.

(28) **Surroundings**

(a) Milk and frozen dessert plant surroundings shall be kept neat, clean, and free from conditions which might attract or harbor flies, other insects, and rodents or which otherwise constitute a nuisance.

(b) Public Health Reason - The surroundings of a plant should be kept neat and clean to prevent attracting rodents, flies, and other insects which may contaminate the milk, milk products, or frozen desserts. Insecticides and rodenticides not approved for use in plants or approved insecticides and rodenticides not used in accordance with label recommendations may contaminate the milk, milk products, or frozen desserts processed by the plant.

(c) Administrative Procedures - This item is deemed to be satisfied when:

1. There is no accumulation of trash, garbage, or similar waste in areas adjacent to the milk or frozen dessert plant. Waste material stored in suitable covered containers shall be considered in compliance.

2. Driveways, lanes, and areas serving milk and frozen dessert plant vehicular traffic are graded, drained, and free from pools of standing water.

3. Outdoor areas for milk tank truck unloading are constructed of smooth concrete or equally impervious material, properly sloped to drain, and equipped with trapped drains of sufficient size.

4. Only insecticides and rodenticides approved for use by the Health Officer and/or registered with the FDA shall be used for insect and rodent control.

5. Rooftops are kept clean of dry milk or milk products, which may accumulate and contribute to unsanitary conditions.

Note: A convenient inspection form for milk and frozen dessert plants, receiving stations, and transfer stations, which summarizes the applicable sanitation requirements are found in Appendix M.

Author: G. M. Gallaspy, Jr.
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