STANDARDS FOR GRADE "A" PASTEURIZED, ULTRA-PASTEURIZED, ASEPTICALLY PROCESSED AND PACKAGED LOW-ACID MILK AND/OR MILK PRODUCTS, RETORT PROCESSED AFTER PACKAGED LOW-ACID MILK AND/OR MILK PRODUCTS AND FERMENTED HIGH-ACID, SHELF-STABLE PROCESSED AND PACKAGED MILK AND/OR MILK PRODUCTS

Milk plants shall comply with all Items of this Section. 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 and/or milk products and/or retort processed after packaging low-acid milk and/or milk products and/or fermented high-acid, shelf-stable processed and packaged milk and/or milk products, the APPS or RPPS or AQFPSS, respectively, as defined by this *Ordinance,* shall be exempt from Items 7p, 10p, 11p, 12p, 13p, 15p, 16p, 17p, 18p, and 19p of this *Ordinance* and shall comply with the applicable portions of 21 CFR Parts 108, 113 and 117. Those Items, contained within the APPS, RPPS and/or AQFPSS, shall be inspected by FDA or a State Regulatory Agency, when designated by FDA. The overall sanitation of a milk plant shall be under the supervision of one (1) or more qualified individuals (QIs) assigned responsibility for this function.

A receiving station shall comply with Items 1p to 15p(A) and (B), inclusive, and 17p, 20p and 22p, except that the partitioning requirement of Item 5p shall not apply.

A transfer station shall comply with Items 1p, 4p, 6p, 7p, 8p, 9p, 10p, 11p, 12p, 14p, 15p(A) and (B), 17p, 20p and 22p and as climatic and operating conditions require the applicable provisions of Items 2p and 3p. Provided, that in every case, overhead protection shall be provided.

Facilities for the cleaning and sanitizing of milk tank trucks shall comply with Items 1p, 4p, 6p, 7p, 8p, 9p, 10p, 11p, 12p, 14p, 15p(A) and (B), 20p and 22p and as climatic and operating conditions require, the applicable provisions of Items 2p and 3p. 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. of this *Ordinance*, 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 Item 16p. Pasteurization, Aseptic Processing and Packaging, Retort Processed after Packaging and Fermented High-Acid, Shelf-Stable Processing and Packaging of this *Ordinance*, 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 of this *Ordinance*.

ITEM 1p. FLOORS – CONSTRUCTION

The floors of all rooms in which milk or milk products are handled, processed, packaged, or stored; or in which milk containers, utensils and/or equipment are washed, shall be constructed of concrete or other equally impervious and easily cleanable material; and shall be smooth, properly sloped, provided with trapped drains and kept in good repair. Provided, that 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/ or packaging materials need not be provided with drains and the floors may be constructed of tightly joined wood.

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 milk plant.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. The floors of all rooms in which milk or milk products are handled, processed, packaged, 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/or milk products need not be provided with floor drains when the floors are sloped to drain to one (1) 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, retort processed after packaged low-acid milk and/or milk products and/or packaging materials and fermented high-acid, shelf-stable processed and packaged milk and/or milk products and/or packaging materials are not required to be provided with drains.

NOTE: Refer to Item 11p of this *Ordinance* for requirements for floors of drying chambers.

ITEM 2p. WALLS AND CEILINGS – CONSTRUCTION

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

PUBLIC HEALTH REASON

Properly finished walls and ceilings are more easily kept clean and are; therefore, more apt to be kept clean. A light-colored finish aids in the even distribution of light and the detection of unclean conditions.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. Walls and ceilings are finished with smooth, washable, light-colored impervious materials.
2. Walls, partitions, windows and ceilings are kept in good repair.

NOTE: Refer to Item 11p of this *Ordinance* 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, retort processed after packaged low-acid milk and/or milk products and fermented high-acid, shelf-stable processed and packaged milk and/or milk products are exempt from the ceiling requirements of this Item.

ITEM 3p. DOORS AND WINDOWS

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.

PUBLIC HEALTH REASON

Freedom from insects in the milk plant reduces the likelihood of contamination of the milk or milk product. (Refer to Item 7r-Public Health Reason of this *Ordinance* for information on disease transmission by flies.)

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. All openings to the outer air are effectively protected by:
   a. Screening; or
   b. Effective electric screen panels; or
   c. Fans or air curtains which provide sufficient air velocity so as to prevent the entrance of insects; or
   d. Properly constructed flaps where it is impractical to use self-closing doors or air curtains; or
   e. Any effective combination of a, b, c, or d 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 milk plant shall be considered under Item 9p of this *Ordinance*.

ITEM 4p. LIGHTING AND VENTILATION

All rooms in which milk or milk products are handled, processed, packaged, or stored, or in which milk containers, utensils and/or equipment are washed shall be well lighted and well ventilated.

PUBLIC HEALTH REASON

Ample light promotes cleanliness. Proper ventilation reduces odors and prevents condensation upon interior surfaces.

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 containers, utensils and/or equipment are washed. Dry storage and cold storage rooms shall be provided with at least five (5) foot-candles (55 lux) of light. Shatter-resistant light bulbs, fixtures, skylights, or otherwise protect against contamination in the case of glass break-age shall be provided where milk or milk products are handled, processed, packaged, or stored; or where containers, utensils and/or equipment are washed.
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.

ITEM 5p. SEPARATE ROOMS

There shall be separate rooms for:

1. The pasteurizing, processing, cooling, reconstitution, condensing, drying and packaging of milk and milk products.
2. Packaging of dry milk or milk products.
3. The cleaning of milk cans and containers, bottles**,** cases and dry milk or milk product containers.
4. 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 and/or fermented high-acid, shelf-stable processed and packaged milk and/or milk products in which the containers and closures are fabricated within the APPS, RPPS or AQFPSS, respectively.
5. Cleaning and sanitizing facilities for milk tank trucks in milk plants receiving milk or whey in such tanks.
6. Receiving cans of milk and milk products in milk plants receiving such cans.

Rooms in which milk or milk products are handled, processed, stored, condensed, dried and packaged, or in which containers, utensils and/or equipment are washed or stored, shall not open directly into any stable or any room used for domestic purposes. All rooms shall be of sufficient size for their intended purposes.
Designated areas or rooms shall be provided for the receiving, handling and storage of returned packaged milk and milk products.

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 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 too public.

ADMINISTRATIVE PROCEDURES[7]

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 and milk products, which have physically left the premises of the processing milk plant, shall be received, handled and stored in separate areas or rooms isolated from the Grade "A" 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 or milk product shall be considered satisfactory.
4. Facilities for the cleaning and sanitizing of milk tank trucks are properly equipped for manual and/or CIP operations. When such facilities are not provided on the milk plant premises, these operations shall be performed at a receiving station, transfer station or separate milk tank truck cleaning facility. Items relating to facilities for cleaning and sanitizing milk tank trucks are listed at the beginning of this Section.
5. Rooms in which milk or milk products are handled, processed or stored; or in which milk containers, utensils and/or equipment are washed or stored, do not open directly into any stable or any room used for domestic purposes.
6. All rooms shall be of sufficient size for their intended purposes.

ITEM 6p. TOILET-SEWAGE DISPOSAL FACILITIES

Every milk plant shall be provided with toilet facilities conforming to the regulations of the ... of ...[1] Toilet rooms shall not open directly into any room in which milk and/or 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.

PUBLIC HEALTH REASON

Human excreta are potentially dangerous and shall 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 or milk product, containers, utensils and equipment from fecal contamination, which may be carried by insects, hands or clothing. When the toilet facilities are of a satisfactory type, are kept clean and are 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 or milk products are processed, condensed or dried makes it less likely that contaminated insects will enter these rooms. It will also minimize the spread of odors.
The wastes resulting from the cleaning and rinsing of containers, utensils, equipment and floors, from flush toilets, and from washing facilities, should be properly disposed of so as not to contaminate the milk containers, utensils or equipment, or to create a nuisance or a public health hazard.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. The milk plant is provided with toilet facilities conforming to the regulations of the ... of ...[1]
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.

ITEM 7p. WATER SUPPLY

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

PUBLIC HEALTH REASON

The water supply should be accessible in order to encourage its use in cleaning operations; it should be adequate so that cleaning and rinsing may be thorough; and it should be of a safe, sanitary quality in order to avoid the contamination of containers, utensils and equipment.

ADMINISTRATIVE PROCEDURES[8]

This Item is deemed to be satisfied when:

1. Water for milk 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 applicable Government Water Control Authority and, in the case of individual water systems, complies with the specification outlined in Appendix D. and the Bacteriological Standards outlined in Appendix G. of this *Ordinance*.
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 preventer, 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 (1 inch).

4. All containers and tanks used in the transportation of water are sealed and protected from possible contamination. These containers and tanks shall be subjected to a thorough cleaning and a bacteriological treatment prior to filling with potable water to be used at the milk plant. To minimize the possibility of contamination of the water during its transfer from the potable tanks to the elevated or groundwater storage at the milk plant, a suitable pump, hose and fittings shall be provided. When the pump, hose and fittings are not being used, the outlets shall be capped and stored in a suitable dust-proof enclosure so as to prevent their contamination. The storage tank at the milk plant shall be constructed of impervious material; provided with a dust and rainproof cover; and also provided with an approved vent and roof hatch. All new reservoirs or reservoirs which have been cleaned shall be disinfected prior to placing them into service. (Refer to Appendix D. of this *Ordinance*.)

5. 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 Item 2 above. Provided, that when approved by the Regulatory Agency, water from sources not complying with Item 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:

   a. Use of a surface type condenser in which the condensing water is physically separated from the vapors and condensate; or

   b. 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 shutoff valve, located on the water feed line to the condenser, automatically actuated by a control which shall 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 shall automatically stop the flow of water into the condenser.

6. Condensing water for milk or milk product evaporators, complying with Item 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. of this *Ordinance*.

7. 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. of this *Ordinance*.) The supply shall be made free of the disinfectant by pumping to waste before any sample for bacteriological testing shall be collected.

8. Samples for bacteriological testing of individual water supplies and Category I and II, when required, water that has been reclaimed from milk and milk products and from heat exchangers of compressors in milk plants as defined in Appendix D. of this *Ordinance* are taken upon the initial approval of the physical structure or water system; at least once every six (6) month period thereafter; and when any repair or alteration of the water system has been made. Provided, that

when water is hauled to the milk plant, such water shall be sampled for bacteriological examination at the point of use and submitted to an official laboratory at least four (4) times in separate months during any consecutive six (6) month period. Samples shall be taken by the Regulatory Agency and examinations 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.

9. Current records of water test results are retained on file with the Regulatory Agency or as the Regulatory Agency directs.

10. A potable water supply, which meets the criteria of this Section, 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 or milk product lines or vessels shall be protected with an effective backflow preventer.

NOTE: Refer to Item 15p.(A), **ADMINISTRATIVE PROCEDURES** of this *Ordinance*, for additional requirements involving the protection of milk and milk products.

ITEM 8p. HANDWASHING FACILITIES

Convenient handwashing facilities shall be provided, including hot and cold and/or warm running water, soap and individual sanitary towels or other approved hand-drying devices. Handwashing facilities shall be kept in a clean condition and in good repair.

PUBLIC HEALTH REASON

Proper use of handwashing facilities is essential to personal cleanliness and reduces the likelihood of contamination of milk and milk products.

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 convenient to all toilets and to all rooms in which milk 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.

ITEM 9p. MILK PLANT CLEANLINESS

All rooms in which milk and milk products are handled, processed or stored; 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 the handling of containers, utensils and equipment shall be permitted in the pasteurizing, processing, cooling, condensing, drying, packaging, and bulk milk or milk product storage rooms.

PUBLIC HEALTH REASON

Clean floors, free of litter, clean walls, ceilings and all other areas of the milk plant are conducive to clean milk and milk product handling operations. Cleanliness and freedom from insects and rodents reduce the likelihood of contamination of the milk or milk product. Excess or unused equipment or equipment not directly related to the milk plant operations can be detrimental to the cleanliness of the milk plant.

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 milk 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 milk plant, except in covered containers. Waste containers at the packaging machine or bottle washer may be uncovered during the operation of such equipment.
4. All rooms in which milk and milk products are handled, processed or stored; or in which containers, utensils, and/or equipment are washed or stored, are kept clean, neat and free of evidence of insects and rodents.
5. Excessive product dust shall be kept under effective control by the use of exhaust and collective systems designed for in-plant dust control. Tailings and materials collected from exhaust collective systems shall not be used for human consumption.

ITEM 10p. SANITARY PIPING

All sanitary piping, fittings and connections which are exposed to milk and milk products or from which liquids may drip, drain or be drawn into milk and milk products shall consist of smooth, impervious, corrosion-resistant, non-toxic, easily cleanable material, which is approved for milk product-contact surfaces. All piping shall be in good repair. Pasteurized milk and milk products shall be conducted from one piece of equipment to another only through sanitary piping.[9]

PUBLIC HEALTH REASON

Milk 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 milk or milk product to contamination.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. All sanitary piping, fittings and connections, which are exposed to milk or milk products or from which liquids may drip, drain or be drawn into milk or milk products, consist of smooth, impervious, corrosion-resistant, non-toxic, easily cleanable material.
2. All sanitary piping, connections and fittings consist of:
   a. Stainless steel of the AISI 300 series; or
   b. Equally corrosion-resistant metal which is non-toxic and nonabsorbent; or
   c. Heat resistant glass; or
   d. Plastic, or rubber and rubber-like materials which are relatively inert, resistant to scratching, scoring, decomposition, crazing, chipping and distortion under normal use conditions; are non-toxic, fat resistant, relatively nonabsorbent; which do not impart flavor or odor to the milk or milk product; 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; free of breaks or corrosion; and contain no dead ends of piping in which milk or milk product 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 CIP cleaned milk 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 Item 2 above. If gaskets are used, they shall be self-positioning, of material meeting the specifications outlined in Item 2 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 as they are made, and such welds shall be approved by the Regulatory Agency.
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 or combinations that are adequate for the 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 Regulatory Agency 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 Regulatory Agency.
6. Pasteurized milk and milk products are conducted from one piece of equipment to another only through sanitary milk piping.
7. For milk plants that dry milk or milk 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.

ITEM 11p. CONSTRUCTION AND REPAIR OF CONTAINERS AND EQUIPMENT

All multi-use containers and equipment that milk and milk products come into contact with shall be of smooth, impervious, corrosion-resistant, non-toxic material; shall be constructed for ease of cleaning; and shall be kept in good repair. All single-service containers, closures, gaskets and other articles that milk and milk products come in contact with shall be non-toxic and shall have been

manufactured, packaged, transported and handled in a sanitary manner. Articles intended for single-service use shall not be reused.

PUBLIC HEALTH REASON

When equipment is not constructed and located so that it can be cleaned easily, and is not kept in good repair, it is unlikely that it will be properly cleaned.
Single-service articles, which have not been manufactured and handled in a sanitary manner, may contaminate the milk or milk product.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. All multi-use containers and equipment that milk and milk products come into contact with are of smooth, impervious, corrosion-resistant and non-toxic material.
2. All milk and milk product-contact surfaces of multi-use containers and equipment consist of:
   a. Stainless steel of the AISI 300 series; or
   b. Equally corrosion-resistant metal which is non-toxic and nonabsorbent; or
   c. Heat resistant glass; or
   d. Plastic or rubber and rubber-like 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 nonabsorbent and do not impart flavor or odor to the milk or milk product; and which maintain their original properties under repeated use conditions.
3. All joints in containers, utensils and equipment are flush and finished as smooth as adjoining surfaces, or if the surface is vitreous, it shall 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 or milk products 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 and milk products. Where a thermometer or temperature-sensing element is inserted through a surface, with which milk or milk products 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 watertight joint is provided.
5. All surfaces with which milk or milk 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, that 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 or milk products except where needed for functional and safety reasons, such as in clarifiers, pumps and separators. Such threads shall be of a sanitary type, except those used on high-pressure lines between the high-pressure pump and the 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, that 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 CIP 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:

a. Plastic materials listed in 2.d. above; or
b. Woven stainless steel wire conforming to 2.a. above; or
c. Cotton, linen, silk, or synthetic fibers which are non-toxic, relatively insoluble, easily cleanable and do not impart a flavor to the product.

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 that milk or milk products come in contact with are non-toxic.
11. The manufacture, packing, transportation and handling of single-service containers, closures, caps, gaskets and similar articles comply with the requirements of Appendix J. of this *Ordinance*. Provided that 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*.
Inspections and tests shall be made by the Regulatory Agency or any Agency authorized by them.

NOTE: The option for "Inspections and tests" as cited in 11 above, shall only be made by a TPC authorized under the ICP.

12. Provided that all paper, plastics, foil, adhesives, and other components of containers and closures used in the packaging of milk and/or milk products that have been aseptically processed and packaged, retort processed after packaging or fermented high-acid, shelf-stable processed and packaged are governed under the applicable provisions of 21 CFR Parts 113 and 117 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.

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

ITEM 12p. CLEANING AND SANITIZING OF CONTAINERS AND EQUIPMENT

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 or milk products shall be effectively cleaned and shall be sanitized before each use. Provided that cloth-

collector systems used on dryers shall be cleaned and sanitized or purged at intervals and by methods recommended by the manufacturer and approved by the Regulatory Agency.

PUBLIC HEALTH REASON

Milk and milk products cannot be kept clean and safe, if permitted to come into contact with containers, utensils and equipment that have not been properly cleaned and sanitized.

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 Regulatory Agency 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 Regulatory Agency prior to initiating the qualification period if required. Finished product produced during an extended run shall meet all applicable requirements of Section 7. of this *Ordinance*. Any significant equipment or processing changes shall be communicated to the Regulatory Agency 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).

The supporting information may include but is not limited to:

a. Statement of proposal, including desired cleaning frequency.
b. Product and equipment description.
c. Intended use and consumers.
d. Distribution and storage temperatures of product.
e. Diagram of process of interest.
f. Process parameters, including temperature and times.
g. Hazard evaluation and safety assessment.
h. Review of equipment for sanitary design.
i. When indicated by a hazard evaluation and safety assessment, a plan for initial qualification shall be developed to address identified critical process parameters.

Otherwise, storage tanks shall be cleaned when emptied and shall be emptied at least every seventy-two (72) hours. The seventy-two (72) hour time period starts when milk first enters a cleaned and sanitized storage tank._Records shall be available to document that milk storage in these tanks does not exceed seventy-two (72) hours. These cleaning records shall be:

a. Identified with the name and location of the milk plant or their milk plant code, dated and the signature or initials of the person performing the activity;
b. Reviewed, dated and signed or;
c. Onsite and shall be reviewed by the Regulatory Agency during each regulatory inspection for at least the previous three (3) months or from the last regulatory inspection, whichever is longer. Electronic records are considered to be onsite if they are accessible from an onsite location; and
d. Retained for at least two (2) years after the date they were created. Offsite storage of these cleaning records is permitted if such records can be retrieved and provided onsite within twenty-four (24) hours of a request for official review.

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 2.b. of this Section 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. of this *Ordinance*. Electronic records that comply with the applicable provisions of Appendix H., IV. and V. of this *Ordinance*, 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.
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 Regulatory Agency. Such methods may include cleaning without water (dry cleaning) by the use of vacuum cleaners, brushes, or scrapers. Product-contact surfaces shall be subjected to an effective sanitizing treatment immediately prior to use, except where dry cleaning is permitted. 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 Regulatory Agency. 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. of this *Ordinance* contains additional information on dry cleaning of drying equipment, packaging equipment, and dry milk product and dry whey storage containers.

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: First use shall be defined as when milk is first transferred into the milk tank truck and the time is documented.

Whenever a milk tank truck has been cleaned and sanitized, as required by the Regulatory Agency, 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 Regulatory Agency.

NOTE: Appendix B. of this *Ordinance* contains additional information on the cleaning and sanitizing requirements for milk tank trucks.

2. Pipelines and/or equipment designed for CIP cleaning meet the following requirements:
   a. An effective cleaning and sanitizing regimen for each separate cleaning circuit shall be followed.

b. A temperature-recording device, complying with the specifications in Appendix H., IV. of this *Ordinance*, or a recording device which provides sufficient information to adequately evaluate the cleaning and sanitizing regimen and which is approved by the Regulatory Agency, shall be installed in the return solution line or other appropriate area 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. of this *Ordinance*, with or without hard copy, may be used in place of the cleaning records described above. For purposes of this Section, recording devices which produce records not meeting the specifications of Appendix H., IV. of this *Ordinance* 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 Regulatory Agency. Electronic records shall meet the criteria of this Section and Appendix H., V. of this *Ordinance*. 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 Regulatory Agency and meet the criteria of this Section and 21 CFR Part 11.

c. Cleaning charts and electronically stored records required by this Section shall be:

(i) Identified with the name and location of the milk plant or their milk plant code, dated and the signature or initials of the person performing the activity;

(ii) Reviewed, dated and signed or initialed;

(iii) Shall be onsite and shall be reviewed by the Regulatory Agency during each regulatory inspection for at least the previous three (3) months or from the last regulatory inspection, whichever is longer. Electronic records are considered to be onsite if they are accessible from an onsite location; and

(iv) Retained for at least two (2) years after the date they were created. Offsite storage of these cleaning records is permitted if such records can be retrieved and provided onsite within twenty-four (24) hours of a request for official review.

d. During each official inspection, the Regulatory Agency shall examine charts and records to verify the cleaning regimens.

3. Milk plants in which containers are washed manually are equipped with a two (2)-compartment wash-and-rinse vat for this purpose. Such milk 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.

4. In milk plants utilizing automatic bottle washers, such washers shall provide for bactericidal treatment by means of steam, hot water or chemical treatment. In 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, which lists the combinations of causticity, time and temperature, of equal bactericidal value, for the soaker tank of soaker-type bottle washers:

Table 2. Combination of Causticity, Time and Temperature, of Equal Bactericidal Value, for the Soaker Tank of Soaker-Type Bottle Washers
(Based on National Soft Drink Association (NSDA) Specification for Beverage Bottles)

Temperature, Degrees							
C	77	71	66	60	54	49	43
F	170	160	150	140	130	120	110

Time in Minutes	Concentration of NaOH (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	2.66	3.98

NOTE: The 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 at least once every (3) month period by the Regulatory Agency.

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 bottle during the rinsing operation.

5. All multi-use containers, utensils and equipment are sanitized before use, employing one or a combination of the methods prescribed under Item 11r of this *Ordinance*. Additionally, for milk plants that condense or dry milk or milk products the following methods are acceptable, or any other method, which has been demonstrated to be equally efficient:
   a. Exposure to an enclosed jet of steam for not less than 1 minute.
   b. 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.

Assembled equipment shall be sanitized prior to each day's run, unless FDA and the Regulatory Agency 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 Regulatory Agency at intervals sufficient to satisfy the Regulatory Agency that the sanitization process is effective.

For milk plants that dry milk or milk 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:
   a. Operate the spray nozzles with water at a temperature and rates at least as high as those employed during the drying operation.
   b. Adjust airflow to give at least 0.5 inch (water) pressure in the drying chamber.
   c. 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.

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.

6. a. The residual bacteria count of multi-use containers shall be conducted as outlined in Appendix J. of this *Ordinance*. The residual bacteria 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 (cm^2) (one (1) colony per square centimeter) of product-contact surface, when the swab test is used. For the sample set containing four (4) multi-use containers, taken at random on a given day, to be in compliance with the bacterial standards of Appendix J. of this *Ordinance* as cited above the sample set shall not have two (2) or more out of the four (4) samples making up the sample set exceeding the bacterial standard. All multi-use containers making up the sample set shall be free of coliform organisms.

   b. 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) cm^2 (one (1) colony per square centimeter) of product-contact surface, when the swab test is used. For the sample set containing four (4) single-service containers and/or closures, taken at random on a given day, to be in compliance with the bacterial standards of Appendix J. of this *Ordinance* as cited above the sample set shall not have two (2) or more out of the four (4) samples making up the sample set exceeding the bacterial standard. All single-service containers and/or closures making up the sample set shall be free of coliform organisms.

   c. When single-service containers and/or closures are fabricated in another plant that conforms to the Standards of Appendix J. of this *Ordinance* and the Regulatory Agency has information that they do comply, the Regulatory Agency 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 Regulatory Agency shall collect, during any consecutive six (6) months, at least four (4) sample sets of containers with applied closures, as defined in Appendix J. of this *Ordinance* from each manufacturing line, as defined in Appendix J. of this *Ordinance*, 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. of this *Ordinance*.

7. Milk plants that utilize multi-use plastic containers, for pasteurized milk and/or milk products, shall comply with the following criteria:

   a. 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, that the code is revealed to the Regulatory Agency.

   b. A device shall be installed in the filling line capable of detecting, in each container be- fore it is filled, volatile organic contaminants in amounts that are of public health significance. Such device shall be constructed so that it may be sealed by the Regulatory Agency 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 shall be sealed. Any container detected by the device, as being unsatisfactory shall be automatically made unusable to prevent refilling. In addition, the device shall be interconnected so that the system shall not operate unless the detecting device is in proper operating condition. Provided, that any other system so designed and operated that will provide equal assurance of freedom from contamination and recognized by FDA to be equally efficient may be accepted by the Regulatory Agency.

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:

(1) 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:

A) The used solution shall have at least a three percent (3%) concentration with a pH of at least 11.9 and an alkalinity expressed as sodium oxide of at least 2.5 percent;

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

C) The temperature of the soaker tank shall be at least 69ºC (155ºF); and

D) The final rinse subsequent to the soaking tank shall be with a sanitizing solution.

iii) 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.

(2) 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.

c. A standard shall be available for use by the Regulatory Agency for testing the proper sensitivity functioning levels of the detection device.

d. The containers shall comply with the applicable construction requirements of Item 11p of this *Ordinance*. The closure for the container shall be single-service. Screw-type closures shall not be used.

e. The container shall not impart, into the product, pesticide residual levels or other chemical contaminants in excess of those considered acceptable under the *FFD&CA* and regulations issued there under.

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

8. 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:

a. Single-service glass containers shall be manufactured from non-toxic materials and packaged and shipped in a manner that protects them from contamination, i.e., shrink-wrapped in plastic or other methods acceptable to the Regulatory Agency. 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.

b. These containers shall be inspected prior to filling to determine general condition, damage,

and/or the presence of foreign materials, broken glass, other contaminates, etc.

c. As determined by the Regulatory Agency, 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/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, including recommended sanitization efficiency tests by the Regulatory Agency.

d. Single-service glass containers shall be labeled with wording to designate "single-service use only".

ITEM 13p. STORAGE OF CLEANED CONTAINERS AND EQUIPMENT

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

PUBLIC HEALTH REASON

If containers and equipment are not protected from contamination, the value of sanitization may be partly or entirely nullified.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

All multi-use containers, utensils and equipment, after cleaning, are transported and/or stored on racks made of impervious food grade materials, or in clean cases elevated above the floor. Containers shall be stored inverted, if practicable, on racks or in cases constructed of relatively nonabsorbent, impervious, food-grade, corrosion-resistant, non-toxic materials, or otherwise protected from contamination.

ITEM 14p. STORAGE OF SINGLE-SERVICE ARTICLES, UTENSILS AND MATERIALS

Single-service closures, closure stock, parchment paper, containers, gaskets, liners, bags and other single-service articles for use in contact with milk and/or milk products 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.

PUBLIC HEALTH REASON

Soiled or contaminated closures, parchment paper, gaskets and single-service containers nullify the benefits of the safeguards prescribed throughout this *Ordinance*. Packing the closures in sanitary tubes, wrappings or cartons, which remain unbroken until they are placed in the bottling machine, is the best method of assuring closure cleanliness.

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 and/or milk products 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.

ITEM 15p. PROTECTION FROM CONTAMINATION

Milk plant operations, equipment and facilities shall be located and conducted to prevent any contamination of milk or milk products, ingredients, containers, utensils and equipment. All milk or milk products or ingredients that have been spilled, overflowed or leaked shall be discarded. The processing or handling of products other than Grade "A" milk or milk products in the milk plant shall be performed to preclude the contamination of such Grade "A" milk and milk products. The storage, handling and use of poisonous or toxic materials shall be performed to preclude the contamination of milk and milk products, or ingredients of such milk and milk products, or the product-contact surfaces of all containers, utensils and equipment. Milk plant operations that handle nondairy food allergens shall have a written food allergen control plan to protect milk and/or milk products from food allergen cross-contact, including during storage and use, and to ensure proper declaration of food allergens on product labeling. Human food by-products held for distribution as animal food without additional manufacturing or processing by the milk plant shall be accurately identified, labeled by the common or usual name and held under conditions that will protect against contamination.

PUBLIC HEALTH REASON

Because of the nature of milk and milk products and their susceptibility to contamination by bacteria, chemicals and other adulterants, as well as the potential for food allergen cross-contact of such products in certain facilities, every effort should be made to provide adequate protection for the milk and milk products 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 and/or milk product or equipment with which the milk and/or milk product comes in contact; such contamination can result in adverse health consequences. Food allergens can cause mild to severe adverse reactions and sometimes may cause life threatening reactions. Thus, it is important not only to declare all food allergens on milk and milk product labels, but also to prevent cross-contact of milk and milk products so they do not contain undeclared food allergens.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

15p.(A)

1. Equipment and operations are so located within the milk plant as to prevent overcrowding and contamination of cleaned and sanitized containers, utensils and equipment by splash, condensation or manual contact.
2. Packaged milk and/or milk products, which have physically left the premises or the processing milk plant, are not re-pasteurized for Grade "A" use. The Regulatory Agency may, on a specific individual request, authorize reprocessing of packaged milk and/or milk products, provided all other aspects of this Item, including proper storage temperature and container integrity are complied with. Provided, that the re-pasteurization of milk and/or milk products shipped in milk tank trucks, which have been pasteurized at another Grade "A" milk plant and have been handled in a sanitary manner and maintained at 7ºC (45ºF) or less is permitted. Equipment, designated areas or rooms utilized for handling, processing and storage of returned packaged milk and/or milk products are maintained, operated, cleaned and sanitized so as to preclude the contamination of Grade "A" milk and/or milk products and equipment and the Grade "A" 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, utensils and equipment 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, vats, etc., shall be capped or otherwise properly protected. While unloading at a milk plant, receiving station or transfer station, one of the following conditions shall be met:
   a. 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.
   b. 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 shall 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 shall be made from valve-to-valve or through the manhole lid. Provided, that all connections are made ferrule-to-ferrule and adequate protection is provided for the air vent.

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 and milk products 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 milk products or is directed at a milk or milk product-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. of this *Ordinance*. 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. of this *Ordinance*.) The use of steam containing toxic substances is expressly prohibited. Whenever steam is used in contact with milk or milk products it shall be of culinary quality and shall comply with the applicable standards of Appendix H. of this *Ordinance*.
6. Air exhausts from dryer systems are covered when dryers are not in operation.
7. Standardization of Grade "A" milk and milk products with other than Grade "A" milk and milk products is prohibited. This *Ordinance* permits standardization as a process of adjusting the milk fat of milk in a milk plant by the addition or removal of cream or non-fat (skim) milk.
8. All multi-use cases used to encase packaged milk and milk product containers are cleaned prior to their use.
9. All ingredients and non-product-contact materials used in the preparation or packaging of milk and milk products 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, that pasteurized milk and milk products that are concentrated (condensed) in membrane processing systems may be filtered provided that 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 milk plant are present in the milk plant.
12. Those poisonous or toxic materials that are necessary are not stored in any room where milk or milk products are received, processed, pasteurized, condensed, dried or stored; or where containers, utensils or equipment 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 milk plant in prominently and distinctly labeled containers. Provided that, this does not preclude the convenient availability of detergents or sanitizers to areas where containers, utensils and equipment are washed and sanitized.
14. Only insecticides and rodenticides approved by the Regulatory Agency 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 and milk products, containers, utensils and equipment.
15. 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 are 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, that 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 Item 15p of this *Ordinance*. (B)2. 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 Item 7p, **ADMINISTRATIVE PROCEDURES** of this *Ordinance*, 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:

a. Separate receiving equipment and unloading pumps shall be provided; or

b. 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

c. 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.

15p.(B)

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

a. 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

b. 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:

(1) 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:

i) 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

ii) 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.

(2) 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., Position Detection Devices of this *Ordinance*.)

(3) 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 and/ or milk product 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 (6) below.

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

(5) Controls for the fail-safe system are secured as directed by the Regulatory Agency in order to prevent unauthorized changes.

(6) 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; and

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. Pasteurization Equipment and Procedures, Section VI. Criteria for the Evaluation of Computerized Systems for Grade "A" Public Health Controls of this *Ordinance*.

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

c. 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 and cleaning and/or chemical sanitizing solutions if:

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

(2) 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;

(3) 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;

(4) 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.

(5) 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; and

(6) Although the automatic control system is not required to comply with Appendix H., VI. of this *Ordinance*, there shall be means provided to test and verify the accuracy of the sensor and the operation of the control system.

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 that, 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 FDA to be equally effective and which are approved by the Regulatory Agency.

2. Except as permitted in Item 16p of this *Ordinance*, 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 that comes in contact with pasteurized milk and/or milk products it shall:

a. Meet at least the minimum times and temperatures provided for in the definition of Pasteurization in equipment that may not meet Item 16p of this *Ordinance*; or

b. Meet the requirements found in Appendix H., Section IX. of this *Ordinance*; or

c. Have undergone an equivalent process found acceptable by FDA and the Regulatory Agency; or

d. Have undergone a hazard evaluation and safety assessment of the specific milk plant's water supply, which may come from an individual water supply, municipal water system or Category I. water that is used for potable water purposes, which has been reclaimed from milk and milk products and from heat exchangers or compressors in the milk plant as defined in Appendix D. of this *Ordinance*, and application involved and has undergone an additional treatment to destroy or remove bacteria acceptable to the Regulatory Agency, in consultation with FDA, to ensure the water will not compromise the safety of the milk or milk product[10]. Supporting information shall be submitted to and approved by the Regulatory Agency. The supporting information may include, but is not limited to the following:

(1) Statement of proposal;
(2) Intended use;
(3) Review of equipment to be used in the process;
(4) Diagram of the process of interest;
(5) Documentation that the specific milk plant's water supply meets or exceeds the EPA Safe Drinking Water Bacteriological Standards. The safety assessment shall include a comparison of samples from the specific milk plant's water supply, pasteurized water, and proposed pasteurized equivalent water. Water samples of the pasteurized equivalent water shall be collected daily for two (2) weeks following approval of the initial installation and at least once every six (6) month period thereafter; and
(6) 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.

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 and milk products that may have been affected during the time that the water utilized may not have been equivalent to pasteurized water. This Section does not require separate raw and pasteurized CIP cleaning systems.

3. 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.

4. 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 7ºC (45ºF) 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 and/or milk products from damaged, punctured or otherwise contaminated containers or product from out-of-code containers shall not be repasteurized for Grade "A" use.

5. 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.

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

7. No product is handled in the milk plant that may create a public health hazard. Permission to handle products other than those defined in Section 1. of this *Ordinance* 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.

8. In no case shall pasteurized milk or milk products, be standardized with unpasteurized milk or milk products, unless the standardized milk or milk product is subsequently pasteurized.

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

10. 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:

a. 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.

b. 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 (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.

c. 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 (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.

d. 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.

e. 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.

f. 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:

(1) 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

(2) 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 Regulatory Agency 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. of this *Ordinance* to assure that the pressure differential controller probes are accurately calibrated. Also, the applicable

procedures cited in Appendix I., Test 9.2.2. of this *Ordinance* 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.

g. 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.

15p.(C)

1. **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:

a. Ensuring protection of milk and/or milk products from allergen cross-contact, including during storage, handling and use.

b. Labeling the finished milk and/or milk products, including ensuring that the finished milk and/or milk products is not misbranded under Section 403(w) of the *FFD&CA* with an undeclared food allergen.

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

d. Prevention of food allergen cross-contact from insanitary objects, from personnel and from non-milk allergen-containing foods to milk and/or milk products, milk and/or milk products packaging material and other milk and/or milk product-contact surfaces.

2. **HOLDING AND DISTRIBUTION OF HUMAN FOOD BY-PRODUCTS FOR USE AS ANIMAL FOOD:**

a. Human food by-products held for distribution as animal food without additional manufacturing or processing by the milk plant shall be held under conditions that will protect against contamination as appropriate for their final use in animal food.

b. Labeling that identifies the by-product shall be affixed to or accompany the human food by-products for use as animal food when distributed.

c. Shipping containers, i.e., totes, drums, tubs, etc., and bulk vehicles used to distribute human food by-products for use as animal food shall be appropriate for transporting the human food by-products for use as animal food and protecting against contamination during transport.

ITEM 16p. PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, RETORT PROCESSED AFTER PACKAGING, AND FERMENTED HIGH-ACID, SHELF-STABLE PROCESSING AND PACKAGING

Pasteurization shall be performed as defined in Section 1., Pasteurization and Item 16p of this *Ordinance*. Aseptic processing and packaging, retort processed after packaging and fermented high-acid, shelf-stable processing and packaging shall be performed in accordance with the applicable requirements of 21 CFR Parts 108, 113 and 117. (Refer to Appendices L. and S. of this *Ordinance*.)

In all cases, except for the specific exemptions provided for in **ADMINISTRATIVE PROCEDURES** #3, pasteurization of raw milk and/or milk product shall be performed before the raw milk and/or milk 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 and/or milk products transported to a milk plant for drying shall be re-pasteurized at the milk plant at which it is dried. If condensed whey containing at least forty percent (40%) 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:

1. The condensed, partially crystallized whey is cooled and maintained at 7°C (45°F) or less.
2. 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.
3. 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.

PUBLIC HEALTH REASON

Health officials unanimously agree upon the public health value of pasteurization. Long experience conclusively shows its value in the prevention of disease that may be transmitted through milk. Pasteurization is the only practical, commercial measure, which if properly applied to all milk, will destroy all milkborne 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 this *Ordinance*, if applied to every particle of milk and/or milk product will devitalize all milkborne pathogens. Compilations of outbreaks of milkborne disease by the USPHS/FDA, over many years, indicate that the risk of contracting disease from raw milk is approximately fifty (50) times as great as from milk that has been "pasteurized".
A note of caution is in order. Although pasteurization destroys 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 and/or milk product is not properly refrigerated before pasteurization. Such toxins may cause severe illness. Aseptic processing and packaging, retort processed after packaging and fermented high-acid, shelf-stable processing and packaging have also been conclusively demonstrated to be effective in preventing outbreaks from milkborne pathogens. Numerous studies and observations clearly prove that the food value of milk is not significantly impaired by pasteurization.

ADMINISTRATIVE PROCEDURES

The pasteurization portion of this Item is deemed to be satisfied when:

1. Every particle of milk and/or milk product is heated in properly designed and operated equipment that meets the requirements of this Item and Appendix H. of this *Ordinance*, 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. Time	
Batch (Vat) Pasteurization	
Temperature	**Time**
63ºC (145ºF)*	30 minutes
Continuous Flow (HTST and HHST) Pasteurization	
Temperature	**Time**
72ºC (161ºF)*	15 seconds
89ºC (191ºF)	1.0 second
90ºC (194ºF)	0.5 seconds
94ºC (201ºF)	0.1 seconds
96ºC (204ºF)	0.05 seconds
100ºC (212ºF)	0.01 seconds

*If the fat content of the milk product is ten percent (10%) or greater, or a total-solids of 18% or greater, or if it contains added sweeteners, the specified temperature shall be increased by 3ºC (5ºF).

Provided, that eggnog shall be heated to at least the following temperature and time specifications:

Table 3. Pasteurization Temperature vs. Time	
Batch (Vat) Pasteurization	
Temperature	**Time**
69ºC (155ºF)	30 minutes
Continuous Flow (HTST) Pasteurization	
Temperature	**Time**
80ºC (175ºF)	25 seconds
83ºC (180ºF)	15 seconds

Provided further, that nothing shall be construed as barring any other process found equivalent to pasteurization for milk and/or milk products, which has been recognized by FDA as provided in Section 403 (h)(3) of the *FFD&CA*.

2. All milk and/or 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:

a. Ingredients permitted by the CFR standards of identity when considering a standardized milk and/or milk product;

b. Fresh fruits and vegetables added to cultured milk and/or 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.

c. Ingredients subjected to prior heating or other technology, which has been demonstrated to FDA to be sufficient to destroy or remove pathogenic microorganisms;

d. Ingredients having a a_w of 0.85 or less;

e. 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));

f. Roasted nuts;

g. Dry sugars and salts;

h. Flavor extracts having a high alcohol content;

i. Safe and suitable bacterial cultures and enzymes; and

j. Ingredients, which have been found to be safe and suitable by FDA.

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

3. All milk and/or 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:

a. If the product is whey, pasteurization is not required, provided:

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

(2) It is processed in RO or UF equipment at temperatures at or below 7ºC (45ºF).

b. 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:

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

(2) The RO or UF filtration system is designed and operated to assure that milk and/or milk product temperature is maintained at or below 18.3ºC (65ºF) throughout the process. Provided that the product temperature may rise above 18.3ºC (65ºF) for a period of not more than fifteen (15) minutes, further provided that should the product temperature rise above 21.1ºC (70ºF), the product shall be either immediately diverted to the system's balance tank until the product is again below 18.3ºC (65ºF) 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;

(3) The RO or UF system shall be equipped with temperature monitoring and recording devices that are acceptable to the Regulatory Agency. At a minimum, milk and/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; and

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

4. 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 that:

a. Prior to processing, all raw milk supplies are sampled and tested for antibiotic residues in accordance with the provisions of Appendix N. of this *Ordinance*; and

b. 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:

(1) The MF system is designed and operated to assure that milk and/or milk product temperature in the circulating retentate loop is maintained at or below 18.3ºC (65ºF), or at or above 51.7°C (125°F) throughout the process. Provided that the product temperature

may rise above 18.3ºC (65ºF) or fall below 51.7°C (125°F) for a period of not more than fifteen (15) minutes, further provided that should the product temperature rise above 21.1ºC (70ºF) 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 18.3ºC (65ºF) 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;

(2) The MF system shall be equipped with temperature monitoring and recording devices that are acceptable to the Regulatory Agency. At a minimum, milk and/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; and

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

5. All condensed milk and/or milk products transported to a milk plant for drying shall be re-pasteurized at the milk plant where it is dried.

6. If condensed whey containing at least forty percent (40%) 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:

a. The condensed, partially crystallized whey is cooled and maintained at 7ºC (45ºF) or less.

b. 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.

c. 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.

7. The design and operation of pasteurization equipment and all appurtenances thereto shall comply with the applicable specifications and operational procedures of Item 16p, Subitems (A), (B), (C) and (D) of this *Ordinance*.

ITEM 16p.(A) BATCH PASTEURIZATION

All indicating and recording thermometers used in connection with the batch pasteurization of milk and/or milk products shall comply with the applicable specifications set forth in Appendix H. of this *Ordinance*. Specifications for test thermometers and other test equipment appear in Appendix I. of this *Ordinance*.

PUBLIC HEALTH REASON

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 shall be performed in equipment which is properly designed and operated, and which insures that every particle of milk and/or milk product will be held continuously at the proper temperature for the specified period of time.

Recording thermometers are the only known means for furnishing the Regulatory Agency 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 thermometer and assurance that proper temperatures are being applied.

The recording thermometer shows the temperature of the milk and/or milk product immediately surrounding its bulb but cannot indicate the temperature of the milk and/or milk product in other

portions of the batch pasteurizer. Similarly, it shows the holding time in manual-discharge vats, but not in automatic-discharge systems. The pasteurizer shall; therefore, be so designed and so operated and, where necessary, provided with such automatic controls, as to assure that every portion of the milk and/or milk product will be subjected to the proper temperature for the required length of time.

Unless the outlet valve and connections to the vats are properly designed and operated, cold pockets of milk and/or milk product may be held in the outlet valve or pipeline and raw or incompletely pasteurized milk and/or milk product may leak into the outlet line during the filling, heating or holding period.

Tests have shown that when foam is present on milk and/or milk 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, milk and/or milk product frequently is splashed on the surfaces and fixtures above the milk and/or milk product level, as well as on the underside of the vat cover. Droplets of this splash may drop back into the body of the milk and/or milk product, and since they may not have been at pasteurization temperature for the required time, they may contain pathogenic organisms. Heating the air above the milk and/or milk product, above pasteurization temperature, remedies these conditions. When air heating is not provided, its need may frequently be demonstrated by swabbing milk and/or milk 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.

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

Obviously, if the design and construction of pasteurization vats and pocket covers do not prevent leakage, condensation and the entrance of water and dust, the milk and/or milk product may become contaminated with material containing disease bacteria. Keeping the covers closed during operation will decrease the chance of contaminants such as dust, insects, drip and splash from entering the milk and/or milk product.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. **TIME AND TEMPERATURE CONTROLS FOR BATCH PASTEURIZERS**

   a. **Temperature Difference:** The pasteurizer shall be so designed that the simultaneous temperature difference between the milk and/or milk product, at the center of the coldest milk and/or milk product and the warmest milk and/or milk product in the vat, will not exceed 0.5°C (1°F) at any time during the holding period. The vat shall be provided with adequate agitation, operating throughout the holding period. No batch of milk and/or milk product shall be pasteurized unless it covers a sufficient area of the agitator to insure adequate agitation.

   b. **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 not read less than the required pasteurization temperature throughout the required holding period. The milk 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 and/or milk product shall be pasteurized unless it is sufficient to cover the bulbs of both the indicating and the recording thermometer.

c. **Assurance of Minimum Holding Periods:** Batch pasteurizers shall be so operated that every particle of milk and/or milk product will be held at not less than the minimum pasteurization temperature continuously for at least thirty (30) minutes. When milk and/or milk products 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 recording chart shall show at least thirty (30) minutes, at not less than minimum pasteurization temperature. When milk and/or milk products are preheated to pasteurization temperature before entering the vat, the recording 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 recording thermometer bulb. When cooling is begun in the batch pasteurizer, after opening the outlet valve, or is done entirely outside the batch pasteurizer, 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 recording time interval on the recording chart at the pasteurization temperature includes filling and/or emptying time, such intervals shall be indicated on the recording chart, by the operator, by removing the recording thermometer bulb from the milk and/or milk 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 recording chart. The filling time and the emptying time for each batch pasteurizer, so operated, shall be determined by the Regulatory Agency, initially and after any change, which may affect these times.

No milk and/or milk product shall be added to the batch pasteurizer after the start of the holding period.

2. **AIRSPACE HEATING**

a. Means shall be provided and used in batch pasteurizers to keep the atmosphere above the milk and/or milk product at a temperature not less than 3ºC (5ºF) higher than the minimum required temperature of pasteurization, during the holding period. (Refer to Appendix H. of this *Ordinance*.)

b. Each batch pasteurizer shall be equipped with an airspace thermometer. The surface of the milk and/or milk product shall be at least 25 millimeters (1 inch) below the bottom of the thermometer bulb when the vat is in operation.

c. The temperature shown by the airspace thermometer shall be recorded on the recording thermometer chart 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 recording chart.

3. **INLET AND OUTLET VALVES AND CONNECTIONS**

The following definitions shall apply to inlet and outlet valves and connections:

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

b. **"The Fully Open Position"** shall mean that position of the valve seat that permits the maximum flow into or out of the pasteurizer.

c. **"The Closed Position"** shall mean any position of the valve seat that stops the flow of milk into or out of the pasteurizer.

d. **"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.

e. **"The Just-Closed Position"** shall mean that closed position of a plug-type valve in which the flow into or out of the pasteurizer is barely stopped, or any position within 2 millimeters (0.078 of an inch) thereof as measured along the maximum circumference of the valve seat.

f. **"Leakage"** shall mean the entrance of unpasteurized milk and/or milk product into a batch pasteurizer during the holding or emptying period, or the entrance of unpasteurized milk and/or milk product into any pasteurized milk and/or milk product line at any time.

g. "**Leak-Protector Valve**" shall mean a valve provided with a leak-diverting device, which when the valve is in any closed position, shall prevent leakage of milk and/or milk product past the valve.

h. **"Close-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 milk and/or milk product in the valve is more than 0.5ºC (1ºF) colder than the milk and/or milk product at the center of the pasteurizer at any time during the holding period.

A close-coupled valve, which is not truly flush, shall be considered as satisfying this requirement when:

(1) 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; and

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

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

4. **DESIGN AND INSTALLATION OF VALVES AND CONNECTIONS**

All valves and connections shall comply with the following requirements:

a. Valves and pipeline connections shall meet the requirements of Item 10p of this *Ordinance*.

b. All pipelines and fittings shall be so constructed and so located that leakage shall not occur.

c. To prevent clogging, and to promote drainage, all leak-protection grooves in plug-type outlet valves shall be at least 5 millimeters (0.187 of an inch wide) and at least 2.3 millimeters (0.094 of an inch) 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 binding. Washers or other parts shall not obstruct leak-protector grooves.

d. A stop shall be provided on all plug-type outlet valves in order to guide the operator in closing the valve so that unpasteurized milk and/or milk product may not inadvertently be permitted to enter the outlet line. 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. 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.

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

f. 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.

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

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

i. 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.

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

5. **RECORDING THERMOMETER CHARTS**

All recording thermometer charts shall comply with all the applicable requirements of Item 16p.(D)1. of this *Ordinance*.

ITEM 16p.(B) CONTINUOUS-FLOW PASTEURIZATION

PUBLIC HEALTH REASON

(Refer to the Public Health Reason under Item 16p and 16p(A). of this *Ordinance*.)

ADMINISTRATIVE PROCEDURES

This Item is 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 continuous-flow pasteurization of milk and/or milk products shall comply with the applicable specifications set forth in Appendix H. of this *Ordinance*.

2. **AUTOMATIC MILK CONTROLLER**

Each continuous-flow 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:

a. **Automatic Milk and/or Milk Product-Flow Controls:**

(1) Milk and/or milk product controls must have a Flow Diversion Device (FDD) which automatically causes the diversion of the milk and/or milk product in response to a sub-legal pasteurization condition.

(2) The controls shall include logic to meet the applicable requirements of Item 16p.(B), Item 16p.(C) and Appendix H. of this *Ordinance* and perform the applicable tests listed in Item 16p.(D)2. and Appendix I. of this *Ordinance*.

(3) The controls vendor shall provide to the Regulatory Agency documentation including a user manual with testing procedures and instructions necessary to supplement those in this *Ordinance*.

b. **FDDs:** All FDDs used in continuous pasteurizers shall comply with the following or equally satisfactory specifications:

(1) The forward-flow of milk and/or milk product below the minimum pasteurization temperature shall be prevented by requiring the motive pumps(s) to be de-energized when the milk and/or milk 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 *Ordinance*.

(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 backpressure is exerted on the forward-flow side of the valve seat, while the milk and/or milk 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 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, that 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 shall 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 and/or milk product.
(6) The FDD shall be located downstream from the holding tube. The flow-control sensor shall be located in the milk and/or milk product line not more than 46 centimeters (18 inches) upstream from the inlet of the FDD.
(7) The FDD may be located downstream from the regenerator and/or cooler section, provided, that the system complies with the criteria for downstream FDDs in Appendix H of this *Ordinance.*
(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.
(9) When 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 *Ordinance.*
(12) In the case of HHST pasteurizing systems utilizing temperatures and holding times to meet the definition of ultra-pasteurization (UP) of this *Ordinance,* 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. of this *Ordinance*.
(13) When switching to the "CIP" position, the FDD shall move to the divert position and shall remain in the diverted-flow position for at least ten (10) minutes, regardless of temperature, and for HTST pasteurization systems the booster pump cannot run during this ten (10) minute time delay.

c. **Milk and/or Milk Product-Flow Controller Instrumentation:** The following requirements shall be met with respect to the instrumentation of the milk and/or milk product-flow controller:

(1) The thermal-limit-controller, with sensor located at the outlet of the holding tube, shall be set and sealed so that forward-flow of milk and/or milk product cannot start unless the temperature at the controller sensor is above the required pasteurization temperature as defined in the definition of Pasteurization of this *Ordinance* for the milk and/or milk product and the process used, nor continue when the temperature is below the required pasteurization temperature. A seal shall be applied by the Regulatory Agency after testing and shall not be removed without immediately notifying the Regulatory Agency. The pasteurization system shall be so designed that no milk and/or milk product can bypass the controller sensor. The controller sensor shall not be removed from its proper position during the pasteurization process. The cut-in and cut-out milk and/or milk product temperatures, as shown by the indicating thermometer, shall be determined at the beginning of each day's operation and entered on the recorder chart daily by the milk plant operator.
(2) For pasteurization systems used for the processing of milk and/or milk products labeled as UP, it is not necessary to set and seal the thermal-limit-controller at or above 138ºC (280ºF). Also, provided that these systems shall meet all the public health control requirements for HHST pasteurization systems, and that the recorder-controller chart shows that the UP milk and/or milk product has been processed at a minimum temperature of 138ºC (280ºF), and has been verified by the Regulatory Agency to have a calculated holding time of at least two (2) seconds. A seal, if required, shall be applied by the Regulatory Agency after the equipment has been tested, and shall not be re- moved without immediately notifying the Regulatory Agency. The system shall be so designed that no milk and/or milk product can be bypassed around the control sensors, which shall not be removed from their proper position during the pasteurization process. For these pasteurization systems, daily measurement by the operator of the cut-in and cut-out temperatures is not required.
(3) Manual switches for the control of pumps, homogenizers or other devices, which produce flow through the FDD, shall be wired so that the circuit is completed only when the milk and/or milk product is above the required pasteurization temperature as defined in the definition of Pasteurization of this *Ordinance* for the milk and/or milk product and the process used, or when the FDD is in the fully-diverted position.

d. **Holding Tube:**
(1) Holding tubes shall be designed to provide for the holding of every particle of the milk and/or milk product for at least the pasteurization time required in the definition of Pasteurization of this *Ordinance* for the milk and/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 milk and/or milk product, in any cross section of flow, at any time during the holding period, will not be greater than 0.5ºC (1ºF). This requirement may be assumed to have been satisfied, without testing, in holding tubes of 17.8 centimeters (7 inches) or smaller diameter that are free of any fittings through which the milk and/or milk product may not be thoroughly swept.
(3) No device shall be permitted for short-circuiting a portion of the holding tube to compensate for changes in rate of milk and/or milk 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 2.1 centimeters per meter (0.25 inch per foot).
(5) Supports for holding tubes shall be provided to maintain all parts of the 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 recorder-controller temperature sensor is heated.

The following Items apply to HHST pasteurization systems:

(7) The holding time for HHST pasteurization systems shall be determined from the pumping rate rather than by the salt conductivity test, because of the short holding tube. The holding tube length shall be such that the fastest flowing particle~~,~~ of any milk and/or milk 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 milk and/or milk products, holding tube lengths shall be calculated as twice the length required to hold the average flow for the required holding time.

(8) With the direct steam heating processes, the holding time is reduced because the milk and/or milk product volume increases as the steam condenses to water during heating in the injector. This surplus water is evaporated as the pasteurized milk and/or milk product is cooled in the vacuum chamber. For example, with a 66ºC (120ºF) increase by steam addition, which is probably the maximum temperature rise that will be used, a volume increase of twelve percent (12%) 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, shall be considered in the calculations.

(9) For those HHST pasteurization 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 and/or milk product pressure falls below a prescribed value. For operating temperatures between 89°C (191ºF) and 100ºC (212ºF) the instrument shall be set at 69 kPa (10 psi). To prevent vaporization in the holding tube, which may substantially reduce residence times, HHST pasteurization systems operating above 100°C (212ºF), 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.

(10) With the steam injection process, a differential pressure limit indicator across the injector is needed to keep the heated milk and/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).

e. **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 milk and/or milk product between the two (2) thermometers does not differ significantly in temperature.

(2) The temperature shown by the recorder/controller shall be checked daily by the milk 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 Item 16p.(D)1. of this *Ordinance*.

f. **Flow-Promoting Devices:**

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

(2) The speed of pumps or other flow-promoting devices, governing the rate of flow through the holding tube, shall be so controlled as to insure the holding of every particle of milk and/or milk product for at least the pasteurization time required as defined in the definition of Pasteurization of this *Ordinance* for the milk and/or milk product and the process used. In all cases, the motor shall be connected to the timing 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 holding time cannot be shortened with- out detection by the Regulatory Agency. This shall be accomplished by the application of a suitable seal(s) after being tested by the Regulatory Agency and such seal(s) shall not be broken without immediately notifying the Regulatory Agency. This provision shall also apply to all homogenizers used as timing pumps. Variable speed drives, used in connection with the timing pump, shall be so constructed that wearing or stretching of the belt results in a slowdown, rather than a speedup, of the pump.

The holding time shall be controlled by a positive-displacement type timing pump or a magnetic flow meter-based timing system as outlined in Appendix H. of this *Ordinance*. 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, and both are located upstream of the holding tube, it shall be one of the following:

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 shall be of at least the same or larger diameter than the inlet pipeline feeding milk and/or milk product to the homogenizer. A check-valve, allowing flow from the outlet line to the inlet line, may be used in the recirculating 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 and located after 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 milk and/or milk product to the constant-level tank or to the outlet of the constant-level tank, upstream of any booster pump or other flow-promoting device.

iii) Of smaller capacity than and located before the timing pump when used to homogenize some but not all of the milk and/or milk product: In which case the unhomogenized milk and/or milk product shall mix with the homogenized milk and/or milk product before the timing pump and an unrestricted, open, homogenizer by-pass line shall be used to connect the unhomogenized milk and/or milk product line with the homogenized milk and/or milk product line. The homogenizer by-pass line shall be at least the same or larger diameter than the inlet pipeline feeding the timing pump.

NOTE: For those systems that do not homogenize all milk and/or milk products and wish to utilize a by-pass line to completely by-pass the homogenizer while processing such milk and/or milk product, the by-pass line shall be connected with valves that 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 that accomplish the same objective. Milk and/or milk products cannot be labeled "homogenized" if some or all of the milk and/or milk product bypasses the homogenizer as described in this note or f.2iii above.

(3) The holding time shall be taken to mean the flow time of the fastest particle of milk and/or milk product at or above the required pasteurization temperature as defined in the definition of Pasteurization of this *Ordinance* for the milk and/or milk product and the process used, throughout the holding tube 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 the 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 holding tube, 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 and/or milk products and utilize by-pass lines as outlined in f.(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.

(4) 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.

(5) The holding time shall be tested by the Regulatory Agency initially; semiannually thereafter; after any alteration or replacement that may affect the holding time; and whenever the seal of the speed setting has been broken. For pasteurization systems utilizing a timing pump, the holding time shall be tested in both forward and diverted flow.

g. **Heating by Direct Injection of Steam:** 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 milk and/or milk product particles being processed below pasteurization temperature. When culinary steam is injected directly into milk and/or milk product, 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 milk and/or milk product and steam flows shall be isolated from pressure fluctuations inside the injection chamber. One (1) method of isolation is to insert supplementary orifices on the milk and/or milk product inlet and the heated milk and/or milk product outlet of each injector. The two (2) supplementary orifices shall be sized for at least a 69 kPa (10 psi) milk and/or milk 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 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 de-aerator. The de-aerator will aid in keeping the product in the holding tube as free as possible of non-condensable gases.

h. **Prevention of Milk and/or Milk Product Adulteration with Added Water:**
(1) When culinary steam is introduced directly into the milk and/or milk product, downstream from the FDD, means shall be provided to preclude the addition of steam to the milk and/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 and/or milk product, automatic means, i.e., a 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 and/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 shutoff valve, located on the water feed line to the vacuum condenser, which is 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 shall automatically stop the flow of water into the vacuum condenser.

ITEM 16p.(C) PASTEURIZERS EMPLOYING REGENERATIVE HEATING

PUBLIC HEALTH REASON

To prevent contamination of the pasteurized milk and/or milk product in regenerators, the raw milk and/or milk product shall always be under less pressure than the pasteurized milk and/or milk product or the heat-transfer medium. This requirement is necessary to prevent contamination of the pasteurized milk and/or milk product by the raw milk and/or milk product should flaws develop in the metal or in the gasketed joints separating the raw and pasteurized milk and/or milk product.

ADMINISTRATIVE PROCEDURES

This Item is deemed satisfied when:

MILK AND/OR MILK PRODUCT-TO-MILK AND/OR MILK PRODUCT REGENERATIVE HEATING

Pasteurizers employing milk and/or milk product-to-milk and/or milk product regenerative heating with both sides closed to the atmosphere shall comply with the following or equally satisfactory specifications:

1. Regenerators shall be constructed, installed and operated so that pasteurized milk and/or milk product in the regenerator will automatically be under greater pressure than raw milk and/or milk product in the regenerator at all times.
2. The pasteurized milk and/or milk product, between its outlet from the regenerator and the nearest point downstream open to the atmosphere, shall rise to a vertical elevation of 30.5 centimeters (12 inches) above the highest raw milk and/or milk product level, downstream from the constant- level tank, and shall be open to the atmosphere at this or a higher elevation.
3. The overflow of the top rim of the constant-level tank shall always be lower than the lowest milk and/or milk product level in the regenerator.
4. No pump or flow-promoting device which can affect the proper pressure relationships within the regenerator shall be located between the pasteurized milk and/or milk product outlet from the regenerator and the nearest downstream point open to the atmosphere.
5. No pump shall be located between the raw milk and/or milk product inlet to the regenerator and the constant-level tank, unless it is designed and installed to operate only when milk and/or milk product is flowing through the pasteurized milk and/or milk product side of the regenerator and when the pressure of the pasteurized milk and/or 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:
   a. The timing pump, if present, is in operation;
   b. The FDD is in forward-flow position; and
   c. The pasteurized milk and/or milk 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 milk and/or milk product inlet to the regenerator and the pasteurized milk and/or milk product outlet of the regenerator or the outlet of the cooler. The accuracy of these required pressure gauges shall be checked, by the Regulatory Agency on installation, quarterly thereafter, and following repair or adjustment.
6. The motor, casing and impeller of the booster pump shall be identified for those systems that rely on a pressure switch, located only on the pasteurized side, and such records maintained as directed by the Regulatory Agency.
7. All electric wiring interconnections for the booster pump 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 this *Ordinance*.
8. When the raw milk and/or milk product pump(s) are shut down, all raw milk and/or milk product in the raw regenerator(s) shall automatically drain freely into the constant-level tank or to the floor.
9. When vacuum equipment is located downstream from the FDD, means shall be provided to prevent the lowering of the pasteurized milk and/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 milk and/or milk product inlet to the regenerator.
10. When culinary steam is introduced directly into milk and/or milk product 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 side of the regenerator may be eliminated. Provided, that the differential pressure controller is installed and wired to control the FDD as described in paragraph 10 of this Section.

MILK AND/ OR MILK PRODUCT-TO-WATER-TO-MILK AND/ OR MILK PRODUCT REGENERATIVE HEATING

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

1. Regenerators of this type shall be so designed, installed and operated that the heat-transfer-medium side of the regenerator, in the raw milk and/or milk product section, will automatically be under greater pressure than the raw milk and/or milk product side at all times.
2. The heat-transfer water shall be a 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 30.5 centimeters (12 inches), than any raw milk and/or milk 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 30.5 centimeters (12 inches) above any raw milk and/or milk product in the system and shall be open to the atmosphere at this or a higher elevation.
3. 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 milk and/or milk product is present in the regenerator.
4. The overflow of the top rim of the constant-level tank shall always be lower than the lowest milk and/or milk product level in the raw milk and/or milk product section of the regenerator. The regenerator shall be designed and installed so that all raw milk and/or milk product shall drain freely back to the upstream supply tank when the raw milk and/or milk product pumps are shut down and the raw milk and/or milk product line is disconnected from the regenerator outlet.
5. No pump shall be located between the raw milk and/or milk product inlet to the regenerator and the constant-level 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 milk and/or milk product. This may be accomplished by wiring the booster pump so that it cannot operate unless:
    a. The heat-transfer water pump is in operation; and
    b. The heat-transfer water pressure exceeds, by at least 6.9 kPa (1 psi), the raw milk and/or milk product pressure in the regenerator. A differential pressure controller shall be installed at the raw milk and/or milk product inlet and the heat-transfer water outlet of the regenerator. The raw milk and/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 Regulatory Agency on installation; quarterly thereafter; and following repair or replacement.

OPTION II: Pasteurizers with the FDD located downstream of the regenerator and/or cooling section and with milk and/or milk product-to-water-to-milk and/or milk product regenerators constructed, installed and operated such that the pasteurized milk and/or milk product in the regenerator will be under greater pressure than the heat-transfer-medium in the pasteurized milk and/or milk product section of the regenerator, shall comply with the following or equally satisfactory specifications:

1. A differential pressure controller shall be used to monitor pressures of the pasteurized milk and/or milk product and the heat-transfer-medium. One (1) pressure sensor shall be installed at the pasteurized milk and/or milk product outlet of the regenerator and the other pressure sensor shall be installed at the heat-transfer-medium inlet of the pasteurized milk and/or milk product section of the regenerator. This controller or recorder-controller shall divert the FDD whenever the lowest pressure of pasteurized milk and/or milk product in the regenerator fails to exceed the highest pressure of the heat-transfer-medium in the pasteurized milk and/or milk product side of the regenerator by at least 6.9 kPa (1 psi). Forward-flow of milk and/or milk product shall be automatically prevented until all milk and/or milk product-contact surfaces between the holding tube and the FDD have been held at or above the required pasteurization temperature continuously and simultaneously for at least the pasteurization time.
2. The heat-transfer-medium pump shall be wired so that it cannot operate unless the timing pump and/or other flow promoting devices are in operation.

NOTE: Refer to Appendix H. of this *Ordinance* for further discussion concerning methods of achieving the required pressure relationships within the regenerator.

ITEM 16p.(D) PASTEURIZATION RECORDS, EQUIPMENT TESTS AND EXAMINATIONS

1. **PASTEURIZATION RECORDS:**
All temperature and flow rate pasteurization recording charts or alternative records, acceptable to FDA and the Regulatory Agency, in place of charts, shall be:

a. Reviewed, dated and signed or initialed;

b. Onsite for review by the Regulatory Agency during each regulatory inspection for at least the previous three (3) months or from the last regulatory inspection, whichever is longer. Electronic records are considered to be onsite if they are accessible from an onsite location; and

c. Retained for at least two (2) years after the date they were created. Offsite storage of these pasteurization records is permitted if such records can be retrieved and provided onsite within twenty-four (24) hours of a request for official review.

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 also be entered on the charts or alternative records acceptable to FDA and the Regulatory Agency in place of charts as applicable:

a. **Batch Pasteurizers:**

(1) Date;
(2) Number or location of recording thermometer when more than one is used;
(3) A continuous record of the product temperature;
(4) Extent of holding period, including filling and emptying times when required;
(5) 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 Regulatory Agency in accordance with Appendix I., Test 4 of this *Ordinance*, the recording of the airspace temperature on the chart shall only be required at the start of the holding period;

(6) Reading of indicating thermometer, at the start of the holding period, at a given time or reference point as indicated on the chart;
(7) Quarterly, the time accuracy of the recording thermometer, as determined by the Regulatory Agency, or in the case of milk plants regulated under the NCIMS voluntary HACCP Program, a qualified industry person acceptable to the Regulatory Agency;
(8) Amount and name of the pasteurized milk and/or milk product, represented by each batch or run on the chart;
(9) Record of unusual occurrences;
(10) Signature or initials of the operator; and
(11) Name and location of the milk plant or their milk plant code.

b. **HTST and HHST Pasteurizers:** Recording thermometer charts shall contain all the information specified in Subitem a. above, except (4), and (5), and 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 milk and/or milk product temperatures, as shown by the indicating thermometer and recorded daily by the operator, at the beginning of the run (HTST only), and initialed quarterly by the Regulatory Agency, or in the case of milk plants regulated under the NCIMS voluntary HACCP Program, a qualified industry person acceptable to the Regulatory Agency; and
(3) Number (6) from above shall also be recorded immediately after a chart has been changed.

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

c. **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 (3), (4), (5), (6), and (7), and in addition, shall include the following:
(1) A continuous record of the status of the high and low-flow/loss of signal alarms; and
(2) A continuous record of the flow rate.

d. **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 Regulatory Agency and meet the criteria of this Section and Appendix H., V. of this *Ordinance*.

2. **EQUIPMENT TESTS AND EXAMINATIONS:**
The Regulatory Agency 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.

The test results for the required pasteurization equipment testing shall be recorded on records that are similar to the reference cited in Appendix M. of this *Ordinance*. The Regulatory Agency shall provide a copy of the records to the milk plant and the milk plant shall retain these records for at least two (2) years after the date they were created. Offsite storage of these pasteurization equipment testing records is permitted if such records can be retrieved and provided onsite within twenty-four (24) hours of a request for official review.

NOTE: A TPC authorized under the ICP may utilize appropriately trained and TPC authorized in-country regulatory personnel to comply with 2. as cited above.

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

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

b. The individual has satisfactorily completed training, acceptable to the Regulatory Agency, on test controls for pasteurization equipment;

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

d. The individual shall be in possession of authorization from the Regulatory Agency to perform these pasteurization equipment tests;

e. The individual shall immediately notify the Regulatory Agency 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 Regulatory Agency 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. of this *Ordinance* for an example.) The individual shall provide to the Regulatory Agency the identity and volume of milk and/or milk products processed during the period that the temporary seal(s) was applied;

f. If regulatory pasteurization equipment testing reveals that the pasteurization equipment or controls are not in compliance with the provisions of this *Ordinance*, all milk and/or milk products that were processed during this period may be recalled by the Regulatory Agency;

g. The Regulatory Agency or a properly trained regulatory official, commissioned by the responsible Regulatory Agency, 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; and

h. 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 Regulatory Agency or a properly trained regulatory official, commissioned by the responsible Regulatory Agency, of each participating non-U.S. country or political subdivision thereof.

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 Regulatory Agency, if the following conditions are met:

a. 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. of this *Ordinance* for an example.)

b. 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 Regulatory Agency.

(1) Industry shall physically demonstrate to the Regulatory Agency that they understand and can perform the required pasteurization equipment tests according to the requirements of this *Ordinance*.

(2) The Regulatory Agency 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 Regulatory Agency, they are not acceptable for conducting such pasteurization equipment tests.

(3) 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.

c. Pasteurization Equipment Tests shall be conducted at a frequency not less than the requirements of this *Ordinance*. Industry shall have responsibility for the performance of all required pasteurization equipment tests. At least each six (6) months the Regulatory Agency 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.

d. Upon initial installation or extensive modification of any pasteurization equipment, pasteurization equipment tests shall be physically supervised or conducted by the Regulatory Agency.

e. Sealing guidance for pasteurization equipment by industry is as follows:

(1) All pasteurization equipment that is required to be sealed within this *Ordinance* 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 Regulatory Agency; and

(2) The Regulatory Agency may verify any pasteurization equipment sealing and evaluate (accept or reject) the skills and knowledge of the individual performing the sealing.

f. 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 Appendix I. of this *Ordinance*.)

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	HTST holding tubes/timing pumps (except magnetic flow meter based timing systems (MFMBTS))	Holding time
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.

ITEM 17p. COOLING OF MILK AND/OR MILK PRODUCTS

All raw milk and milk products shall be maintained at 7ºC (45ºF) or less until processed. All whey and whey products for condensing and/or drying shall be maintained at a temperature of 7ºC (45ºF) 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.

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. of this *Ordinance*, 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 7ºC (45ºF) or less, or at a temperature of 66ºC (150ºF) or greater and maintained thereat.

All pasteurized milk and milk products, except the following, shall be cooled immediately prior to filling or packaging, in approved equipment, to a temperature of 7ºC (45ºF) 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* and:
   a. Filled at 63°C (145°F) or above* for containers of four (4) ounces (118 ml) or larger, or
   b. Filled at 69°C (155°F) or above* for containers of 2.9 ounces (85.6 ml), and
   c. 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
   d. The addition of potassium sorbate at a minimum concentration of 0.06% and filled at 13ºC (55°F) or less*, or
   e. 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 13ºC (55°F) or less*; and
7. 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 57ºC (135ºF), 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 Regulatory Agency. 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 Regulatory Agency.

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 Regulatory Agency and FDA.

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

1. All yogurt products at all milkfat levels, cultured in the cup after filling (cup-set) and subsequently moved out of the culturing room when reaching a pH of 4.80 or below, and a pH of 4.6 or below within the following twenty-four (24) hours* and cooled to 7°C (45°F) or less within ninety-six (96) hours of being moved out of the culturing room**;
2. 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**;
3. 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**;
4. 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**;
5. 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**;
6. Cultured cottage cheese at all milkfat levels with a pH of 5.2 or below* and:
   a. 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
   b. 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
   c. The addition of potassium sorbate at a minimum concentration of 0.06% and filled at 13ºC (55°F) or less*, cooled to 10ºC (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
   d. 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 13ºC (55°F) or less*, cooled to 10ºC (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 Regulatory Agency. 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 Regulatory Agency.

   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 Regulatory Agency 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.

All pasteurized milk and milk products to be condensed and/or dried, shall be stored at a temperature of 10ºC (50ºF) or less and be maintained thereat until further processed.

Every tank or silo, 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.
Every refrigerated room, in which milk and/or milk products are stored, shall be equipped with an accurate indicating thermometer, temperature-measuring device, or temperature-recording device.
On delivery vehicles, the temperature of milk and milk products shall not exceed 7ºC (45ºF).
Aseptically processed and packaged low-acid milk and/or milk products, retort processed after packaged low-acid milk and/or milk products and fermented high-acid, shelf-stable processed and packaged milk and/or milk products to be packaged in hermetically sealed containers shall be exempt from the cooling requirements of this Item.
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 Regulatory Agency. Electronic records that comply with the applicable provisions of Appendix H., IV. and V. of this *Ordinance*, with or without hard copy, may be used in place of the cleaning records.

PUBLIC HEALTH REASON

When milk and milk products are not cooled within a reasonable time, after being received at the milk plant, its bacterial content will be materially increased. The same reasoning applies to cooling the milk and milk products after pasteurization, unless drying is commenced immediately after condensing.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. All raw milk and milk products shall be maintained at 7ºC (45ºF) or less 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. Provided, that 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 7ºC (45ºF) or less; or 57ºC (135ºF) or greater until processed. Storage tanks containing whey and whey product above 7°C (45°F) and below 57ºC (135ºF) 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 to be injected within a HTST pasteurization system as a part of a liquid ingredient injection system as outlined in Appendix H. of this *Ordinance*, 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 7ºC (45ºF) or less, or at a temperature of 66ºC (150ºF) or greater and maintained thereat.
4. All pasteurized milk and milk products, except the following, are cooled immediately in approved equipment prior to filling or packaging to a temperature of 7ºC (45ºF) or less, unless drying is commenced immediately after condensing:
    a. Those to be cultured;
    b. Cultured sour cream at all milkfat levels with a pH of 4.70 or below*;

c. Acidified sour cream at all milkfat levels with a pH of 4.60 or below*;
d. All yogurt products at all milkfat levels with an initial pH of 4.80 or below* at filling;
e. Cultured buttermilk at all milkfat levels with a pH of 4.60 or below*;
f. Cultured cottage cheese at all milkfat levels with a pH of 5.2 or below* and:
(1) Filled at 63°C (145°F) or above* for containers of four (4) ounces (118 ml) or larger, or
(2) Filled at 69°C (155°F) or above* for containers of 2.9 ounces (85.6 ml), and
(3) 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
(4) The addition of potassium sorbate at a minimum concentration of 0.06% and filled at 13ºC (55°F) or less*, or
(5) 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 13ºC (55°F) or less*; and
g. 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 57ºC (135ºF), 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 Regulatory Agency. 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 Regulatory Agency.

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 Regulatory Agency and FDA.

5. All pasteurized milk and milk products, except the following, shall be stored at a temperature of 7°C (45ºF) or less and be maintained thereat following filling or until further processed:
a. All yogurt products at all milkfat levels, cultured in the cup after filling (cup-set) and subsequently moved out of the culturing room when reaching a pH of 4.80 or below and a pH of 4.6 or below within the following twenty-four (24) hours* and cooled to 7°C (45°F) or less within ninety-six (96) hours of being moved out of the culturing room**;
b. 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**;
c. 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**;
d. 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**;
e. 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**; and
f. Cultured cottage cheese at all milkfat levels with a pH of 5.2 or below* and:

(1) 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
(2) 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
(3) The addition of potassium sorbate at a minimum concentration of 0.06% and filled at 13ºC (55°F) or less*, cooled to 10ºC (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
(4) 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 13ºC (55°F) or less*, cooled to 10ºC (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 Regulatory Agency. 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 Regulatory Agency.

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 Regulatory Agency 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.

6. All pasteurized milk and milk products to be condensed and/or dried, shall be stored at a temperature of 10ºC (50ºF) 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 10ºC (50ºF) and below 57ºC (135ºF) shall be completely emptied and cleaned after each six (6) hours of operation or less. ***
7. Each refrigerated room in which milk and/or milk products are stored, is equipped with an accurate indicating thermometer, temperature-measuring device, or temperature-recording device that complies with the applicable specifications of Appendix H. of this *Ordinance*. Such indicating thermometer, temperature-measuring device, or temperature-recording device shall be located in the warmest zone of the refrigerated room.
8. Each storage tank or silo 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 or silo contains no more than twenty percent (20%) of its calibrated capacity. Such thermometer shall comply with the applicable specifications of Appendix H. of this *Ordinance*.
9. On delivery vehicles, the temperature of milk and milk products shall not exceed 7ºC (45ºF).
10. All surface coolers comply with the following specifications:
a. 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.
b. 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.

c. The location of supports of cooler sections shall prevent condensation and leakage from entering the milk or milk product.

d. All open-surface coolers shall be provided with tight-fitting shields that protect the milk and milk 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 at least once every six (6) month period and shall comply with the Bacteriological Standards of Appendix G. of this *Ordinance*. Samples shall be taken by the Regulatory Agency 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 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.

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:

a. 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**.**

b. 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.

c. 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.

d. 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.

e. The Isolation System shall meet one (1) of the following:

(1) 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., VII. of this *Ordinance*.)

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.

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; and

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

(2) 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. of this *Ordinance*.)

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.

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. of this *Ordinance*.);

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. This drain valve shall be normally open (spring-to-open); and

iv) 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.

(3) Variations from the above Isolation Systems may be individually evaluated and found to also be acceptable by the Regulatory Agency, if the level of protection required by this **ADMINISTRATIVE PROCEDURE** is not compromised.

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 Regulatory Agency 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 Regulatory Agency.

ITEM 18p. BOTTLING, PACKAGING AND CONTAINER FILLING

Bottling, packaging and container filling of milk and milk products shall be done at the place of pasteurization in a sanitary manner by approved mechanical equipment.[11]
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.
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.
Condensed and dry milk product packaging containers shall be stored in a sanitary manner.

PUBLIC HEALTH REASON

Manual bottling, packaging and container filling is very apt to result in the exposure of the milk and milk products to contamination, which would nullify the effect of pasteurization. The transfer of milk and milk 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.

ADMINISTRATIVE PROCEDURES [12]

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 Items 10p and 11p of this *Ordinance*. 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 pipes 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:

1. 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.
2. All pipes, connections and similar appurtenances comply with Items 10p and 11p of this *Ordinance*.
3. 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.
4. 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.
5. All condensed and dry milk product containers are filled in a sanitary manner by methods which:
   a. Protect the product from airborne contamination;
   b. Prevent manual contact with condensed and dry milk product-contact surfaces; and
   c. Minimize manual contact with the product.
6. 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.
7. If portable storage bins are used, they comply with the applicable provisions of Items 10p and 11p of this *Ordinance*.
8. Containers are closed immediately after being filled.

ITEM 19p. CAPPING, CONTAINER CLOSURE AND SEALING AND DRY MILK PRODUCT STORAGE

Capping, closing or sealing of milk and milk product containers shall be done in a sanitary manner by approved mechanical capping, closing and/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 regard to fluid product containers, removal cannot be made without detection.

PUBLIC HEALTH REASON

Improper closing or sealing and 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 product that has been forced out by temperature expansion and 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.

ADMINISTRATIVE PROCEDURES[13]

This Item is deemed to be satisfied when:

1. The capping, closing or sealing of milk and milk product containers is done in a sanitary manner on approved mechanical capping, closing and/or sealing equipment. The term "approved mechanical capping, closing and/or sealing equipment" shall not exclude manually operated machinery. Hand capping shall be prohibited. Provided, that if suitable mechanical equipment, for the capping or closing of container(s) of 12.8 liters (3 gallons) or more is not available, other methods which eliminate all possibility of contamination may be approved by the Regulatory Agency.
2. All mechanical capping, closing or sealing mechanisms are designed to minimize the need for adjustment during operation.
3. Bottles and packages that have been imperfectly capped or closed are emptied immediately into approved sanitary containers. Such milk or milk products shall be protected from contamination, maintained at 7ºC (45ºF) or less, except dry milk products, and subsequently repasteurized 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 milk and milk 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 that are left in the cappers at the end of an operating period, after removal from the cap tubes, shall be a violation of this Item, 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 capping device shall be discarded.
6. All dry milk products are stored in a sanitary manner.

ITEM 20p. PERSONNEL – CLEANLINESS AND PRACTICES

No person affected with any disease in a communicable form, or while a carrier of such disease, and no person with an illness, open lesion, including boils, sores or infected wounds, shall work in any processing area in any capacity where there is a likelihood of such person contaminating milk or milk products or milk or milk product-contact surfaces with pathogenic organisms unless conditions such as open lesions, boils and infected wounds are adequately covered, e.g., by an impermeable cover. Personnel shall be instructed to report such health conditions to their supervisors. Hands shall be thoroughly washed before commencing milk 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 their hands. All persons, while engaged in

the handling, processing, pasteurization, storage, transportation, or packaging of milk or milk products, containers, utensils and equipment shall wear clean outer garments suitable to the operation in a manner that protects against food allergen cross-contact and against the contamination of milk and/or milk products, milk or milk product-contact surfaces or milk or milk product packaging materials. Unsecured jewelry and the storage of clothing or other personal belongings shall not be permitted in those areas cited above. All persons, while engaged in the processing of milk or milk products, shall wear adequate hair nets, caps, beard covers or other effective hair restraints and shall not use tobacco or chewing gum.

PUBLIC HEALTH REASON

Clean clothing and clean hands, including clean fingernails, reduce the possibility of milk or milk products, containers, utensils and equipment becoming contaminated.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. No person affected with any disease in a communicable form, or while a carrier of such disease, and no person with an illness, open lesion, including boils, sores or infected wounds shall work in any processing area in any capacity where there is a likelihood of such person contaminating milk or milk products or milk or milk product-contact surfaces with pathogenic organisms, unless conditions such as open lesions, boils and infected wounds are adequately covered, e.g., by an impermeable cover. Personnel shall be instructed to report such health conditions to their supervisors. (Refer to Sections 13. and 14. of this *Ordinance*.)
2. Hands are thoroughly washed before commencing milk plant functions and as often as may be required to remove soil and contamination.
3. Each employee washes their hands following a visit to the toilet room and prior to resuming work.
4. All persons while engaged in the handling, processing, pasteurization, storage, transportation, or packaging of milk or milk products containers, utensils, and equipment wear clean outer garments suitable to the operation in a manner that protects against food allergen cross-contact and against the contamination of milk and/or milk products, milk or milk product-contact surfaces or milk or milk product packaging materials. Unsecured jewelry and the storage of clothing or other personal belongings shall not be permitted in these areas.
5. The use of tobacco products, chewing gum or eating food or drinking beverages is prohibited in all rooms in which milk and milk products are handled, processed or stored, or in which milk or milk product containers, utensils and/or equipment are washed. These rooms shall include, but are not limited to, the receiving, processing, packaging, milk and milk 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 or milk products wears adequate hair nets, caps, beard covers or other effective hair restraints.
6. 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.

ITEM 21p. VEHICLES

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

PUBLIC HEALTH REASON

Milk and milk products, as well as empty containers, should be protected against contamination at all times.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. All vehicles are kept clean.
2. Material that is capable of contaminating milk or milk products is not transported with milk or milk products.
3. Milk and milk products, except dry milk products, are maintained at 7^0C (45^0F) or less.
4. The operation of milk tank cars and shipping bins comply with the following provisions:
   a. Milk and milk 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.
   b. Inlets and outlets of shipping bins shall be provided with tight-fitting dust caps or covers.
   c. Facilities shall be provided for the adequate washing and sanitizing of shipping bins, piping, and accessories at all milk plants receiving or shipping milk or milk products in shipping bins.
   d. 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.
   e. 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. of this *Ordinance* by means of a tag attached to the tank car or shipping bin.
6. Vehicles have fully enclosed bodies with well-fitted, solid doors.

ITEM 22p. SURROUNDINGS

Milk 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.

PUBLIC HEALTH REASON

The surroundings of a milk plant should be kept neat and clean to prevent attracting rodents, flies and other insects, which may contaminate the milk or milk products. Insecticides and rodenticides, not approved for use in milk plants, or approved insecticides and rodenticides, not used in

accordance with label recommendations, may contaminate the milk or milk products processed by the milk plant.

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 plant. Waste material stored in suitable covered containers shall be considered in compliance.
2. Driveways, lanes and areas serving milk 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 Regulatory Agency and/or registered with EPA 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: Appendix M. of this *Ordinance* provides a source for milk plant, receiving station and transfer station inspection forms, which summarize the applicable sanitation requirements of this Section.

SECTION 8. ANIMAL HEALTH

1. All milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, retort processed after packaging or fermented high-acid, shelf-stable processing and packaging shall be from herds under a tuberculosis eradication program, which meets one (1) of the following conditions:
   a. Areas which have Modified Accredited Advanced Tuberculosis (TB) status or higher as determined by the USDA; or
   b. An Area which fails to maintain such status:
      (1) Any herd shall have been accredited by USDA; or
      (2) Shall have passed an annual tuberculosis test; or
      (3) The Area shall have established a tuberculosis testing protocol for livestock that assures tuberculosis protection and surveillance of the dairy industry within the Area and that is approved by FDA, USDA and the Regulatory Agency.

NOTE: Under the Federal USDA Bovine Tuberculosis Eradication Program, only cattle, bison and captive cervids are covered under the USDA State tuberculosis status determination. Therefore, other hooved mammals (goats, sheep, water buffalo, camels, etc.) are not covered within the program and shall comply with one (1) of the options cited under 3 below.

2. All milk for pasteurization, ultra-pasteurization, aseptic processing and packaging, retort processed after packaging or fermented high-acid, shelf-stable processing and packaging shall be from herds under a brucellosis eradication program, which meets one (1) of the following conditions:
   a. Located in a Certified Brucellosis-Free Area as defined by USDA and enrolled in the testing program for such areas; or
   b. Meet USDA requirements for a Certified Brucellosis-Free Herd; or