

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.

PUBLIC HEALTH REASON

Because of the nature of milk and milk products and their susceptibility to contamination by bacteria, chemicals and other adulterants, every effort should be made to provide adequate protection for the milk and milk products at all times. Misuse of pesticides and other harmful chemicals can provide opportunities for contamination of the milk and milk product or equipment with which the milk or milk product comes in contact.

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 7°C (45°F) 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. Air intakes for drying equipment shall be located so as to minimize the amount of atmospheric contamination and shall be equipped with suitable single-service filters, multi-use filters, or continuous air filter systems. (Refer to Appendix H.) The use of steam containing toxic substances is expressly prohibited. Whenever steam is used in contact with milk or milk products it shall be of culinary quality and shall comply with the applicable standards of Appendix H.

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.(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**, 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.)

(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.

(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., 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, 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 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; or
- b. Meet the requirements found in Appendix H, Section IX; 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 water supply 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 product¹⁰. 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 source water shall meet or exceed the EPA Safe Drinking Water Bacteriological Standards. Safety Assessment comparison of samples from the facility's water source, pasteurized water, and proposed equivalent water. Water samples shall be collected daily for two (2) weeks following approval of the initial installation and every six (6) months thereafter; 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 7°C (45°F) or less. When the handling and/or cooling of such milk and/or milk products are not in compliance with this requirement, they shall be discarded. Milk 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 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 to assure that the pressure differential controller probes are accurately calibrated. Also, the applicable procedures cited in Appendix I, Test 9.2.2 shall be utilized to assure that the pressure differential controller is accurately calibrated and will de-energize the heat-transfer water pump at the required differential pressure set point.

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.

ITEM 16p. PASTEURIZATION, ASEPTIC PROCESSING AND PACKAGING, AND RETORT PROCESSED AFTER PACKAGING

Pasteurization shall be performed as defined in Section 1, Pasteurization and Item 16p of this *Ordinance*. Aseptic processing and packaging and retort processed after packaging shall be performed in accordance with the applicable requirements of 21 CFR Parts 108, 110 and 113. (Refer to Appendix L.)

In all cases, except for the specific exemptions provided for in **ADMINISTRATIVE PROCEDURES #3**, pasteurization of raw milk or milk product shall be performed before the raw milk 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 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-