

330 CMR 27.00: STANDARDS AND SANITATION REQUIREMENTS FOR GRADE A RAW MILK

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27.01: Scope and Purpose

330 CMR 27.00 establishes standards and sanitation requirements for raw milk and milk products for pasteurization, ultra pasteurization or aseptic processing and standards and sanitization requirements for raw milk for retail sale. It is applicable to all regulations filed pursuant to M.G.L. c. 94, § 13. It describes the requirements for producing and processing raw milk by all producers holding a Massachusetts Dairy Farm Certificate of Registration. The purpose of 330 CMR 27.00 is to provide sanitary standards for the production, processing, and sale of fluid milk.

27.02: Definitions

The following definitions shall apply in the interpretation and enforcement of 330 CMR 27.00:

Adulterated - in the case of milk or milk products, means the definition in M.G.L. c. 94, § 186 which pertains to food.

Aseptic Processing - means the process whereby milk or a milk product has been subjected to sufficient heat processing and packaged in a hermetically sealed container in conformance with the applicable requirements of 21 CFR 113 and the provisions of 105 CMR 541.010(S), (T) and (U) to maintain the commercial sterility of the product under normal nonrefrigerated conditions.

Board of Health - means the appropriate and legally designated health authority of the city, town, or other legally constituted governmental unit within the Commonwealth of Massachusetts having the usual powers and duties of the board of health of a city or town.

Bulk Milk Pickup Tanker - means a vehicle, including the truck and tank and those appurtenances necessary for its use, used by a milk hauler to transport bulk raw milk for pasteurization from a dairy farm to a transfer station, receiving station or pasteurization plant.

27.02: continued

Bureau - shall mean the Bureau of Dairying in the Division of Regulatory Services of the Massachusetts Department of Food and Agriculture.

Certificate of Registration and Certification - means approval by the Commonwealth of Massachusetts to produce and sell milk as provided by M.G.L. c. 94, § 16.

Commissioner - means the Commissioner of the Department of Food and Agriculture.

Dairy Farm - means a place or premises where more than two cows are kept and a part or all of the milk produced thereof is sold or delivered for sale to any person.

Department - means the Massachusetts Department of Food and Agriculture.

Director - means the Director of the Division of Regulatory Services.

Drug - means articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or the official National Formulary, or any supplement to any of them; and articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals, and articles (other than food) intended to affect the structure or any function of the body of humans or other animals, and; articles intended for use as a component of any articles specified in the above, but does not include devices or their components, parts or accessories.

Grade "A" - means milk and milk products which comply with the provisions of 330 CMR 27.00.

Grade "A" Fluid Milk and Milk Products - shall include skim milk, lowfat milk, buttermilk, cultured buttermilk, acidified buttermilk, cultured skim milk, acidified milk, acidified lowfat milk, acidified skim milk, low sodium milk, lactose-reduced acidified milk, lactose-reduced skim milk, ultra pasteurized milk, aseptically processed and packaged milk, milk or lowfat milk or skim milk with added safe and suitable microbial organisms, and any other milk products made by the addition or subtraction of milk fat or addition of safe and suitable optional ingredients for protein, vitamin, or mineral fortification herein, irrespective of the way that the product is flavored, and any other dairy product designated by the Commissioner.

As defined here, "Fluid milk and Milk Products" is not intended to include products such as butter, cottage cheese, lowfat cottage cheese, dry curd cottage cheese, hard and soft cheeses, cream, light cream, light whipping cream, whipped cream, whipped light cream, sour cream, acidified sour cream, cultured sour cream, dietary products, half-and-half, infant formula, ice cream and other desserts, concentrated milk, concentrated milk products, condensed milk, dry milk and milk products, evaporated milk, evaporated skim milk, reconstituted or lowfat yogurt, nonfat yogurt, whey, condensed and dry whey, and whey products, or any other dairy product designated by the Commissioner, except when they are combined with other substances to produce any pasteurized, ultra-pasteurized, or aseptically processed milk or milk product defined herein.

Any product referred to in this definition shall comply with the provisions of 330 CMR 27.00.

Law - means all applicable federal, state and local statutes, ordinances and regulations.

Milk - means the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows or goats. Milk that is in final package form for beverage use shall contain not less than 8.25% milk solids not fat and not less than 3.25% milkfat for cow milk. Goat milk shall contain not less than 2.5% milkfat and not less than 7.5% milk solids not fat. Milk may be adjusted by separating part of the milkfat therefrom or by adding cream thereto.

27.02: continued

Milk Dealer - means any person who offers for sale or sells to another any milk or milk product.

Milk Plant - means any place, premises or establishment where milk or milk products are collected, handled, processed, stored, pasteurized, aseptically processed, bottled, or prepared for distribution.

Milk Producer - means any person who operates a dairy farm and provides, sells, or offers milk for sale to a milk plant, receiving station or transfer station, or as raw for retail.

Milk Tank Truck - means either a bulk milk pickup tanker or a milk transport tank.

Milk Transport Tank - means a vehicle, including the truck and tank, used by a milk hauler to transport bulk shipments of milk or milk products from a transfer station, receiving station or milk plant to another transfer station, receiving station or milk plant.

Misbranded - in the case of milk and milk products, means the definition in M.G.L. c. 94, § 187 which pertains to food.

Official Laboratory - an official laboratory is a biological, chemical, or physical laboratory which is under the direct supervision of the state or a local regulatory agency.

Officially Designated Laboratory - an officially designated laboratory is a commercial laboratory authorized to do official work by the regulatory agency, or a milk industry laboratory officially designated by the regulatory agency for the examination of producer samples of Grade A raw milk for pasteurization and commingled milk tank truck samples of raw milk for antibiotic residues and bacterial limits.

Pasteurization or Pasteurized - or a similar term means the process of heating every particle of milk or milk product, in properly designed and operated equipment, to one of the applicable temperatures described in 105 CMR 541.010(P) and holding every such particle continuously at or above that temperature for at least the corresponding time specified.

Pasteurization Plant - means any place, premises or establishment where raw milk, milk or milk products are pasteurized, ultra-pasteurized or aseptically processed. A pasteurization plant may include milk plants, receiving stations, and transfer stations.

Person - means any individual, plant operator, partnership, corporation, company, firm, trustee, association or institution.

Potable Water Source - means any source or supplier of water approved by the Department of Environmental Protection or the Department of Public Health.

Raw Milk for Pasteurization - means Grade "A" milk and raw products thereof which comply with sanitary standards for production, transportation, receiving, handling, storage, processing, distribution and sale as determined by the Commissioner of Food and Agriculture in 330 CMR 27.00.

Receiving Station - means any place, premises, or establishment where raw milk is received, collected, handled, stored, or cooled and prepared for further transporting.

Regulatory Agency - means the Massachusetts Department of Food and Agriculture and its subdivisions.

27.02: continued

Sanitization - means the application of any effective method or substance to a clean surface for the purpose of inactivation or destruction of pathogens, and of other organisms as far as is practicable. Such treatment shall not adversely affect the equipment, the milk or milk product or the health of consumers, and shall be acceptable to the Department.

Sterilized - as applied to piping, equipment or containers used for milk and milk products, means the condition achieved by application of heat, chemical sterilant(s), or other appropriate treatment that renders the piping, equipment or containers free of viable microorganisms.

Transfer Station - means any place, premises or establishment where milk or milk products are transferred directly from one milk tank truck to another.

Ultra Pasteurized - means thermally processed at or above 280°F (138°C) for at least two seconds, either before or after packaging, so as to produce a product that has an extended shelf life when kept at 45°F or below.

3-A Sanitary Standards - for dairy equipment are promulgated jointly by the Sanitary Standards Subcommittee of the Dairy Industry Committee, the Committee on Sanitary Procedure of the International Association of Milk, Food and Environmental Sanitarians, Inc., and the Milk Safety Branch, Bureau of Foods, Food and Drug Administration, Public Health Service, Department of Health and Human Services. Equipment manufactured in conformity with 3-A Sanitary Standards complies with the sanitary design and construction standards of 330 CMR 27.00.

27.03: Animal Health

(A) All milk for manufacturing or processing shall be from herds which are located in an accredited free bovine tuberculosis area as determined by the U.S. Department of Agriculture; provided, that the herds located in an area that fails to maintain such accredited status shall have been accredited by the Department as tuberculosis free or shall have passed a full herd tuberculosis test within one year from the date of the preceding test.

(B) All milk for pasteurization shall be from herds under the cooperative State-Federal brucellosis eradication program and located in a classified brucellosis-free, or Class A state, as defined by the U.S. Department of Agriculture. If located in Class B or C states, they shall meet U.S. Department of Agriculture requirements for an individually certified herd. All brucellosis reactors disclosed on blood agglutination tests shall be separated immediately from the milking herd.

(C) For diseases other than brucellosis and tuberculosis, the Commissioner may require such physical, chemical or bacteriological tests as he deems necessary. The diagnosis of other diseases in dairy cattle shall be based upon the findings of a licensed veterinarian or a veterinarian in the employ of the Department of Food and Agriculture. Any diseased animal disclosed by such test(s) shall be disposed of as the Department directs.

27.04: Personnel Health

(A) Prohibition. No person affected with any disease in a communicable form, or while a carrier of such disease, shall work at any dairy farm in any capacity which brings him into contact with the production, handling, storage, or transportation of milk, milk products, containers, equipment and utensils; and no dairy farm operator shall employ in any such capacity any such person, or any person suspected of having any disease in a communicable form, or of being a carrier of such disease. Any producer or distributor of milk or milk products, upon whose dairy farm any communicable disease occurs, or who suspects that any employee has contracted any disease in a communicable form, or has become a carrier of such disease, shall notify the department immediately.

(B) Procedure when Infection is Suspected. When reasonable cause exists to suspect the possibility of transmission of infection from any person concerned with the handling of milk and/or milk products, the department is authorized to require any or all of the following measures:

- (1) The immediate exclusion of that person from milk handling.
- (2) The immediate exclusion of the milk supply concerned from distribution and use.
- (3) Adequate medical and bacteriological examination of the person, of her/his associates, and of her/his and their body discharges.

27.05: Standards for Grade "A" Raw Milk for Pasteurization, Ultra Pasteurization and Aseptic Processing

All Grade A raw milk for pasteurization, ultra pasteurization or aseptic processing shall be produced to conform with the following chemical, bacteriological, and temperature standards, and the sanitation requirements of 330 CMR 27.07.

GRADE A RAW MILK FOR PASTEURIZATION, ULTRA PASTEURIZATION ASEPTIC PROCESSING	Temperature....	Cooled to 40°F (4.45°C) or less within two hours after milking, provided that the blend temperature after the first and subsequent milkings does not exceed 50°F (10°C).
	Bacterial Limits.....	Individual producer milk shall not exceed 100,000 per ml. prior to commingling with other producer milk. Individual producer milk shall not exceed 2,500 per ml. after laboratory pasteurization.
	Optional Pre- liminary In- cubation Count when used.....	Individual producer milk shall not exceed 100,000 per ml.
	Drugs.....	No zone greater than or equal to 16mm with <i>Bacillus Sterothermophilus</i> disc assay method specified in Appendix G of the most recent edition of the PMO or any other method approved by the department. No Individual producer milk shall have a positive result for drug residue in excess of the allowable level in the most recent edition of the PMO.

27.05: continued

Somatic Cell...	Individual producer milk shall not exceed 1,000,000 per ml. Beginning July 1, 1993 individual producer milk shall not exceed 750,000 per ml.
Cryoscope.....	(-)0.525°C unless proved to be free of added water.

27.06: Standards for Grade "A" Raw Milk for Retail Sale

All Grade "A" raw milk for retail sale shall be produced and handled to conform with the following chemical, bacteriological, and temperature standards, and the sanitation requirements of 330 CMR 27.06

GRADE "A" RAW FOR RETAIL MILK	Temperature....	Cooled to 40°F (4.45°C) or less within two hours after milking, provided that the blend temperature after the first and subsequent milkings does not exceed 50°F (10°C).
	Bacterial Limit.....	Individual producer milk shall not exceed 20,000 per ml.
	Coliform.....	Not to exceed 10 per ml.
	Drugs.....	No zone greater than or equal to 16mm with <i>Bacillus Sterothermophilus</i> disc assay method specified in Appendix G of the most recent edition of the PMO or any other method approved by the department. No Individual producer milk shall have a positive result for drug residue in excess of the allowable level in the most recent edition of the PMO.
	Somatic Cell...	Individual producer milk shall not exceed 750,000 per ml.
	Cryoscope.....	(-)0.525°C unless proved to be free of added water.

27.07: Sanitation Requirements For Grade "A" Raw Milk

The following requirements shall be applicable to raw milk for pasteurization, ultrapasteurization or aseptic processing and Grade A raw milk for retail sale.

(A) Abnormal Milk. Cows which show evidence of the secretion of abnormal milk in one or more quarters, based upon bacteriological, chemical, or physical examination, shall be milked last or with separate equipment and the milk shall be discarded. Cows treated with, or cows which have consumed chemical, medicinal or radioactive agents which are capable of being secreted in the milk and which, in the judgement of the regulatory agency, may be deleterious to human health, shall be milked last and the milk disposed of as the department may direct.

(B) Milking Barn, Stable, or Parlor -- Construction. A milking barn, stable, or parlor shall be provided on all dairy farms in which the milking herd shall be housed during milking time operations. The areas used for milking purposes shall:

- (1) In the case of new construction, have floors constructed of concrete or equally impervious material that are easily cleanable. Convalescent (maternity) pens located in milking areas of stanchion-type barns may be used subject to departmental approval;
- (2) Have walls and ceiling which are smooth, painted or finished in an approved manner, in good repair, the ceiling shall be dust tight;
- (3) Have separate stalls or pens for horses, calves, and bulls;
- (4) Be provided with natural and/or artificial light, well distributed for day and/or night milking;
- (5) Provide sufficient air space and air circulation to prevent condensation and excessive odors;
- (6) Not be overcrowded;
- (7) Have dust tight covered boxes or bins, or separate storage facilities for ground, chopped, or concentrated feed.

(C) Milking Barn Stable or Parlor -- Cleanliness. The interior shall be kept clean. Floors, walls, ceilings, windows, pipelines, and equipment shall be clean. Swine and fowl will be kept out of the milking barn.

(D) Cowyard. The cowyard shall be graded and drained and shall have no standing pools of water or accumulations of organic wastes: provided, that in loafing or cattle-housing areas, cow droppings and soiled bedding shall be removed, or clean bedding added, at sufficiently frequent intervals to prevent the soiling of the cow's udder and flanks. Waste feed shall not be allowed to accumulate. Manure packs shall be properly drained and shall provide a reasonably firm footing. Swine shall be kept out of the cowyard.

(E) Milkhouse or Room -- Construction and Facilities.

- (1) A milkhouse or room of sufficient size shall be provided, in which the cooling, handling, and storing of milk and the washing, sanitizing, and storing of milk containers and utensils shall be conducted: Except as provided for in 330 CMR 27.07(L).
- (2) The milkhouse shall be provided with a smooth floor constructed of concrete or equally impervious material graded to drain and maintained in good repair. Liquid waste shall be disposed of in a sanitary manner; all floor drains shall be accessible and shall be trapped if connected to a sanitary sewer system.
- (3) The walls and ceilings shall be constructed of smooth material, in good repair, well painted, or finished in an equally suitable manner.
- (4) The milkhouse shall have adequate natural and/or artificial light and be well ventilated.
- (5) The milkhouse shall be used for no other purpose than milkhouse operations; there shall be no direct opening into any barn, stable, or into a room used for domestic purposes: provided, That a direct opening between the milkhouse and milking barn, stable, or parlor is permitted when a tight-fitting, self-closing solid door(s) hinged to be single or double acting is provided.
- (6) Hot and cold water under pressure shall be piped into the milkhouse.
- (7) The milkhouse shall be equipped with a two-compartment wash vat and adequate hot water heating facilities.

27.07: continued

(8) A properly constructed cooling tank of sufficient size and depth or other approved cooling facilities shall be provided in the milk house, milkroom or other approved location.

(9) The cooling facilities shall be used for no other purposes than the cooling and storage of milk. They shall be protected from contamination and maintained in a sanitary condition.

(10) When a transportation tank is used for the cooling and/or storage of milk on the dairy farm, such tank shall be provided with a suitable shelter for the receipt of milk. Such shelter shall be adjacent to, but not a part of, the milkroom and shall comply with the requirements of the milkroom with respect to construction, light, drainage, insect and rodent control, and general maintenance.

(F) Milkhouse or Room -- Cleanliness. The floors, walls, ceilings, windows, tables, shelves, cabinets, washvats, non-product contact surfaces of milk containers, utensils and equipment and other milkroom equipment shall be clean. Only articles directly related to milkroom activities shall be permitted in the milkroom. The milkroom shall be free of trash, animals, and fowl.

(G) Toilet. Every dairy farm shall be provided with one or more toilets, conveniently located and properly constructed, operated, and maintained in a sanitary manner. The waste shall be inaccessible to flies and shall not pollute the soil surface or contaminate any water supply.

(H) Water Supply. Water for milkhouse and milking operations shall be from a potable water source properly located, protected, and operated, and shall be easily accessible, adequate and of a safe, sanitary quality.

(I) Utensils and Equipment -- Construction.

(1) All multiuse containers, equipment, and utensils used in the handling, storage, or transportation of milk, or with which milk or milk products otherwise come into contact, shall be made of smooth, nonabsorbent, corrosion-resistant, nontoxic materials, and shall be so constructed as to be easily cleaned. All containers, utensils, and equipment shall be in good repair. All milk pails shall be seamless and milk pails used for hand milking shall be of the hooded type. Multiple-use woven material shall not be used for straining milk. All single-service articles shall be non-toxic and have been manufactured, packaged, transported, and handled in a sanitary manner. Articles intended for single-service use shall not be reused.

(2) Farm holding/cooling tanks, welded sanitary piping, and transportation tanks shall comply with 3-A Sanitary Standards.

(J) Utensils and Equipment -- Cleaning. The product-contact surfaces of all multiuse containers, equipment, and utensils used in the handling, storage, or transportation of milk shall be cleaned after each usage.

(K) Utensils and Equipment -- Sanitization. The product-contact surface of all multi-use containers, equipment and utensils used in the handling, storage or transportation of milk shall be sanitized before each usage.

(L) Utensils and Equipment -- Storage. All containers, utensils and equipment used in the handling, storage, or transportation of milk, unless stored in sanitizing solutions, shall be stored to assure complete drainage, and shall be protected from contamination prior to use provided that pipeline milking equipment such as milking claws, inflations, weigh jars, meters, milk hoses, milk receivers, tubular coolers, plate coolers and milk pumps which are designed for mechanical cleaning and other equipment as accepted by FDA, which meets these criteria may be stored in the milking barn or parlor provided this equipment is designed, installed and operated to protect the product and solution-contact surfaces from contamination at all times.

27.07: continued

(M) Utensils and Equipment -- Handling. After sanitization, all containers, utensils, and equipment shall be handled in such manner as to prevent contamination of any product-contact surface.

(N) Milking-- Flanks, Udders, and Teats. Milking shall be done in the milking barn, stable, or parlor. The flanks, udders, bellies, and tails of all cows shall be free from visible dirt. All brushing shall be completed prior to milking. The udders and teats of all milking cows shall be clean and dry before milking. Teats shall be treated with a sanitizing solution just prior to the time of milking, and shall be wiped dry before milking. Wet hand milking is prohibited.

(O) Milking-- Surcingles, Milk Stools, and Antikickers. Surcingles, milk stools, and antikickers shall be kept clean and stored above the floor.

(P) Protection from Contamination. Milking and milk house operations, equipment, and facilities shall be located and conducted to prevent any contamination of milk, equipment, containers, and utensils. No milk shall be strained, poured, transferred, or stored unless it is properly protected from contamination.

(Q) Personnel -- Hand-Washing Facilities. Adequate hand-washing facilities shall be provided, including a lavatory fixture with running water, soap or detergent, and individual sanitary towels, convenient to the milkhouse, milking barn, stable, parlor, and flush toilet.

(R) Personnel-- Cleanliness. Hands shall be washed clean and dried with an individual sanitary towel immediately before milking, before performing any milkhouse function and immediately after the interruption of these activities. Milkers and milk haulers shall wear clean outer garments while milking or handling milk, milk containers, utensils, or equipment.

(S) Cooling. Raw milk for pasteurization or retail sale shall be cooled to 40°F (4.45°C) or less within two hours after milking: Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 50°F (10°C).

(T) Vehicles. Vehicles used to transport milk from the dairy farm to the milk plant or receiving station shall be constructed and operated to protect their contents from sun, freezing, and contamination. Such vehicles shall be kept clean, inside and out and no substance capable of contaminating milk shall be transported with milk.

(U) Insect and Rodent Control. Effective measures shall be taken to prevent the contamination of milk, containers, equipment, and utensils by insects and rodents and by chemicals used to control such vermin. Milk rooms shall be free of insects and rodents. Surroundings shall be kept neat, clean, and free of conditions which might harbor or be conducive to the breeding of insects and rodents.

27.08: Additional Requirements For Grade "A" Raw Milk For Retail Sale

The following requirements shall be applicable to raw milk for retail sale, in addition to the requirements in 330 CMR 27.07.

(A) Storage. Milk shall be stored in an approved milk tank or stainless steel cans. All containers shall be stored at 40°F (4.45°C) or below in facilities which have been approved by the commissioner or her/his agent. A commercial refrigeration unit constructed of impervious material that is smooth and easily cleaned may be used for the purpose of storing retail raw milk in containers. A household refrigeration unit in good mechanical and physical condition is also permitted. All facilities shall be equipped with an accurate thermometer graduated in no more than two degree increments. The use of wet storage facilities shall be prohibited under all circumstances for the handling of consumer type containers.

27.08: continued

(B) Containers. All sanitary containers shall be provided/supplied by the dairy. All containers shall be stored in a manner that minimizes contamination of the containers. Single-service containers and lids must come from an approved source and not be reused. Returnable containers must be washed, rinsed, and sanitized before refilling. Lids for returnable containers shall not be reused.

(C) Bottling and Capping. All bottling and capping of Grade A raw milk for retail sale shall be done on approved mechanical equipment, except for those dairies where volume causes this to be impractical. All caps shall be designed and constructed so that the removal of such caps cannot be made without detection. Hand capping is allowed provided:

- (1) All caps or lids must be kept immersed in a 50 ppm solution of chlorine for a minimum of one minute and immediately placed on a container.
- (2) Operator must wear disposable plastic gloves while filling and capping, or hands must be thoroughly washed and sanitized prior to and during operations.
- (3) Milk is withdrawn through bottom (outlet) valve of tank. "No Dipping."
- (4) Filling of containers must be done in a sanitary manner to preclude possible contamination: container filling by the consumer is prohibited.

(D) Date. The date on the container of retail raw milk shall indicate the last date on which the container may be offered for sale. There shall be a five day maximum period for the sale of retail raw milk which shall commence from the time of filling. Said five day maximum period may be shortened by the Commissioner if she/he deems such modification to be in the best interest of the consumer.

(E) Labeling. The name of the product is Raw Cow's Milk or Raw Goat's Milk and shall be so plainly labeled. The label shall contain the name, address and zip code of the producing farm.

(F) Consumer Warning Statement

- (1) All retail containers of raw cow's or raw goat's milk shall be conspicuously labeled with the following statement: "Raw milk is not pasteurized. Pasteurization destroys organisms that may be harmful to human health". The minimum size of the printed words shall not be less than 1/16 inch in height, with the words "not pasteurized" being not less than 1/8 inch in height or twice the height of any other lettering in the label, whichever is greater.
- (2) A sign must be posted in the area where the raw milk is sold and placed in a location where it can be easily observed by anyone entering therein. Such sign shall not be less than eight by eleven inches in total dimension and shall display the following statement: "Raw milk is not pasteurized. Pasteurization destroys organisms that may be harmful to human health." The minimum size of the printed words shall not be less than 1/2 inch in height, with the words "not pasteurized" being not less than one inch in height.

(G) Sales and Storage. Milk cannot be offered for sale or consumption if such milk has been stored in a bulk tank or other approved storage container beyond 48 hours. All bulk tanks or other approved storage containers must be cleaned and sanitized before reuse.

27.09: Review of Plans for Construction or Remodeling of Milking Centers

When a milking center or potable water source is to be constructed or extensively remodeled, or an existing structure is to be converted for use as a milking center, properly prepared plans and specifications for such construction, remodeling or alteration, showing layout, arrangement and construction materials of work areas, and the location, size and type of fixed equipment and facilities, shall be submitted to the Bureau, or the appropriate out-of-state regulatory authority for approval before such work is begun.

27.10: Administration and Enforcement

(A) General Administration. The following provisions shall cover the administration and enforcement of 330 CMR 27.00.

27.10: continued

(B) State Enforcement

- (1) The Department may enforce 330 CMR 27.00 by suspension or revocation of certificates of registration in accordance with 330 CMR 27.016.
- (2) If the Commissioner or her/his agent determines, as a result of any study, inspection or survey made by the Department, that compliance with 330 CMR 27.00 has not been effected, she/he shall take appropriate action to effect compliance.
- (3) Notwithstanding any other provision of 330 CMR 27.00, if the Commissioner or her/his agent determines that an imminent health hazard exists, resulting from the operation of a dairy farm, she/he may without prior notice to the board of health take whatever action is necessary to effect compliance with 330 CMR 27.00.

(C) Interpretation of Regulations. The Department may from time to time issue written interpretations and guidelines as necessary to promote uniform application of 330 CMR 27.00. The Department may advise the certificatee or the board of health on particular questions regarding interpretations of 330 CMR 27.00.

27.11: Certificate of Registration: Issuance

(A) General

- (1) No person shall sell or offer or expose milk for sale produced on a dairy farm for use or disposal elsewhere than on such farm, unless as to such farm a Certificate of Registration has been issued by the Commissioner.
- (2) Only a person who complies with the requirements of 330 CMR 27.00 shall be entitled to receive and retain a certificate.
- (3) The certificate shall be posted in the milkroom.
- (4) A certificate shall not be transferable from a person or a place.

(B) Application for Certificate

- (1) Any person desiring to operate a dairy farm shall make written application for a certificate on a form provided by the Department in accordance with M.G.L. c. 94, § 16(B).

(C) Expiration and Renewal of Certificate

- (1) A certificate shall expire no later than one year from the date issued.
- (2) A certificate may be renewed by applying at least 30 days prior to the expiration of the certificate. An application for a renewal certificate shall be made in writing on a form provided by the Department.

(D) Conditions for Issuance

- (1) After completion of an application for an original certificate or renewal certificate the Department shall cause an inspection of the dairy farm to take place. This inspection may be conducted by the Bureau. When the inspection reveals that the applicable requirements of 330 CMR 27.00 have been met, a certificate shall be issued to the applicant by the Department: provided that the applicant is found to be responsible and suitable for certification in accordance with 330 CMR 27.011(D)(2).
- (2) After completion of an application for an original certificate or a renewal certificate, the Department shall make a finding concerning the responsibility and suitability of the applicant for certification. Factors which have a significant bearing on such finding include but are not limited to the following:
  - (a) The applicant's history of prior compliance with 330 CMR 27.00.
  - (b) The applicant's ability and willingness to take corrective action when notified by the Department of violations of 330 CMR 27.00.

(E) Notification of Changes. Change in ownership, name or location A certificatee shall notify the Department and the Bureau within five business days after any change in ownership, and at least 30 days prior to any change of the name or location of the dairy farm, and shall promptly submit an application for a new or amended certificate, along with written documentation reflecting such change.

27.12: Inspections

(A) General

- (1) The department shall cause an inspection to be made of every dairy farm within the commonwealth at least once every six months, and may cause the inspection of dairy farms operating outside the commonwealth once every six months, and as often as necessary for the enforcement of 330 CMR 27.00. These inspections may be conducted by the Bureau.
- (2) Agents of the Department, may enter all parts of any dairy farm at any reasonable time for the purpose of making an inspection to ascertain whether the farm is in compliance with 330 CMR 27.00. No prior notice of inspection is required. They may examine the records of the farm to obtain information pertaining to the number of dairy cows over two years of age, the number of dairy cows currently milking, the number of heifers less than two years of age, the production of milk per day, and a determination of where the milk is being shipped.
- (3) If the certificatee or person in charge at the time of the inspection refuses entry to an agent of the Department, or refuses to permit an authorized inspection, the Commissioner or her/his agent may immediately suspend the certificate of the dairy farm, without prior notice or hearing, in accordance with 330 CMR 27.016(A).
- (4) If the certificatee or any of her/his employees interferes with the Department in the performance of its duties, the Department may take steps to suspend or revoke the certification of the dairy farm in accordance with 330 CMR 27.016(B), (C), and (D).
- (5) The Department may accept inspections by out-of-state regulatory authorities, for renewal purposes, for producers shipping milk into the commonwealth from out-of-state locations for compliance with 330 CMR 27.00.
- (6) Violations of 330 CMR 27.07 and 27.08 shall be recorded on appropriate ledgers for evaluation of compliance with 330 CMR 27.012(C)(4). A computer or other information retrieval system may be used.

(B) Inspection Report

- (1) Whenever an inspection of a dairy farm is made, the findings shall be recorded on an inspection report. The inspection report shall serve as an order to the producer to correct all violations of 330 CMR 27.00 noted thereon by the date indicated on the report by the inspector.
- (2) The inspection report shall include, but need not be limited to, the following information:
  - (a) The name of the inspector;
  - (b) The date and time of the inspection;
  - (c) The name and location of the dairy farm inspected;
  - (d) A listing of the specific provisions of 330 CMR 27.00 that have been violated;
  - (e) A determination by the inspector whether any of the violations create an imminent health hazard;
  - (f) A space for the signature of the person in charge of the dairy farm at the time of the inspection.

(C) Conduct of Inspections

- (1) The inspections performed pursuant to 330 CMR 27.011(D) and 330 CMR 27.012(A)(1) shall be full inspections.
- (2) A copy of the completed inspection report form shall be furnished to the person in charge of the Dairy farm at the conclusion of the inspection, posted on an inside wall of the milkroom, or left in some other conspicuous place. This inspection report shall not be defaced and shall be made available to the Department upon request. An identical copy of the inspection report shall be filed with the records of the Department and retained for at least three years.
- (3) Inspections shall be made of dairy farms at different times of the day in order to ascertain if the processes of equipment assembly, sanitizing, cleaning and other procedures comply with the requirements of 330 CMR 27.00.

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(4) Should the violation of any significant requirement set forth in 330 CMR 27.05, 330 CMR 27.06, 330 CMR 27.07 or 330 CMR 27.08 be found to exist during an inspection of a dairy farm, a second inspection shall be required after a time deemed necessary by the Department to remedy the violation, but not before three days. Any violation of the same requirement on such second inspection may result in the immediate suspension of the certificate, without a prior hearing, in accordance with 330 CMR 27.016(A), and may also result in court action.

27.13: Examination of Milk

Milk may be examined or sampled by the Department.

(A) Sampling

(1) During any consecutive six month period, at least one sample per month shall be taken of raw milk for pasteurization, ultra-pasteurization, or aseptic processing and raw for retail sale at the dairy farm.

(2) All samples of milk for pasteurization, ultrapasteurization or aseptic processing shall be collected and delivered to a milk plant, receiving station, or other location approved by the regulatory agency.

(3) Samples of raw milk for retail sale shall be taken while in the possession of the farm or at any time prior to delivery to the plant or consumer.

(B) Testing

(1) Required bacterial counts, DMSCC, drug, and cooling temperature checks shall be performed on raw milk.

(2) Samples shall be analyzed at an official laboratory or officially designated laboratory. The results of all tests on milk and milk products shall be forwarded to the Department.

(3) All sampling procedures and required laboratory examinations shall be in substantial compliance with the latest edition of Standard Methods for the Examination of Dairy Products of the American Public Health Association, or any successor document, and the latest edition of Official Methods of Analysis of the Association of Official Analytical Chemists, or any successor document.

(4) Such procedures, including the certification of sample collectors, and examinations shall be evaluated in accordance with the Evaluation of Milk Laboratories, the most recent edition of the Recommendations of the United States Public Health Service/ Food and Drug Administration, or any successor document.

(5) Examinations and tests to detect adulterants, including pesticides, shall be conducted as the Department requires.

(C) Procedures

(1) Violations of bacteria, confirmed somatic cell counts, adulterants, pesticides, and cooling temperature standards shall be followed promptly by inspection to determine and correct the cause.

(D) Laboratory Techniques

(1) Procedures for the collection and holding of samples; the selection and preparation of apparatus, media and reagents; and the analytical procedures, incubation, reading, and reporting of results, shall be in substantial compliance with Standard Methods for the Examination of Dairy Products and the Official Methods of Analysis, Association of Official Analytical Chemists (AOAC). The procedures shall be those specified therein for:

(a) Standard plate count at 32°C.

(b) Simplified methods for viable counts of raw milk at 32°C.

(c) Alternate methods for viable counts for raw milk and the petrifilm method for raw milk;

(d) Coliform test with solid media at 32°C for all milk and milk products;

(2) Disc assay methods for antibiotics shall be as specified in the U.S. Grade "A" Pasteurized Milk Ordinance.

## 27.13: continued

- (3) Screening and confirmatory methods for the detection of abnormal milk.
- (4) Any other tests may be required which have been approved by the U.S. Food and Drug Administration and the Commissioner to be equally accurate, precise, and practical.
- (5) Any one of the following three tests may be used for screening raw milk samples to indicate a range of somatic cell levels: California Mastitis Test, Modified Whitside Test, or Wisconsin Mastitis Test.
- (6) One of the following confirmatory tests shall be used: Direct Microscopic Somatic Cell Counting, Electronic Somatic Cell Counting, Optical Somatic Cell Counting for Membrane Filter DNA Somatic Cell Count, or any other standard procedure previously approved, in writing, by the Department.
- (7) Laboratories using acceptable screening tests shall confirm that sample of herd milk which exceeds any of the following screening test results:
  - (a) California Mastitis Test-- 1
  - (b) Modified Whitside Test-- 1+
  - (c) Wisconsin Mastitis Test-- 18 mm

The results of the screening test, or confirmatory test, shall be recorded on the official records of the dairy farm and a copy of the results sent to the milk producer.
- (8) When a warning letter has been sent because of excessively high somatic cell counts, an official inspection of the dairy shall be made by regulatory personnel. This inspection shall be made during milking time.
- (9) When bacterial counts and temperature determinations are made of several samples of the same milk collected from the same supply on the same day these values are averaged arithmetically, and the results recorded as the count for that day.
- (10) A computer or other information retrieval system may be used.

(E) Disease Transmission

- (1) When samples of raw milk are taken, they shall be drawn following adequate agitation.
- (2) Raw milk must be produced under clean, sanitary conditions to limit the possibility of any disease transmission via raw milk.
- (3) Raw milk is known to transmit disease, including (but not limited to):
  - (a) Listeriosis;
  - (b) Yersiniosis;
  - (c) Campylobacteriosis;
  - (d) Salmonellosis;
  - (e) Brucellosis;
  - (f) Q-fever;
  - (g) Tuberculosis; and
  - (h) Any other disease so designated by the Department.

27.14: Enforcement Standards(A) Enforcement

- (1) Whenever two of the last four consecutive bacterial counts, somatic cell counts, or cooling temperature checks, taken on separate days, exceed the limit of the standard for the milk and/or milk products, the Department shall send by first class mail a written notice thereof to the certificatee. This notice shall also inform the certificatee of the provisions of 330 CMR 27.14(A)(2), and shall remain in effect as long as two of the last four consecutive samples exceed the limit of the standard. An additional sample shall be taken within 21 days of the sending of such notice, but not before the lapse of three days.
- (2) Whenever the standard is violated by three of the last five bacterial counts, somatic cell counts, or cooling temperature checks, the Department shall immediately suspend the certificate in accordance with 330 CMR 27.16(A).
- (3) The department may accept determinations of 330 CMR 27.14 by out-of-state regulatory authorities for producers shipping milk into the Commonwealth from out-of-state locations.

27.14: continued

(4) When the somatic cell count of a re-check sample of the producer's milk is above 1,000,000 cells per ml., the producer shall be sent written notification. It shall be suggested in the notification that all in-state producers enroll in the Massachusetts Mastitis Control Program.

(5) Whenever a drug or pesticide residue test is positive, an investigation shall be made to determine the cause, and the cause shall be corrected. An additional sample shall be taken and tested for drug or pesticide residues, and no milk shall be offered for sale, nor shall any milk be received from a contaminated source until it is shown by a subsequent sample to be free of drug or pesticide residues or below the action levels established for such residues.

27.15: Hearings

(A) The person or persons to whom any order issued pursuant to 330 CMR 27.016(A) or (B) has been directed may request a hearing before the bureau.

(B) A request for a hearing may be made by the certificatee to the bureau in writing or by telephone to a person authorized to schedule a hearing.

(C) Upon receipt of a request for a hearing, the bureau shall set a time and a place for such hearing and shall inform the petitioner thereof. Hearings may be requested for violations of 330 CMR 27.14 or 330 CMR 27.16(A) or (B) and shall normally be held within 72 hours of the request. However, upon application of the petitioner, the bureau may postpone the date of the hearing for a reasonable time if in the judgment of the bureau the petitioner has submitted a good and sufficient reason for such postponement.

(D) At the hearing the petitioner shall be given an opportunity to be heard and to show why the order should be modified or withdrawn. Any oral testimony given at a hearing may be recorded verbatim.

(E) After the hearing, the bureau shall make a final decision based upon the complete hearing record, and shall inform the petitioner in writing of the decision. If the bureau sustains or modifies an order, it shall be carried out within the time period allotted in the original order or in the modification.

(F) Every notice, order, decision and other record prepared by the bureau in connection with the hearing shall be entered as a matter of public record in the office of the bureau.

(G) Any person aggrieved by the final decision of the bureau may seek relief in a court of competent jurisdiction in the Commonwealth.

27.16: Certificate: Suspension or Revocation

(A) Suspension without a Prior Hearing

(1) The commissioner or her/his agent may, without prior notice or hearing, immediately suspend a certificate to operate a dairy farm if an imminent health hazard is found to exist.

(2) The commissioner or her/his agent may, without granting a prior hearing, immediately suspend a certificate if:

(a) A second violation of the same requirement of 330 CMR 27.05, 330 CMR 27.06, 330 CMR 27.07, or 330 CMR 27.08 is found to exist on a second inspection, in accordance with 330 CMR 27.12(C)(4); or

(b) A violation as specified in 330 CMR 27.14(A)(2) is found to exist.

(3) The commissioner or her/his agent may, without prior notice or hearing, immediately suspend a certificate to operate a dairy farm if an agent of the Department is refused entry to the farm or is prevented from conducting an authorized inspection, as specified in 330 CMR 27.12.

27.16: continued

- (4) Whenever a suspension is ordered pursuant to 330 CMR 27.16(A)(1), (2), or (3), the order shall state:
- (a) The reason(s) for the immediate suspension;
  - (b) The violation(s) leading to the determination that an imminent health hazard exists, if applicable; and
  - (c) That a hearing will be held if a request for a hearing is made to the bureau, in writing or by telephone to a person authorized to schedule a hearing, by the certificatee.
- (5) The order recommending immediate suspension of the certificate shall be effective upon determination at the premises by an authorized agent of the Department. If the certificatee is not present at the time of such posting, a copy of the order of suspension shall be served in accordance with 330 CMR 27.17(C).
- (6) The bureau shall hold a hearing after a request for a hearing has been made to the bureau, in writing or by telephone to a person authorized to schedule a hearing, by the certificatee.
- (7) Whether or not a hearing is requested, the Department may end the suspension at any time if reasons for the suspension no longer exist.

(B) Ten Day Letter Process

- (1) The Department may take steps to exclude milk from the markets of the Commonwealth of Massachusetts and may suspend the producer's Certificate of Registration if the milk has been produced on a dairy farm where serious sanitary code violations are found to exist.
- (2) If a serious sanitary code violation is found to exist during an inspection, the Bureau may issue a notice to provide for an additional inspection at least ten days after the date of the receipt of such notice. Such notice may be given during either an initial or subsequent inspection.
- (3) The notice shall specify the violation(s) for which the dairy farm is under question, and that the certificate may be suspended.
- (4) To obtain a hearing after the subsequent reinspection, the certificatee shall make a request for a hearing to the bureau, in writing or by telephone to a person authorized to schedule a hearing, within five days of the reinspection following notice. If no request for a hearing is made within the five day period, the revocation or suspension shall be imposed at the end of the time period specified in the order; six days after the reinspection.

(C) Suspension after a Hearing

- (1) The Department may, after providing opportunity for hearing, suspend a certificate to operate a dairy farm if the farm does not comply with any one or more of the requirements of 330 CMR 27.00.
- (2) The order shall be in writing and sent to the certificatee or her/his authorized agent in accordance with 330 CMR 27.17(C).
- (3) The order shall specify the specific violations for which the certificate is to be suspended and that the certificate shall be suspended by the Department following notice of such order.

(D) Permanent Revocation of Certificate

- (1) The Department may, after providing opportunity for a hearing, order the revocation of a certificate for any one of the following:
  - (a) Serious or repeated violations of any of the requirements of 330 CMR 27.00;
  - (b) Interference with the Department in the performance of its duty;
  - (c) A criminal conviction of the certificatee relating to the operation of the dairy farm;
  - (d) Keeping or submitting any misleading or false records or documents required by 330 CMR 27.00.
- (2) The inspection shall be in writing and shall be served on the certificatee or her/his authorized agent in accordance with 330 CMR 27.17(C).

27.17: Orders for Suspension or Revocation

- (A) If, pursuant to 330 CMR 27.16, the Department orders the suspension or revocation of a dairy farm certificate, the certificatee shall be so notified by a written order.
- (B) The order shall include, but need not be limited to, the following:
- (1) The name and location of the dairy farm;
  - (2) The reasons for the suspension or revocation, and a description of such operation;
  - (3) The date the suspension or revocation is or will become effective;
- (C) Orders for suspension or revocation shall be served on the certificatee or her/his authorized agent as follows:
- (1) By sending him a copy of the order by registered or certified mail, return receipt requested; or
  - (2) Personally, by any person authorized by the department to serve; or
- If the aforementioned methods of service are unsuccessful, service may be made by any person authorized to serve civil process as follows:
- (1) By leaving a copy of the order at her/his last and usual place of abode; or
  - (2) By posting a copy of the notice in a conspicuous place on or about the farm premises if her/his last and usual place of abode is unknown.

27.18: Certificate: Reinstatement after Suspension

- (A) Any certificatee whose certificate has been suspended may make written application to the department for the reinstatement of her/his certificate.
- (B) When the certificate suspension has been due to a violation of any of the bacterial, DMSCC and anti-biotic, or cooling temperature standards, the department shall, after notification by a producer-applicant, or after laboratory results have been received, reinstate the certificate after determining by an inspection of the facilities and operating methods that the conditions responsible for the violations have been corrected. This inspection may be conducted by the bureau.
- (C) Whenever the certificate suspension has been due to violation of a requirement other than bacteriological, DMSCC and antibiotic or cooling temperature standards, the application shall indicate that the violation(s) has been corrected. Within one week of the receipt of such application, the department shall cause an inspection of the applicant's establishment to take place, and as many additional inspections thereafter as are deemed necessary, to determine that the applicant's establishment is in compliance with 330 CMR 27.07 and/or 330 CMR 27.08. These inspections may be conducted by the bureau. When the findings justify, the department shall reinstate the certificate.

27.19: Grade A Fluid Milk from Outside the Commonwealth

- (A) Fluid milk from a dairy farm outside the Commonwealth may be sold or served within the Commonwealth if such dairy farm has received a Certificate of Registration from the Massachusetts Department of Food and Agriculture pursuant to M.G.L. c. 94.
- (1) Upon arrival at the plant, commingled milk for pasteurization shall comply with the bacteriological, chemical and temperature standards of 330 CMR 27.05.
  - (2) Raw and pasteurized milk received from sources outside the Commonwealth shall be sampled as the Department requires.
  - (3) Grade A fluid milk shall be produced under regulations substantially equivalent to those of 330 CMR 27.00.
  - (4) Grade A fluid milk shall be under routine official supervision.
  - (5) Grade A fluid milk must have been awarded, by a State Milk Sanitation Rating Officer certified by the U.S. Food and Drug Administration, a milk sanitation compliance rating of 90% or higher and an enforcement rating of 90% or higher. Milk not meeting these requirements shall be prohibited from entering the Massachusetts market.
  - (6) All ratings are made on the basis of procedures outlined in the latest revision of Methods of Making Sanitation Ratings of Milk Supplies and the most recent edition of the Recommendations of the United States Public Health Service/Food and Drug Administration, or any successor

document.

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27.20: Severability

If any provision of 330 CMR 27.00 shall be declared invalid for any reason whatsoever, that decision shall not affect any other portion of 330 CMR 27.00, which shall remain in full force and effect; and to this end the provisions of 330 CMR 27.00 are hereby declared severable.

27.21: Adoption of the Appendixes to the Grade "A" Pasteurized Milk Ordinance (PMO)

The Department hereby adopts and incorporates by reference the Appendixes to the Grade "A" Pasteurized Milk Ordinance (PMO) as promulgated and as amended by the United States Department of Health and Human Services as they relate to farms and milk producers, except for those provisions specifically omitted by 330 CMR 27.21. The following Appendixes to the PMO are not adopted: A, E, H, I, J and L.

REGULATORY AUTHORITY

330 CMR 27.00: M.G.L. c. 94, § 13.