

1 NYCRR PART 2
REQUIREMENTS FOR THE PRODUCTION, PROCESSING, MANUFACTURING AND
DISTRIBUTION OF MILK AND MILK PRODUCTS

Statutory Authority: Agriculture and Markets Law, §§ 16, 18, 46-a,
50-k, 71-a and 71-n, 214-b)

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§ 2.1 APPLICABILITY.

The provisions of this Part shall apply to the production of milk and to the processing of milk, lowfat milk, skim milk, goat milk and sheep milk, and to the manufacture of milk products, goat milk products, sheep milk products, melloreum and frozen desserts. Except as provided in section 71-1 of the Agriculture and Markets Law, the provisions of this Part shall preempt any local law, ordinance, rule or regulation enacted by any city, village, town, county or by any department, agency, board, office or other division thereof, whether prior to or after the effective date of this Part, to the extent that any such enactment is different from or inconsistent with the provisions of this Part.

§ 2.2 DEFINITIONS.

The following definitions shall apply to the terms used in this Part, except as set forth in section 2.29 of this Part.

(a) *Aseptically processed*, when modifying the term milk, lowfat milk, skim milk, milk products, goat milk, goat milk products, sheep milk, sheep milk products, melloreum or frozen desserts, means that the food has been subjected to sufficient processing to maintain the commercial sterility of the product under normal non-refrigerated conditions and has been packaged in a hermetically sealed container, in conformance with Part 113 of Title 21 of the *Code of Federal Regulations* (revised as of April 21, 1993; U.S. Government Printing Office, Washington, D.C. 20402) and with Appendix L and Item 16p(c) of the *Pasteurized Milk Ordinance*. A copy of Title 21 of the *Code of Federal Regulations* and of the *Pasteurized Milk Ordinance* are available for public inspection at the Division of Milk Control, Department of Agriculture and Markets, 1 Winners Circle, Albany, New York 12235.

(b) *Assembly of milk* means the pickup, transport or general physical delivery of prepasteurized milk from dairy farms to a milk plant, transfer station or receiving station.

(c) *Bulk milk pickup tanker* means a vehicle, including the truck, tank and those appurtenances necessary for its use, used by a milk hauler to transport commingled or prepasteurized milk from dairy farms to a transfer station, receiving station or milk plant.

(d) *Bulk tank unit* means a group of dairy farms designated by the permit holder who assembles the milk produced by such dairy farmers.

(e) *Commingled milk* means the full load or partial load of prepasteurized milk received from two or more dairy farms which has been combined in a milk tank truck or in a storage tank in a milk plant, receiving station or transfer station.

(f) *Commissioner* means the Commissioner of Agriculture and Markets of the State of New York or an employee of the Department of Agriculture and Markets of the State of New York designated by the Commissioner.

(g) *Cultured product* means a milk product, goat milk product or sheep milk product to which a microbiological organism has been added for the purpose of developing desired organoleptic and/or textural qualities.

(h) *Dairy farm* means a place or premises where prepasteurized milk or raw milk is produced from cows, goats or sheep.

(i) *Dairy farmer* means a person who operates a dairy farm and produces prepasteurized milk.

(j) *Department* means the Department of Agriculture and Markets of the State of New York.

(k) *Direct microscopic smears* means the dried and stained representations of prepasteurized milk affixed to slides for the purpose of determining bacterial and/or somatic cell count levels.

(l) *Division of Milk Control* means that division of the Department of Agriculture and Markets.

(m) *Drug* means an article intended:

(1) for use in the diagnosis, cure, mitigation, treatment or prevention of disease in animals or humans;

(2) to affect the structure or function of the body of an animal or human; or

(3) for use as a component of an article set forth in paragraphs (1) or (2) of this subdivision, but not including a device or its components, parts or accessories.

(n) *Flavoring agent* means a fluid additive which gives a frozen dessert its characteristic taste or smell.

(o) *FDA* means the Food and Drug Administration of the United States Department of Health and Human Services.

(p) *Frozen dessert* means a food that meets a standard of identity set forth in sections 17.8 through 17.17 of this Title or provided for in section 17.19 of this Title, or is defined in section 71-a(2) of the Agriculture and Markets Law.

(q) *Goat milk* means the food that has been pasteurized and that meets the definition for milk provided for in section 17.18 of this Title, except that

(1) the term *goats* and *goat milk* are substituted for the terms *cows* and *milk* therein, respectively; and

(2) the provisions in such definition for milk relating to milk solids not fat and milk fat are not applicable.

(r) *Goat milk product* means a milk product as defined in subdivision (cc) of this section:

(1) except that milk from goats or a product thereof may be and has been substituted for the milk from cows or milk product component of such food; or

(2) which does not meet the provisions of paragraph (1) of this subdivision but which is commonly and usually characterized as a goat milk product.

(s) *Grade A prepasteurized milk* means prepasteurized milk produced in compliance with the applicable provisions of sections 2.8 through 2.28 of this Part.

(t) *Grade A milk, lowfat milk, skim milk, non-storable milk products, goat milk, non-storable goat milk products, sheep milk and non-storable sheep milk products* means those foods processed or manufactured from or with Grade A prepasteurized milk.

(u) *He, him or his* means she, her or hers depending upon the context.

(v) *Licensed technician* means an individual who, when performing biological, chemical and/or physical test(s) upon prepasteurized milk, commingled milk, raw milk, milk, lowfat milk, skim milk, milk products, goat milk, goat milk products, sheep milk or sheep milk products, is licensed by the commissioner pursuant to Article 4 of the Agriculture and Markets Law to perform such test(s).

(w) *Lowfat milk* means the food that meets the definition for lowfat milk provided for in section 17.18 of this Title which has been pasteurized.

(x) *Melloream* means the food defined in section 50-f of the Agriculture and Markets Law.

(y) *Milk* means the food that meets the definition for milk provided for in section 17.18 of this Title, which has been pasteurized.

(z) *Milk and Dairy Beef Residue Prevention Protocol* means the October 1, 1991 edition of that document, published by Agri-Education, Inc., 801 Shakespeare Avenue, Stratford, Iowa 59249 and written by Steve Boeckman and Keith R. Carlson. A copy of such document is available for public inspection at the Division of Milk Control, New York State Department of Agriculture and Markets, 1 Winners Circle, Albany, New York 12235.

(aa) *Milk hauler* means a person who transports prepasteurized milk, commingled milk or non-storable unpackaged milk products, goat milk products or sheep milk products to a milk plant, receiving station or transfer station.

(bb) *Milk plant* means any place, premises or establishment engaged solely or predominantly in the receipt of prepasteurized milk, commingled milk or milk products which is or are subsequently processed or manufactured into milk, lowfat milk, skim milk, milk products, goat milk, goat milk products, sheep milk, sheep milk products, melloreum and/or frozen desserts and any place, premises or establishment engaged solely or predominantly in the receipt of cheese or butter, as defined in Part 17 of this Title, which is or are grated, shredded, cut, mixed, blended, heated or otherwise treated and whichh is or are the predominant component of the resulting milk product, goat milk product or sheep milk product.

(cc) *Milk product* means a food, other than milk, lowfat milk or skim milk:

(1) that meets a standard of identity set forth in sections 17.2 through 17.7 of this Title or provided for in section 17.18 of this Title, or

(2) for which a standard of identity has not been prescribed but which is commonly and usually characterized as a milk product.

(dd) *Milk tank truck* means both a bulk milk pickup tanker and a milk transport tank.

(ee) *Milk transport tank* means a vehicle, including the truck, tank and those appurtenances necessary for its use, used by a milk hauler to transport commingled milk from a transfer station, receiving station or milk plant to another transfer station, receiving station or milk plant.

(ff) *Non actionable level* means an amount of an animal drug detected in a sample of prepasteurized milk that is below the maximum safe level established by the FDA for such drug.

(gg) *Non-storable milk product* means:

(1) flavored dairy drink and dairy shake, as defined in sections 17.2 and 17.6 of this Title, respectively, as well as acidified milk, cultured milk, lowfat dry milk, nonfat dry milk, nonfat dry milk fortified with vitamins A and D, acidified lowfat milk, cultured lowfat milk, acidified skim milk, cultured skim milk, dry whole milk, dry cream, heavy cream, light cream, light whipping cream, sour cream, acidified sour cream, eggnog, half-and-half, sour half-and-half, yogurt, lowfat yogurt, nonfat yogurt, cottage cheese, dry curd cottage cheese and lowfat cottage cheese, as defined in sections 131.111, 131.112, 131.123, 131.125, 131.127, 131.136, 131.138, 131.144, 131.146, 131.147, 131.149, 131.150, 131.155, 131.157, 131.160, 131.162, 131.170, 131.180, 131.185, 131.187, 131.200, 131.203, 131.206, 133.128, 133.129, and 133.131 of Title 21 of the *Code of Federal Regulations* (revised as of April 1, 1994), which standards of identity are incorporated by reference in section 17.18 of this Title. A copy of 21 CFR is available for public inspection at the Division of Milk Control, New York State Department of Agriculture and Markets, 1 Winners Circle, Albany, New York 12235:

(2) a food that would meet a standard of identity for a food listed in paragraph (1) of this subdivision except that the food does not comply with the applicable standard of identity because of a deviation that is described by an expressed nutrient content claim, in accord with the sections of 21 CFR (revised as of April 1, 1994) incorporated by reference in section 17.20 of this Title;

(3) a food that would meet a standard of identity for a food listed in paragraph (1) of this subdivision except that milk from goats or a product thereof or milk from sheep or a product thereof, as the case may be, has been substituted for the milk from cows or milk product component of such food;

(4) a food as described in paragraph (2) of this subdivision except that milk from goats or a product thereof or milk from sheep or a product thereof, as the case may be, has been substituted for the milk from cows or milk product component of such food; or

(5) a food not defined or described in paragraphs (1), (2), (3) and (4) of this subdivision but which is commonly and usually characterized as a non-storable milk product or which shares the essential attributes of a non-storable milk product.

(hh) *Official sample* means a sample of prepasteurized milk required to be taken pursuant to the provisions of this Part.

(ii) *Officially designated laboratory* means a laboratory which contains all the equipment and facilities necessary for the proper testing of samples of prepasteurized milk, commingled milk, raw milk, milk, lowfat milk, skim milk, milk products, goat milk, goat milk products, sheep milk and sheep milk products, as set forth in Chapter 2 of Standard Methods for the Examination of Dairy Products, to determine compliance with the applicable standard or standards set forth in section 2.8 of this Part.

(jj) *Pasteurized*, when modifying the term milk, lowfat milk, skim milk, milk products, goat milk, goat milk products, sheep milk, sheep milk products, melloram or frozen desserts, means that every component thereof has been subjected to the process set forth in section 2.44 of this Part.

(kk) *PMO* means the *Pasteurized Milk Ordinance* (1989 edition), published by the Food and Drug Administration of the United States Department of Health and Human Services, Washington, D.C. The term PMO shall also include the following transmittals that have been issued by FDA and that supplement the PMO, which are set forth below by title, identification number and date of issuance.

(1) Foxboro Magnetic Flow Meter System to be Used in Lieu of a Metering Pump; M-b-237; February 6, 1981.

(2) Use of an AC-Variable Frequency Controller on a Metering Pump for an HTST Pasteurizer; M-b-242; September 30, 1982.

(3) Foxboro Magnetic Flow Meter System to be Used in Lieu of a Metering Pump M-b-237, Supplement 1; October 29, 1982.

(4) Taylor Magnetic Flow Meter System to be Used in lieu of a Metering Pump; M-b-238, Supplement 1; October 29, 1982.

(5) Foxboro Magnetic Flow Meter System to be Used in Lieu of a Metering Pump; M-b-238, Supplement 2; January 7, 1983.

(6) Taylor Magnetic Flow Meter System to be Used in Lieu of a Metering Pump; M-b-238, Supplement 2; January 7, 1983.

(7) Accurate Metering Systems Proposal to Replace the Metering Pump with a Magnetic Flow Meter System for HTST pasteurizers; M-b-266; March 14, 1984.

- (8) Use of Magnetic Flow Meter Based Timing Systems with A-C Variable Frequency Motor Control Drives on a Centrifugal Pump in Lieu of a Positive Displacement Metering Pump on HTST Pasteurizing Systems; M-b-285; September 19, 1986.
- (9) Sulfamethazine and other Animal Drugs - Use and Storage on Dairy Farms; M-1-88-5; May 4, 1988.
- (10) Extra-Label Use of Sulfamethazine; M-1-88-9; June 22, 1988.
- (11) Sulfamethazine and other animal drugs - use and storage on dairy farms; M-1-88-5 Sup. 1; June 23, 1988.
- (12) Use of Computers on Public Health Controls of Grade A Pasteurizers; M-I-88-11; July 22, 1988.
- (13) FDA policy regarding disposition of raw milk that contains drug residue at a level exceeding the tolerance or safe level (Adulterated Milk); M-1-90; November 16, 1990.
- (14) Tolerance and/or Safe Levels of Animal Drug Residues in Milk; M-1-91-4; July 21, 1991.
- (15) Actions of the 1991 National Conference on Interstate Milk Shipments; IMS-a-30, August 22, 1991.
- (16) Withdrawal of approval of two nitrofurantoin animal drugs; M-1-91-6, October 8, 1991.
- (17) Beta Lactam Screening Methods; M-1-92-1; March 6, 1992.
- (18) Use of B. stearothermophilus Disc Assay for Confirmation; M-1-92-8; October 27, 1992.
- (19) Chloramphenicol Screening Test Methods; M-1-92-11, November 20, 1992.
- (20) Item 16r(i) - current information; M-1-92-10; December 3, 1992.
- (21) Withdrawal of approval of combination procaine penicillin/streptomycin/dihydrostreptomycin drugs; M-1-92-14; December 7, 1992.
- (22) Certification of Industry Personnel (Supervisors) in the Use of FDA Evaluated Drug Residue Tests (1991 NCIMS Conference Problem 239) for Screening Bulk Milk Pickup Tankers; M-a-86; June 13, 1994.

(23) Beta Lactam Test Methods for Use Under Appendix N of the PMO; M-a-85; July 22, 1994.

A copy of the PMO and of all the above-cited transmittals are available for public inspection at the Division of Milk Control, New York State Department of Agriculture and Markets, 1 Winner's Circle, Albany, NY 12235.

(ll) *Person* means an individual, firm, partnership, corporation, cooperative association, unincorporated association or agency of the State.

(mm) *Prepasteurized milk* means the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows, goats or sheep which is to be pasteurized prior to being processed into milk, lowfat milk, skim milk, goat milk or sheep milk or prior to being manufactured into a milk product, goat milk product, sheep milk product, melloream or frozen dessert.

(nn) *Producer-dealer* means a person who has and exercises complete and exclusive control over the operation and management of a milk plant, which receives prepasteurized milk, which was produced on a dairy farm also under the complete and exclusive control of such person.

(oo) *Quality Milk Promotion Services Program* means the service operated by the College of Veterinary Medicine of Cornell University and by the Department of Agriculture and Markets for the purpose of improving milk quality and reducing the incidence of mastitis in milk cows.

(pp) *Raw milk* means the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows, goats or sheep which will not be pasteurized prior to being sold or offered for sale to consumers.

(qq) *Raw milk producer* means a person who operates a dairy farm and produces raw milk.

(rr) *Receiving station* means a place, premises or establishment where prepasteurized milk is received, collected, handled, stored or cooled and prepared for further transporting.

(ss) *Safe and suitable* means the term defined in section 17.1(d) of this Title.

(tt) *Sanitization* means the application of an effective method or substance to equipment for the destruction of pathogens and of other organisms as far as is practicable. Such method or substance shall not adversely affect the equipment or adversely affect the purity and quality of food.

(uu) *Sheep milk* means the food that has been pasteurized and that meets the definition for milk provided for in section 17.18 of this Title, except that:

(1) the terms *sheep* and *sheep milk* are substituted for the terms *cows* and *milk* therein, respectively; and

(2) the provisions in the definition for milk provided for in section 17.18 of this Title relating to milk solids not fat and milk fat are not applicable.

(vv) *Sheep milk product* means a milk product as defined in subdivision (cc) of this section:

(1) except that milk from sheep or a product thereof may be and has been substituted for the milk from cows or milk product component of such food, or

(2) which does not meet the provisions of paragraph (1) of this subdivision but which is commonly and usually characterized as a sheep milk product.

(ww) *Skim milk* means the food that meets the definition for skim milk provided for in section 17.18 of this Title which has been pasteurized.

(xx) *Standard Methods for the Examination of Dairy Products* means the 16th edition of that document published by the American Public Health Association, Washington, D. C. 20005. A copy of *Standards Methods for the Examination of Dairy Products* is available for public inspection at the Division of Milk Control, Department of Agriculture and Markets, 1 Winners Circle, Albany, New York 12235.

(yy) *State* means the State of New York.

(zz) *Transfer station* means a place, premises or establishment where commingled milk is transferred directly from one milk tank truck to another.

(aaa) *Ultra-pasteurized*, when modifying the term milk, lowfat milk, skim milk, milk products, goat milk, goat milk products, sheep milk products, melloreem or frozen desserts means that every component thereof has been thermally processed at or above 280°F (138°C) for at least two seconds so that the food has an extended shelf life under refrigerated conditions.

§ 2.3 GENERAL PERMITS; permit to sell raw milk; permit to ship into the State; permit to produce milk.

(a) General permits. Every person who operates a transfer station, receiving station, bulk tank unit or milk plant (other than a plant at which melloreem or frozen desserts are manufactured) in the State shall hold a general permit issued

by the commissioner. A general permit holder, a person holding a frozen desserts license pursuant to Agriculture and Markets Law section 71-d ("frozen desserts licensee") and a person holding a melloream license pursuant to Agriculture and Markets Law section 50-g ("melloream licensee") shall:

(1) if in control of the assembly of the milk shall:

(i) assign to each dairy farmer who produces milk assembled by the permit holder an identification number;

(ii) employ a certified milk inspector and ensure that he properly carries out his duties;

(iii) arrange to have the required samples of prepasteurized milk taken from dairy farms from which such prepasteurized milk is received, in accordance with section 2.6 of this Part, tested and analyzed by a licensed technician at an officially designated laboratory to determine compliance with the standards set forth in section 2.8 of this Part. The permit holder, frozen desserts licensee and melloream licensee shall, if requested, accurately inform the commissioner when samples will be taken from any dairy farm from which prepasteurized milk is received prior to having such samples taken;

(iv) arrange to have the required inspections done of dairy farms from which prepasteurized milk is received, in accord with section 2.5 of this Part;

(v) receive no prepasteurized milk from a new source unless the commissioner has been notified at least four days in advance and such source has been inspected by an employee of the Division of Milk Control and found to be in compliance with sections 2.9 through 2.28, 2.58 and 2.65 of this Part; and

(vi) receive no commingled milk from a permit holder who controls the assembly of the milk from whom milk is not received on a regular basis, unless a sample thereof has been properly submitted to a licensed technician for analysis at an officially designated laboratory and determined to be in compliance with the applicable standards set forth in section 2.8 of this Part;

(2) receive or handle no prepasteurized milk from a dairy farm:

(i) which has not been properly inspected as required in section 2.5 of this Part;

(ii) which is not in substantial compliance with sections 2.9 through 2.28 and sections 2.58 and 2.65 of this Part;

(iii) whenever the prepasteurized milk exceeds the temperature standard or fails to meet the abnormal milk standard set forth in section 2.8 of this Part, or whenever the milk is otherwise adulterated within the meaning of this Title or of the Agriculture and Markets Law;

(iv) for the period of time specified in section 2.7(e) of this Part, when the prepasteurized milk fails to meet the drug standard set forth in section 2.8 of this Part, except that a general permit holder who manufactures a non-Grade A storable milk product, goat milk product or sheep milk product may receive prepasteurized milk that does not exceed said drug standard, notwithstanding the provisions of section 2.7(e) of this Part, if such prepasteurized milk has been analyzed as provided for in the provisions of section 2.7(b)(2) of this Part and found to be in compliance with the applicable provisions of section 2.8 of this Part. The general permit holder and the dairy farmer who produced such prepasteurized milk shall have requested and received approval from the commissioner prior to the receipt of such prepasteurized milk by such general permit holder;

(v) whenever three of the last five samples of prepasteurized milk exceed the bacterial limit set forth in section 2.8 of this Part; and

(vi) whenever three of the last five samples of prepasteurized milk exceed the somatic cells standard set forth in section 2.8 of this Part or whenever the dairy farmer is required to enroll in the Quality Milk Promotion Services Program and has failed to do so;

(3) Receive, deal in, sell, offer for sale or otherwise distribute no prepasteurized milk, commingled milk, milk, lowfat milk, skim milk, milk product, goat milk, goat milk product, sheep milk, sheep milk product, melloream or frozen dessert from a person who does not hold a required permit or license issued pursuant to this Title or the Agriculture and Markets Law;

(4) Receive no commingled milk that exceeds the drug standard, as provided in section 2.7(b)(1) of this Part and shall, when commingled milk exceeds the drug standard, immediately notify the commissioner in

writing that the commingled milk has failed to meet such standard;

(5) Prepare, maintain and make available, for at least two years, unless otherwise provided, in a form and at a location satisfactory to the commissioner, the following records and materials:

(i) A record of bacteriological examinations of the water supply of:

(a) dairy farms, the prepasteurized milk of which is assembled by the permit holder, frozen dessert licensee or mellorealm licensee, in accord with section 2.15 of this Part; and

(b) the permit holder's, frozen dessert licensee's or mellorealm licensee's milk plant, in accord with section 2.35 of this Part;

(ii) A record of the results of required analyses of samples of prepasteurized and commingled milk for compliance with the standards set forth in section 2.8 of this Part. The records of results of analyses of samples of prepasteurized milk shall set forth the:

(a) name and identification number of the dairy farmer who produced the prepasteurized milk from which the sample was taken;

(b) date of sampling;

(c) date of analysis;

(d) method used and result of analysis; and

(e) signature and license number of the licensed technician who analyzed the sample;

(iii) A record of each inspection and reinspection of dairy farms conducted pursuant to section 2.5 of this Part. Each inspection report shall set forth:

(a) the name and identification number of the dairy farmer;

(b) the date of the inspection or reinspection;

(c) the signature of the certified milk inspector who conducted the inspection; and

(d) whether the dairy farm was in substantial compliance with sections 2.9 through 2.28 and sections 2.58 and 2.65 of this Part;

(iv) A record of the name of the owner, identification number and address of all dairy farms from which prepasteurized milk is assembled by the permit holder, frozen dessert licensee or melloream licensee;

(v) For analyses made by means of reading direct microscopic smears, the direct microscopic smears, and retain for at least thirty days

(vi) If operating a milk plant at which frozen desserts are manufactured:

(a) a daily record of receipts and disposition of all ingredients, other than flavors, cocoa, chocolate, fruits, nuts, malted milk, confectionery, stabilizers, emulsifiers, microcrystalline cellulose and sweetening agents, and a monthly inventory of each ingredient for which a record is kept which reflects the name and address of the person from whom each ingredient was received;

(b) for each frozen dessert containing fat, a record setting forth the name of the frozen dessert, the name of the fat and the percent of fat contained in each frozen dessert;

(c) a daily record of each frozen dessert manufactured or received, the volume of each frozen dessert manufactured or received, and the fat content of each frozen dessert manufactured or received; and

(d) a biannual report setting forth the amount of each kind of frozen dessert manufactured, the ingredients used in the manufacture of each frozen dessert, and other information deemed necessary by the commissioner for the administration of this Part. A report shall be submitted to the commissioner on or before January 20 and on or before July 20 of each year, giving the required information for each of the six calendar months preceding such date;

(vii) such other records or materials required to be kept pursuant to the provisions of this Part;

(6) if operating a milk plant, receiving station, or a plant where frozen desserts are manufactured:

(i) handle and process and/or manufacture milk, lowfat milk, skim milk, milk products, goat milk, goat milk products, sheep milk, sheep milk products,

frozen desserts and melloream in substantial compliance with sections 2.30 through 2.65 of this Part and with Appendices 3-11 to this Part; and

(ii) designate a processing plant superintendent ("PPS") and ensure that he properly carries out his duties;

(7) receive, deal in, sell, offer for sale or otherwise distribute no milk, lowfat milk, skim milk, milk products, goat milk, goat milk products, sheep milk, sheep milk products, frozen desserts or melloream that do not comply with the applicable standards and requirements set forth in this Title and in the Agriculture and Markets Law, or that are in violation of any provision of this Title or of the Agriculture and Markets Law;

(8) receive, deal in, sell, offer for sale or otherwise distribute no milk, lowfat milk, skim milk, non-storable milk products, goat milk, non-storable goat milk products, sheep milk, non-storable sheep milk products or frozen desserts:

(i) the prepasteurized milk component of which has not been produced in substantial compliance with the provisions of this Part applicable to the production of Grade A prepasteurized milk;

(ii) the prepasteurized milk component of which does not meet the standards for prepasteurized milk for Grade A use set forth in section 2.8 of this Part;

(iii) which has not been processed or manufactured in compliance with the provisions of this Part applicable to the processing or manufacture of Grade A milk, lowfat milk, skim milk, non-storable milk products, goat milk, non-storable goat milk products, sheep milk, and non-storable sheep milk products; and

(iv) which do not meet the standards for such foods set forth in section 2.8 of this Part;

(9) properly carry out such other responsibilities and duties required of a general permit holder, frozen dessert licensee or melloream licensee pursuant to the provisions of this Part.

(b) *PERMIT TO SELL RAW MILK.*

(1) Every person who sells, offers for sale or otherwise makes available raw milk for consumption by consumers shall hold a permit to sell raw milk issued by the commissioner. A person who holds a permit to sell

raw milk may sell, offer for sale or otherwise make available raw milk only:

(i) directly to a consumer;

(ii) on the dairy farm where such raw milk is produced;

(iii) in a bottle or in a single service container mechanically filled and capped as set forth in this Part or in a container provided by the consumer filled in his presence; and

(iv) if at the point of sale a sign is conspicuously posted, easily capable of being read, from such point, stating: "NOTICE: Raw milk sold here. Raw milk does not provide the protection of pasteurization."

(2) A person who holds a permit to sell raw milk shall:

(i) ensure that the dairy farm at which the raw milk was produced is in substantial compliance with the provisions of this Part applicable to the production of Grade A prepasteurized milk;

(ii) sell, offer for sale or make available no raw milk when and as required in section 2.7(c) and(d) of this Part;

(iii) sell, offer for sale or make available no raw milk that exceeds the applicable temperature, drugs or abnormalities standard set forth in section 2.8 of this Part;

(iv) sell or offer for sale no raw milk that is in violation of any provision of this Title or of the Agriculture and Markets Law; and

(v) enroll in the Quality Milk Promotion Services when and/or as required by sections 2.7 and 2.60 of this Part.

(c) PERMIT TO SHIP PREPASTEURIZED MILK, MILK, LOWFAT MILK, SKIM MILK, NON-STORABLE MILK PRODUCTS, GOAT MILK AND SHEEP MILK PRODUCTS INTO THE STATE.

(1) Every person who ships prepasteurized milk, milk, lowfat milk, skim milk, non-storable milk products, goat milk or sheep milk into the State shall hold a permit issued by the commissioner. Such permit shall be known as a "permit to ship milk and milk products into the State." A permit shall expire on June 30 and an application for renewal shall be made no later than June 1. An application for renewal shall be made upon a blank prepared under the direction of the commissioner and shall

set forth the information deemed necessary by the commissioner for the administration of this Part.

(2) A person who holds a permit to ship milk or milk products into the State shall:

(i) if shipping prepasteurized milk into the State:

(a) ensure that the prepasteurized milk if to be used in Grade A milk, Grade A lowfat milk, Grade A skim milk, Grade A non-storable milk products, Grade A goat milk or Grade A sheep milk, was produced on dairy farms in substantial compliance with rules and regulations substantially the same as the applicable provisions of this Part regulating the production of Grade A prepasteurized milk and that such prepasteurized milk complies with and meets the provision of section 2.8 of this Part for prepasteurized milk for Grade A use;

(b) ensure that the prepasteurized milk if not to be used in Grade A milk, Grade A lowfat milk, Grade A skim milk, Grade A non-storable milk products, Grade A goat milk or Grade A sheep milk was produced on dairy farms in substantial compliance with rules and regulations substantially the same as the applicable provisions of this Part regulating the production of non-Grade A prepasteurized milk and that such prepasteurized milk complies with and meets the provisions of section 2.8 of this Part for prepasteurized milk for non-Grade A use; and

(c) if shipping prepasteurized milk into the State for use in Grade A milk, Grade A lowfat milk, Grade A skim milk, Grade A non-storable milk products, Grade A goat milk or Grade A sheep milk, have an acceptable milk sanitation compliance and enforcement rating given by a State milk sanitation rating officer certified by FDA and have an Interstate Milk Shippers Rating of ninety percent or higher;

(ii) if shipping milk, lowfat milk, skim milk, non-storable milk products, goat milk or sheep milk into the State shall:

(a) ensure:

(1) that the prepasteurized milk in such foods was produced on dairy farms in substantial compliance with rules and regulations substantially the same as the provisions of this Part regulating the production of Grade A prepasteurized milk;

(2) that such foods were processed or manufactured in substantial compliance with rules and regulations substantially the same as the provisions of this Part regulating the processing and manufacture of Grade A milk, lowfat milk, skim milk, non-storable milk products, goat milk and sheep milk;

(3) that such foods comply with and meet applicable provisions and standards set forth in the Agriculture and Markets Law and this Title; and

(4) that such foods are not in violation of the provisions of the Agriculture and Markets Law or of this Title nor is their possession, sale or distribution in violation of such Law or of this Part;

(b) ensure that such foods have been processed or manufactured in a plant that currently possesses:

(1) an acceptable milk sanitation compliance and enforcement rating given by a state milk sanitation rating officer certified by the FDA; and

(2) an Interstate Milk Shippers Rating of ninety percent or higher.

(3) A person who holds a permit to ship milk and milk products into the State shall also ensure that every milk tank truck containing commingled milk that he ships or causes to be shipped into the State contains documents available to the commissioner which set forth

(i) the name and address of the person who holds the permit;

(ii) the name and address of the milk hauler;

(iii) the weight of the commingled milk.

(d) *PERMIT TO PRODUCE MILK.* Every dairy farmer who produces prepasteurized milk shall hold a permit to produce milk issued by the commissioner. A dairy farmer who holds a permit to produce shall:

(1) if his prepasteurized milk is to be used in milk, lowfat milk, skim milk, non-storable milk products, goat milk or sheep milk, operate his dairy farm in substantial compliance with the provisions of this Part applicable to the production of Grade A prepasteurized milk;

(2) if his prepasteurized milk is to be used in storable milk products, operate his dairy farm in substantial compliance with the provisions of this Part applicable to the production of non-Grade A prepasteurized milk;

(3) produce no prepasteurized milk that does not comply with the Agriculture and Markets Law;

(4) enroll in the Quality Milk Promotion Services program ("QMPS") when and as required in section 2.6(d) of this Part;

(5) review the Milk and Dairy Beef Residue Prevention Protocol, when and as required in section 2.7(e)(2) of this Part;

(6) deal in, sell, offer for sale or otherwise distribute no prepasteurized milk when and as required in section 2.7(c)(d) and (e) of this Part; and

(7) deal in, sell, offer for sale or otherwise distribute no prepasteurized milk that exceeds the temperature standard or fails to meet the abnormal milk standard set forth in section 2.8 of this Part.

(e) GRANTING, DENYING THE RENEWAL OF, REVOKING AND SUSPENDING PERMITS

(1) The provisions of this section shall apply to the granting, denying the renewal of, revoking and suspending permits required pursuant to this Part, unless otherwise provided in this Part. An applicant for a general permit, a permit to sell raw milk, a permit to ship milk and milk products into the State or a permit to produce shall file an application upon a blank prepared under the direction of the commissioner and shall set forth the information deemed necessary by the commissioner for the administration of this Part. Except for a permit to ship milk and milk products into the State, a permit shall be effective until revoked or suspended. The commissioner may decline to grant or renew a permit, or may suspend or revoke a permit, upon due notice and opportunity for a hearing, when he is satisfied by substantial evidence that the applicant or permit holder:

(i) is not capable of complying with the requirements of this Part or of the Agriculture and Markets Law; or

(ii) has failed to comply with or has violated the requirements of this Part or of the Agriculture and Markets Law.

(2) A permit may be summarily suspended without a hearing if the commissioner has reason to believe that raw milk, prepasteurized milk, commingled milk, milk, lowfat milk, skim milk, milk products, goat milk, goat milk products, sheep milk or sheep milk products produced, possessed, processed, manufactured, sold, offered for sale or otherwise distributed by the permit holder create or appear to create, if consumed, an immediate hazard to human health. After summarily suspending a permit, the commissioner shall schedule a hearing to consider revocation of the permit, which hearing shall be held as soon as reasonably possible after the date the permit was suspended. The summary suspension shall be effective until the permit holder satisfies the commissioner that no raw milk, prepasteurized milk, commingled milk, milk, lowfat milk, skim milk, milk product, goat milk, goat milk product, sheep milk or sheep milk product creates, or appears to create, an immediate hazard to the public health.

§ 2.4 LABELING; IDENTIFICATION OF VEHICLES.

(a) A general permit holder who processes or manufactures milk, lowfat milk, skim milk, milk products, goat milk, goat milk products, sheep milk or sheep milk products shall ensure that such foods are packaged and labeled in compliance with the applicable provisions of Parts 17, 38 and 221 of this Title. Milk, lowfat milk, skim milk, non-storable milk products, goat milk, non-storable goat milk products, sheep milk, non-storable sheep milk products or frozen desserts may be labeled "Grade A" if the prepasteurized milk in such foods was produced, and if such foods were processed or manufactured, in compliance with the applicable requirements of this Part.

(b) A general permit holder who processes or manufactures milk, lowfat milk, skim milk, milk products, goat milk, goat milk products, sheep milk or sheep milk products, a person who ships milk or milk products into the State, a person holding a frozen desserts license and a person holding a melloream license shall ensure that:

(1) all commercial bulk shipping containers containing milk, lowfat milk, skim milk, milk products, goat milk, goat milk products, sheep milk, sheep milk products, frozen desserts and melloream are legibly marked with the name of the food, net weight or content, and name and address of the processor or manufacturer and distributor, if applicable; and

(2) all packages containing foods set forth in paragraph (1) of this subdivision for sale directly to consumers shall be legibly marked with the name of the food, net weight or content, and name and address of the

processor, manufacturer, packer or distributor. If the name and address is not the name and address of the processor or manufacturer, the processor's or manufacturer's plant number shall appear on the package.

(c) A general permit holder in control of the assembly of the milk, a general permit holder who processes or manufactures milk, lowfat milk, skim milk, milk products, goat milk, goat milk products, sheep milk or sheep milk products, and a person who holds a permit to ship milk and milk products into the State shall ensure that every vehicle containing commingled milk operated by him or that he has caused to be operated shall have the name and address of such permit holder prominently displayed and/or the name and address of the milk hauler transporting the food(s) prominently displayed. Such name(s) and address(es) shall be plainly visible from twenty yards away.

§ 2.5 INSPECTIONS. The general permit holder who controls the assembly of the milk shall ensure that all dairy farms from which prepasteurized milk is received are inspected or reinspected:

(a) at least once every six months. Ten percent of all inspections done in a six-month period shall be conducted at milking time;

(b) prior to beginning to ship prepasteurized milk to such general permit holder;

(c) promptly when prepasteurized milk is determined to exceed the standards set forth in section 2.8 of this Part; and

(d) promptly when the dairy farm is not in substantial compliance with sections 2.9 through 2.28 and sections 2.58 and 2.65 of this Part.

§ 2.6 CERTIFIED MILK INSPECTORS AND PROCESSING PLANT SUPERINTENDENTS

(a) *Certified Milk Inspectors.*

(1) Every person who performs the duties of a certified milk inspector shall apply for and hold a certificate issued by the commissioner. An applicant for a certificate shall file an application upon a blank prepared under the direction of the commissioner and shall set forth the information deemed necessary by the commissioner for the administration of this Part. No certificate shall be granted unless the applicant has passed an examination designed to ascertain his ability to carry out the duties set forth in paragraph (2) of this subdivision, has attended a training course held by the commissioner within one year of receiving his

certificate, has successfully completed a six-month probationary period and:

(i) has a degree in dairy science or has completed college level courses acceptable to the commissioner;

(ii) has at least six months satisfactory experience in dairy farm inspection; or

(iii) has at least one year's satisfactory experience in the dairy industry and at least one month's satisfactory training in dairy farm inspection.

(2) A certified milk inspector shall:

(i) inspect each dairy farm from which prepasteurized milk is assembled by the permit holder in accord with section 2.5 of this Part, accurately record and maintain the results of each inspection and promptly furnish a copy of an inspection report to the commissioner when requested to do so;

(ii) assure that a sample is obtained and submitted for analysis, when and as required by the provisions section 2.7(c),(d) and (e) of this Part;

(iii) promptly ascertain the results of all analyses of samples of prepasteurized milk, and act as required by the provisions of section 2.7 of this Part;

(iv) inform a dairy farmer that when a sample of prepasteurized milk taken from his dairy farm exceeds the temperature or abnormal milk standard set forth in section 2.8 of this Part, that such prepasteurized milk may not be shipped to or received by a general permit holder;

(v) inform a dairy farmer that when a sample of prepasteurized milk taken from his dairy farm exceeds the drug standard set forth in section 2.8 of this Part, prepasteurized milk may not be shipped to or received by a general permit holder, as provided in section 2.7(e) of this Part;

(vi) inform a dairy farmer that when samples of prepasteurized milk taken from his dairy farm have exceeded, on three of the last five times analyzed, the bacterial limit or somatic cell standard set forth in section 2.8 of this Part, prepasteurized milk may not be shipped to or received by a general

permit holder, as provided in section 2.7(c) and (d) of this Part;

(vii) inform a dairy farmer that when his dairy farm is not in substantial compliance with sections 2.9 through 2.28 and sections 2.58 and 2.65 of this Part, prepasteurized milk may not be shipped to or received by a general permit holder;

(viii) inform the general permit holder by whom he is employed of the identity of a dairy farmer whenever the milk of such dairy farmer may not be received, pursuant to the provisions of this Part;

(ix) inform a dairy farmer when the prepasteurized milk produced on his dairy farm exceeds a standard set forth in section 2.8 of this Part;

(x) maintain and submit to the commissioner when requested the records required to be kept by a general permit holder pursuant to section 2.3(a)(5) of this Part;

(xi) obtain and submit for analysis to a licensed technician a sample of water taken from a dairy farm the milk of which is assembled by the general permit holder, as required by section 2.15 of this Part;

(xii) attend an annual course in dairy farm inspection held by the commissioner; and

(xiii) properly carry out such other responsibilities and duties required of a certified milk inspector pursuant to the provisions of this Part.

(3) A certificate shall be effective until suspended or revoked. The commissioner may decline to grant a certificate, or may suspend or revoke a certificate, upon due notice and opportunity for a hearing, when he is satisfied that the applicant or certificate holder does not have the qualifications set forth in paragraph (1) of this section or has not properly carried out the duties set forth in paragraph (2) of this subdivision. A certified milk inspector shall inform the commissioner when any information set forth in his application is no longer accurate.

(4) A certified milk inspector is not an employee of the Department of Agriculture and Markets, and except as provided herein is not under the control or supervision of the State.

(b) *PROCESSING PLANT SUPERINTENDENTS.*

(1) Every person who performs the duties of a processing plant superintendent ("PPS"), as set forth in paragraph (2) of this subdivision, shall apply for and hold a certificate issued by the commissioner. An applicant for a certificate shall file an application upon a blank prepared under the direction of the commissioner and shall set forth the information deemed necessary by the commissioner for the administration of this Part.

(2) A PPS shall:

(i) ensure that the milk plant, receiving station or frozen desserts manufacturing plant at which he is employed is in substantial compliance with sections 2.30 through 2.65 (except sections 2.58 and 2.60) of this Part;

(ii) ensure that all milk, lowfat milk, skim milk, milk products, goat milk, goat milk products, sheep milk, sheep milk products, melloream and frozen desserts comply with applicable standards and requirements set forth in this Title or in the Agriculture and Markets Law, or are not in violation of any provision of this Title or of the Agriculture and Markets Law;

(iii) ensure that no commingled milk is received that exceeds the drug standard set forth in section 2.8 of this Part;

(iv) keep and submit to the commissioner the records and the materials required to be kept; and

(v) attend an annual course in processing plant operation held by the commissioner.

(3) A certificate shall be effective until suspended or revoked. The commissioner may decline to grant a certificate, or may suspend or revoke a certificate, upon due notice and opportunity for a hearing, when he is satisfied that the applicant or certificate holder is incapable of carrying out or has not properly carried out the duties set forth in paragraph (2) of this subdivision. A PPS shall inform the commissioner when any information set forth in his application is no longer accurate.

§ 2.7 SAMPLING AND ANALYSIS OF PREPASTEURIZED MILK;
requirements when prepasteurized milk fails to meet standards set forth in section 2.8 of this Part.

(a) A licensed technician who has been given a sample of prepasteurized milk or commingled milk to analyze shall

promptly perform the appropriate test(s) at an officially designated laboratory and shall promptly notify the permit holder of the result of the test(s), in writing.

(b) Sampling and analysis of prepasteurized milk and commingled milk.

(1) The permit holder who controls the assembly of the milk shall ensure that a sample of prepasteurized milk is properly taken by a person licensed pursuant to Agriculture and Markets Law, section 57 each time prepasteurized milk is picked up from a dairy farm and that a sample of commingled milk is properly obtained at least once a month. At least once a month, an official sample of prepasteurized milk from each dairy farm and a sample of commingled milk shall be submitted to a licensed technician for analysis at an officially designated laboratory, to determine compliance with the standards set forth in section 2.8 of this Part. The licensed technician shall continuously maintain samples under adequate refrigeration and sanitary conditions until analyzed. Notwithstanding the foregoing, the permit holder shall ensure that a sample of commingled milk is properly obtained, for each load of milk shipped to a milk plant in a milk tank truck, and submitted to a licensed technician for analysis at an officially designated laboratory, to determine compliance with the drug standard set forth in section 2.8 of this Part. When a sample of commingled milk exceeds the drug standard set forth in this Part or is found to contain a drug at the non-actionable level, the samples from all dairy farms represented in the commingled sample shall be submitted to a licensed technician for analysis at an officially designated laboratory, to determine which sample(s) is/are in violation of such standard or which sample(s) contain(s) a drug at the non-actionable level. When a sample of commingled milk exceeds the drug standard set forth in this Part, the milk from which such sample was taken shall not be accepted or received.

(2) All sampling and analysis required to be made pursuant to this Part shall be made in compliance with the applicable provisions of Part 6 of this Title, Standard Methods for the Examination of Dairy Products and the PMO.

(c) Requirements when prepasteurized milk or raw milk exceeds bacterial limit.

(1) When an official sample of prepasteurized milk or raw milk has been analyzed and determined to exceed the bacterial limit set forth in section 2.8 of this Part, the certified milk inspector or an employee of the Division of Milk Control in the case of a producer-dealer

or raw milk producer, shall notify the dairy farmer, producer-dealer or raw milk producer, as the case may be, of the results of the analysis and shall inspect the dairy farm to determine the cause.

(2) Whenever two of a series of four consecutive official samples exceed the bacterial limit, another official sample of prepasteurized milk or raw milk, as the case may be, shall be taken from three to twenty-one days after notification and shall be submitted to a licensed technician for analysis at an officially designated laboratory, and the dairy farmer, producer-dealer or raw milk producer shall be informed by the certified milk inspector or by an employee of the Division of Milk Control, as applicable, that no prepasteurized milk or raw milk may be shipped, processed or sold if three of any series of five consecutive official samples exceed the bacterial limit.

(3) After the prepasteurized milk of a dairy farmer or producer-dealer is no longer prohibited from being shipped or processed, or after the raw milk of a raw milk producer is no longer prohibited from being sold, offered for sale or made available pursuant to the provisions of this section, four official samples of prepasteurized milk or raw milk from different milkings shall be taken within a five to twenty-one day period. No more than two official samples shall be taken during any one seven day period. Such official samples shall be submitted to a licensed technician for analysis at an officially designated laboratory. The official samples required to be taken pursuant to the provisions of this paragraph shall not be considered to be part of a prior series of samples.

(d) Requirements when prepasteurized milk or raw milk exceeds the somatic cells standard.

(1) When an official sample of prepasteurized milk or raw milk has been analyzed and determined to exceed the somatic cells standard set forth in section 2.8 of this Part, the certified milk inspector or an employee of the Division of Milk Control in the case of a producer-dealer or raw milk producer, shall notify the dairy farmer, producer-dealer or raw milk producer as the case may be, of the results of the analysis and another official sample of prepasteurized milk or raw milk shall be taken from five to twenty-one days after notification ("the official recheck sample") and submitted to a licensed technician for analysis at an officially designated laboratory.

(2) When an official recheck sample has been analyzed and determined to exceed the somatic cells standard, the

certified milk inspector or employee of the Division of Milk Control, as applicable, shall notify the dairy farmer, producer-dealer or raw milk producer of the results of the analysis and inform him that he must, within ten days, enroll in the Quality Milk Promotion Services program ("QMPS"). The dairy farmer, producer-dealer or raw milk producer shall remain properly enrolled in the QMPS program for at least six months from the date of enrollment and until three of a series of four consecutive official samples are analyzed and determined to be in compliance with the somatic cells standard.

(3) Whenever two of a series of four consecutive official samples exceed the somatic cells standard, another official sample of pasteurized milk or raw milk, as the case may be, shall be taken from five to twenty-one days after notification and shall be properly submitted to a licensed technician for analysis at an officially designated laboratory, and the dairy farmer, producer-dealer or raw milk producer shall be informed by the certified milk inspector or by an employee of the Division of Milk Control, as applicable, that no pasteurized milk or raw milk may be shipped, processed or sold if three of any series of five consecutive samples exceed the somatic cells standard. The dairy farmer, producer-dealer or raw milk producer shall also be informed by the certified milk inspector or by an employee of the Division of Milk Control, as applicable, that he must, within ten days, enroll in the QMPS program and remain properly enrolled therein for at least six months and until three of a series of four consecutive official samples are analyzed and determined to be in compliance with the somatic cells standard.

(4) After the pasteurized milk of a dairy farmer or producer-dealer is no longer prohibited from being shipped or processed, or after the raw milk of a raw milk producer is no longer prohibited from being sold, offered for sale or made available pursuant to the provisions of this section, four official samples of pasteurized milk or raw milk from different milkings shall be taken within a five to twenty-one day period. No more than two samples shall be taken during any one seven day period. Such samples shall be submitted to a licensed technician for analysis at an approved laboratory. The samples required to be taken pursuant to the provisions of this paragraph shall not be considered to be part of a prior series of samples.

(e) *Requirements when pasteurized milk exceeds the drug standard.* When a sample of pasteurized milk has been determined to exceed the drug standard set forth in section 2.8 of this Part, the certified milk inspector shall

immediately notify the dairy farmer of the results of the analysis and shall inform him

(1) that no prepasteurized milk may be shipped until the milk no longer exceeds the drug standard and for a period of at least:

(i) two days from the date the prepasteurized milk was determined to exceed the drug standard if such excessive sample was the first excessive sample in a twelve month period; or

(ii) four days from the date the prepasteurized milk was determined to exceed the drug standard, if such excessive sample was the second or more excessive sample in a twelve month period; and

(2) that he shall immediately contact a licensed veterinarian, inform such licensed veterinarian that his milk has been found to contain a drug, meet with such licensed veterinarian as soon as practicable after contacting him, and in no event later than thirty days thereafter, and review with such licensed veterinarian the provisions of the Milk and Dairy Beef Residue Prevention Protocol. Immediately after such review, the dairy farmer shall sign the certificate at page 57 of the Protocol and retain it for at least two years.

Notwithstanding the provisions of subparagraphs 1(i) and (ii) of this subdivision, prepasteurized milk that does not exceed the drug standard may be shipped if the dairy farmer pays a penalty to the permit holder who receives his milk, in an amount equal to the value of such prepasteurized milk at the applicable uniform price or, if there is no applicable uniform price, at the generally prevailing price.

§ 2.8 QUALITY STANDARDS

MILK AND MILK PRODUCTS

Prepasteurized milk for Grade A use Temperature..... Cooled to 45°F (7°C) or less within two hours after milking, provided that the blend temperatures following subsequent milkings shall not exceed 50°F (10°C).

Bacterial limits.. Individual producer milk not to exceed 100,000 per ml. prior to commingling with other producer milk. Not to exceed 300,000 per ml. as commingled milk prior to pasteurization.

Sediment..... Less than 1.5 mg. on individual producer milk; less than 1.0 mg. on commingled producer milk as determined by the provisions of 1 NYCRR Part 12.

Drugs..... Not to exceed the applicable standard or tolerance set forth in transmittals supplementing the PMO bearing identification numbers M-1-94-4, IMS-a-30, M-1-91-6, M-1-92-1, M-1-92-10, M-1-92-14, and M-a-86, more fully described in section 2.2(kk)(14), (15), (16), (17), (20), (21) and (22) of this Part.

Abnormalities..... Milk to have normal odor and appearance.

Somatic cells..... Not to exceed 1,000,000 per ml., except that after 7/1/93, not to

exceed 750,000 per ml.
for prepasteurized milk
from cows.

Prepasteurized milk
for non-Grade A use

Temperature..... In cans, cooled to 55°F
(13°C) or lower within 2
hours after milking and
delivered to the plant
at 60°F (16°C) or lower.
In bulk, cooled to 45°F
(7°C) or less within 2
hours provided that the
blend temperatures
following subsequent
milking shall not
exceed 50°F (10°C).

Bacterial limits... Not to exceed 1,000,000
per ml. prior to
commingling with other
producer milk. Not to
exceed 3,000,000 per ml.
as commingled milk prior
to pasteurization.

Drugs..... Not to exceed the
applicable standard or
tolerance set forth in
transmittals supplementing
the PMO bearing identifica-
tion numbers M-1-94-4,
IMS-a-30, M-1-91-6, M-1-92-
1, M-1-92-10, M-1-92-14,
and M-a-86 more fully-
described in section
2.2(kk)(14),(15),(16),
(17),(20),(21), and (22)
of this Part.

Sediment.....	Less than 1.5 mg on individual producer milk; less than 1.0 mg on commingled producer milk as determined by the provisions of 1 NYCRR Part 12.
Abnormalities.....	Has normal odor and appearance.
Somatic cells.....	Not to exceed 1,000,000 per ml except that after 7/1/93, not to exceed 750,000 per ml. for prepasteurized milk from cows.
Pasteurized milk lowfat milk, skim milk, milk products, goat milk, goat milk products, sheep milk and sheep milk products, melloream, frozen desserts and frozen dessert mix	Temperature..... Cooled to 45°F (7°C) or less and maintained thereat.
Bacterial limits*..	20,000 per ml except with respect to frozen desserts, not to exceed 100,000 per ml.
Coliform.....	Not to exceed 10 per ml. except with respect to frozen desserts, not to exceed 20 per ml.; provided, that in the case of bulk milk transport tank shipments, shall not exceed 100 per ml.

*Not applicable to cultured products.

	Phosphatase.....	Less than 1 microgram per ml. by the Scharer Rapid Method or equivalent.
	Drugs.....	Not to exceed the applicable standard or tolerance set forth in transmittals supplementing the PMO bearing identification numbers M-1-94-4, IMS-a-30, M-1-91-6, M-1-92-1, M-1-92-10, M-1-92-14, and M-a-86 more fully described in section 2.2(kk), (14), (15), (16), (17), (20), (21) and (22) of this Part.
Raw milk	Temperature.....	Cooled to 45°F (7°C).
	Bacterial limits...	30,000 per ml.
	Drugs.....	Not to exceed the applicable standard or tolerance set forth in transmittals supplementing the PMO bearing identification numbers M-1-94-4, IMS-a-30, M-1-91-6, M-1-92-1, M-1-92-10, M-1-92-14 and M-a-86, more fully-described in section 2.2(kk)(14), (15), (16), (17). (20), (21) and (22) of this Part.
	Sediment.....	Less than 1.5 mg as determined by the provisions of 1 NYCRR Part 12.
	Abnormalities.....	Milk to have normal odor and appearance.
	Somatic cells.....	Not to exceed 1,000,000 per ml except that after 7/1/93, not to exceed 750,000 per ml. for raw milk from cows.

Pasteurized cultured products Temperature..... Same as pasteurized milk.

Coliform..... Same as pasteurized milk.

Phosphatase..... Same as pasteurized milk.

Butter, 80% cream, plastic cream, mixtures of butterfat, sugar or sweetening agent, moisture and flavoring shall conform to the following:

SPC not to exceed
100,000 per gram,
Coliform count not to
exceed 20 per gram,
yeast and/or mold not to
exceed 100 per gram.

Nonpasteurized
frozen desserts

SPC not to exceed
100,000 per gram,
coliform count not to
exceed 20 per gram.

Whipped cream, instant
whipped cream, instant
topping, milkshake

SPC not to exceed
100,000 per
gram, coliform count not
to exceed 20 per gram.

Dry whole milk when used as an ingredient in a frozen dessert or a Grade A non-storable milk product shall be U.S.D.A. Extra grade or its equivalent. Nonfat dry milk, dry whey and dry buttermilk when used as an ingredient in a frozen dessert or a Grade A non-storable milk product shall meet the requirements of U.S.D.A. extra grade or its equivalent. Fats and oils other than from milk shall conform to the applicable provisions of the United States Food, Drug and Cosmetic Act as amended or those of any applicable State regulation for fats and oils of food grade standard.

Condensed milk, condensed whey
mixes, blends and similar
products received in bulk
shall conform to the following:

SPC not to exceed
100,000 per gram,
coliform count not
to exceed 100 per gram

Milk products and goat milk
products separated from milk
or goat milk heated between
45°F and 125°F

Not to exceed the
temperature and drug
standard and
bacterial limit for
prepasteurized milk for
Grade A use.

Milk products and goat milk
products separated from milk

Not to exceed the
temperature and drug

or goat milk heated to a temperature greater than 125°F and less than 161°F

standard and bacterial limit for pasteurized milk, lowfat milk, skim milk, milk products, goat milk, goat milk products and frozen desserts.

SANITATION REQUIREMENTS FOR DAIRY FARMS

§ 2.9 MILKING BARN, STABLE, OR PARLOR - CONSTRUCTION AND MAINTENANCE - (Item 2r).

(a) 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 meet the following requirements:

(1) Floors, feed troughs (and gutters if present) shall be constructed of good quality concrete or equally impervious material. Floors shall be constructed so as to be easily cleaned (brushed surfaces permitted) and shall be graded to drain.

(2) Walls and ceilings are finished with wood, tile, smooth-surfaced concrete, cement plaster, brick, or other equivalent materials with light colored surfaces. Walls, partitions, doors, shelves, windows, and ceilings shall be kept in good repair, and surfaces shall be refinished whenever wear or discoloration is evident. Whenever feed is stored overhead, ceilings shall be constructed to prevent the sifting of chaff and dust into the milking barn, stable or parlor. If a hay opening is provided from the loft into the milking portion of the barn, such opening shall be provided with a dust tight door which shall be kept closed during milking operations.

(3) Separate pens shall be provided for bulls, horses and calves. These areas shall be separated by tight partitions, from the milking area. Such portion of the barn not so separated shall comply with all items of this section. In addition, a curbing shall be provided to separate horses, bulls, and calves from the milking area. The curbing shall effectively eliminate the flow of manure and urine from such areas.

(4) The milking barn is provided with natural and/or artificial light to insure that all surfaces and particularly the working areas will be plainly visible. The equivalent of at least 10 foot-candles of light in all working areas shall be provided; notwithstanding the foregoing, a dairy farm which produces milk for non-Grade A

use shall be exempt from the 10 foot-candles requirement of this paragraph.

(5) Air circulation is sufficient to minimize odors and to prevent condensation upon walls and ceilings.

(6) Overcrowding is not evidenced by the presence of calves, cows, or other barnyard animals in walks or feed alleys. Inadequate ventilation and excessive odors may also be evidence of an overcrowded barn.

(7) A dust tight partition, provided with doors that are kept closed except when in actual use, shall separate the milking portion of the barn from any feed room or silo in which feed is ground or mixed, or in which sweet feed is stored. Feed may be stored in the milking portion of the barn only in such manner as will not increase the dust content of the air, attract flies, or interfere with cleaning of the floor (as in covered, dust tight boxes or bins). Open feed dollies or carts may be used for distributing the feed, but not storing feed, in the milking barn.

(b) When conditions warrant, the Commissioner may approve a barn without four walls extending from floor to roof, or a shed-type barn provided the requirement of Section 2.10 of this Part (Item 3r) prohibiting animals and fowl entering the barn, is satisfied. Cattle-housing areas (stables without stanchions, such as loose-housing stables, pen stables, resting barns, free stall barns, holding barns, loafing sheds, wandering sheds) may be of shed-type construction, provided no milking is conducted therein. They are classified as part of the cowyard under Section 2.11 of this Part (Item 4r).

§ 2.10 MILKING BARN, STABLE OR PARLOR - CLEANLINESS -Item 3r.

The interior of the milking barn, stable, or parlor shall meet the following standards of cleanliness:

(a) The interior of such facilities shall be kept clean.

(b) Leftover feed in feed mangers appears fresh and is not wet or soggy.

(c) The bedding material, if used, does not contain more manure than has accumulated since the previous milking.

(d) Outside surfaces of pipeline systems located in the milking barn, stable, or parlor are reasonably clean.

(e) Gutter cleaners are reasonably clean.

(f) All pens, calf stalls, and bull pens, if not separated from the milking barn, stable or parlor, are clean.

(g) Swine and fowl are kept out of the milking barn.

§ 2.11 COWYARD - Item 4r.

Cowyards shall meet the following requirements:

(a) The cowyard, which is the enclosed or unenclosed area adjacent to the milking barn, in which the cows may congregate, including cattle-housing areas and feed lots, is graded and drained; depressions and soggy areas are filled; cow lanes are reasonably dry.

(b) Approaches to the barn door and the surroundings of stock watering and feeding stations are solid to the footing of the animal.

(c) Wastes from the barn or milk house are not allowed to pool in the cowyard. Cowyards which are muddy due to recent rains should not be considered as violating this item.

(d) Manure, soiled bedding and waste feed are not stored or permitted to accumulate therein in such a manner as to permit the soiling of cows' udders and flanks. Cattle-housing areas (stables without stanchions, such as loose-housing stables, pen stables, resting barns, holding barns, loafing sheds, wandering sheds, free-stall housing) shall be considered a part of the cowyard. Manure packs shall be solid to the footing of the animal.

(e) Cowyards are kept reasonably free of cattle droppings. Cattle droppings shall not be allowed to accumulate in piles that are accessible to the animals.

§ 2.12 MILK HOUSE OR ROOM -CONSTRUCTION AND FACILITIES - Item 5r.

The milk house or room shall meet the following construction requirements:

(a) A separate milk house of sufficient size is 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 Section 2.19 of this Part (Item 12r).

(b) The floors of all milk houses are constructed of good quality concrete (float finish permissible), or equally impervious tile, or brick laid closely with impervious material, or metal surfacing with impervious joints, or other material the equivalent of concrete and maintained free of breaks, depressions and surface peelings.

(c) The floor slopes to drain so that there are no pools of standing water. The joints between the floor and the walls shall be watertight.

(d) The liquid wastes are disposed of in a sanitary manner; all floor drains are accessible and are trapped if connected to a sanitary sewer.

(e) Walls and ceilings are constructed of smooth dressed lumber or similar material, well painted with a light-colored washable paint, and are in good repair. Surfaces and joints shall be tight and smooth. Sheet metal, tile, cement block, brick, concrete, cement plaster, or similar materials of light color may be used; the surfaces and joints shall be smooth.

(f) A minimum of 20 foot-candles of light is provided for all working areas from natural and/or artificial light for milk house operations.

(g) Windows and solid doors are closed during dusty weather.

(h) The milk house is adequately ventilated to minimize odors and condensation on floors, walls, ceilings, and clean utensils.

(i) Vents, if installed, and lighting fixtures are installed in a manner to preclude the contamination of bulk milk tanks or clean utensil storage areas.

(j) The milk house is used for no other purpose than milk house operations.

(k) There is no direct opening into any barn, stable, or room used for domestic purposes; except that an opening between the milk house 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.

(l) A vestibule, if used, complies with the applicable milk house construction requirements.

(m) The transfer of milk from a bulk-holding/cooling tank to a transport tank is through a hose port located in the milk house wall. The port shall be fitted with a tight door, which shall be in good repair. It shall be kept closed except when the port is in use. An easily cleanable surface shall be constructed under the hose port, adjacent to the outside wall, sufficiently large to protect the milk hose from contamination. Such surface shall be at least 36 inches wide and shall extend from the working area the rear of the bulk tank truck to the hose port.

(n) Water under pressure is piped into the milk house; provided, however, that a dairy farm that produces prepasteurized milk for non-Grade A use shall have water available to the milkhouse.

(o) Each milk house is provided with facilities for heating water in sufficient quantity and to such temperatures for the

effective cleaning of all equipment and utensils; provided, however, that a dairy farm that produces prepasteurized milk for non-Grade A use shall have water available to the milkhouse in sufficient quantities and heated to sufficient temperatures to properly clean all equipment and utensils.

(p) The milk house is equipped with a wash-and-rinse vat having at least two compartments. Each compartment must be of sufficient size to accommodate the largest utensil or container used. The cleaning-in-place vat for milk pipelines and milk machines may be accepted as one part of the two-compartment vat: provided, that the cleaning-in-place station rack in or on the vat and the milking machine inflations and appurtenances are completely removed from the vat during the washing, rinsing and/or sanitizing of other utensils and equipment.

(q) A suitable shelter is provided for a transportation truck used for cooling and storing milk. Such shelter shall be adjacent to, but not a part of, the milk room and shall comply with the requirements of the milk room with respect to construction, light, drainage, insect and rodent control, and general maintenance.

§ 2.13 MILK HOUSE OR ROOM -CLEANLINESS -Item 6r.

The milk house or room shall meet the following cleanliness requirements:

(a) The milk house structure, equipment and other milk room facilities used in its operation or maintenance are clean at all times.

(b) Incidental articles such as desks, refrigerators, and storage cabinets may be in the milk room, provided they are kept clean and ample space is available to conduct the normal operations in the milk room and will not cause contamination of the milk.

(c) Vestibules, if provided, are kept clean.

(d) Animals and fowl are kept out of the milk room.

§ 2.14 TOILET - Item 7r.

Toilet facilities shall meet the following standards:

(a) There is at least one flush toilet connected to a public sewer system or to an individual sewage-disposal system or a chemical toilet, earth pit privy, or other type of privy. Such sewerage systems shall be constructed and operated in accordance with plans and instructions acceptable to the Commissioner.

(b) A toilet or privy is convenient to the milking barn and the milk room. There shall be no evidence of human defecation or urination about the premises.

(c) No privy opens directly into the milk room.

(d) The toilet room, including all fixtures and facilities, is kept clean and free of flies and odors.

(e) Where flush toilets are used, doors to toilet rooms are tight and self-closing. All outer openings in toilet rooms shall be screened or otherwise protected against the entrance of flies.

(f) Vents of earth pits are screened.

§ 2.15 WATER SUPPLY - Item 8r.

The water supply shall meet the following requirements:

(a) Water for milk house and milking operation shall be from a supply properly located, protected, and operated, and shall be easily accessible, adequate, and of a safe, sanitary quality.

(b) The water supply shall contain an MPN (most probable number of coliform organisms) of less than 1.1 per 100 ml by the multiple tube fermentation method, or less than 1.1 per 100 ml by the membrane filter technique, or absent (less than 1 per 100 ml) by the chromogenic substrate (MMO-MUG) presence-absence method.

(c) No cross-connection shall exist between a safe water supply and any unsafe or questionable water supply, or any other source of pollution.

(d) There shall be no submerged inlets through which a safe water supply may be contaminated.

(e) The well or other source of water shall be located and constructed in such a manner that neither underground nor surface contamination from any sewerage systems, privy, or other source of pollution can reach such water supply. All drilled wells constructed after the effective date of this Part shall have casings extended above the surface level of the surrounding ground.

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

(g) Water supplies which are otherwise found satisfactory but which are unable to meet the bacteriological standards set forth in this section shall be subjected to continuous disinfection by a method and with equipment acceptable to the commissioner.

(h) All containers and tanks used in the transportation of water shall be 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 dairy farm. To minimize the possibility of contamination of the water during its transfer from the potable tanks to the elevated or groundwater storage at the dairy farm, 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 dairy farm shall be constructed of impervious material provided with a dustproof and rainproof cover, and also provided with an approved-type vent and roof hatch. All new reservoirs or reservoirs which have been cleaned shall be disinfected prior to placing them into service.

(i) Samples for bacteriological examination shall be taken upon the initial approval of the physical structure based upon the requirements of this Part and when any repair or alteration of the water supply system has been made, and at least every three years; provided, that water supplies with buried well casing seals, installed prior to the adoption of this section, shall be tested at intervals no greater than six months apart. Whenever such samples indicate either the presence of bacteria of the coliform group, or whenever the well casing, pump or seal need replacing or repair, the well casing and seal shall be brought above the ground surface and shall comply with all other applicable construction criteria of this section: provided, that when water is hauled to the dairy farm, such water shall be sampled for bacteriological examination at the point of use and submitted to a laboratory each month. Bacteriological examinations shall be conducted in an officially designated laboratory.

(j) Current records of water tests shall be retained on file at the dairy farm.

§ 2.16 UTENSILS AND EQUIPMENT -CONSTRUCTION - Item 9r.

Construction of utensils and equipment shall meet the following requirements:

(a) All multiuse containers, equipment, and utensils which are exposed to milk or milk products, or from which liquids may drip, drain, or be drawn into milk or milk products are made of smooth impervious, non-absorbent, safe materials of the following types:

(1) stainless steel of the AISI (American Iron and Steel Institute) 300 series;

(2) equally corrosion-resistant, non toxic metal;

(3) heat-resistant glass; or

(4) 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 non-absorbent, relatively insoluble, do not release component chemicals or impart flavor or odor to the product, and which maintain their original properties under repeated-use conditions.

(b) Single-service articles have been manufactured, packaged, transported and handled in a sanitary manner and comply with the applicable requirements of Section 2.39 of this Part (Item 11p).

(c) Articles intended for single-service use are not reused.

(d) All containers, equipment, and utensils are free of breaks and corrosion.

(e) All joints in such containers, equipment, and utensils are smooth and free from pits, cracks or inclusions.

(f) Cleaned-in-place milk pipelines and return-solution lines are self-draining. If gaskets are used, they shall be self-positioning and of material meeting specifications described in paragraph (a)(4) of this section, and shall be of such design, finish and application as 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 of pits, cracks and inclusions.

(g) Detailed plans for cleaned-in-place pipeline systems are submitted to the Commissioner for written approval prior to installation. No alteration or addition shall be made to any milk pipeline system without prior written approval of the Commissioner.

(h) Strainers, if used, are of perforated metal design, or so constructed as to utilize single-service strainer media.

(i) Seamless hooded pails having an opening not exceeding one-third the area of that of an open pail of the same size are used for hand milking and hand stripping.

(j) All milking machines, including heads, milk claws, milk tubing, and other milk-contact surfaces can be easily cleaned and inspected.

(k) Milk cans have umbrella-type lids.

(l) Farm holding/cooling tanks, welded sanitary piping, and transportation tanks comply with the applicable requirements of Sections 2.38 and 2.39 of this Part (Items 10p and 11p).

§ 2.17 UTENSILS AND EQUIPMENT - CLEANING - Item 10r.

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. Bulk tanks and milk cans shall be cleaned when emptied and shall be emptied at least once every 48 hours, except bulk tanks and milk cans used on a dairy farm that produces prepasteurized milk for non-Grade A use shall be emptied and cleaned at least once every 72 hours.

§ 2.18 UTENSILS AND EQUIPMENT - SANITATION - Item 11r.

Utensils and equipment shall meet the following requirements for sanitation. All product-contact surfaces of multiuse containers, utensils, and equipment used in the handling, storage, or transportation of milk are sanitized before each usage by one of the following methods, or by any method which has been demonstrated to be equally effective:

(a) Complete immersion in hot water at a temperature of at least 170°F (77°C) for at least five minutes, or exposure to a flow of hot water at a temperature of at least 170°F (77°C) as determined by use of a suitable accurate thermometer (at the outlet) for at least five minutes.

(b) Complete immersion for at least one minute in, or exposure for at least one minute to a flow of a chemical sanitizer of acceptable strength. All product-contact surfaces must be wetted by the sanitizing solution, and piping so treated must be filled. Sanitizing sprays may be used. Chemical solutions, once used, shall not be reused for sanitizing but may be reused for other purposes.

§ 2.19 UTENSILS AND EQUIPMENT - STORAGE - Item 12r.

Utensils and equipment shall meet the following storage requirements:

(a) All milk containers, utensils and equipment, including milking machine vacuum hoses, are stored in the milk house in a sanitizing solution, or on racks, until used. Milk pipelines and pipeline milking equipment such as: milker claws, inflations, weigh jars, meters, milk hoses, milk receivers and milk pumps which are designed for mechanical cleaning may be mechanically cleaned, sanitized and stored in the milking barn or parlor provided this equipment is designed, installed and operated to protect the product and solution-contact surface from contamination at all times. Some of the parameters to be considered in determining protection are: proper location of equipment, proper drainage of equipment and adequate and properly located lighting and ventilation. The milking barn or parlor must be used only for milking. Concentrates may be fed in the barn during milking but the barn shall not be used for the housing of cattle. When manual cleaning of product-contact

surfaces is necessary, the cleaning shall be done in the milk house.

(b) Means are provided to effect complete drainage of equipment when such equipment cannot be stored to drain freely.

(c) Clean cans or other containers are stored in the milk house within a reasonable time after delivery to the dairy farm.

(d) Strainer pads, parchment papers, gaskets, and similar single-service articles are stored in a suitable container or cabinet and protected against contamination.

§ 2.20 UTENSILS AND EQUIPMENT -HANDLING - Item 13r.

Utensils and equipment handling shall meet the following requirements:

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

(a) Sanitized product-contact surfaces, including farm cooling tank openings and outlets, are protected against contact with unsanitized equipment and utensils, hands, clothing, splash, condensation and other sources of contamination.

(b) Any sanitized product-contact surface, which has been otherwise exposed to contamination, is again cleaned and sanitized before being used.

§2.21 MILKING - FLANKS, UDDERS, AND TEATS - Item 14r.

Milking practices shall meet the following requirements:

- (a) Milking is done in a milking barn, stable, or parlor.
- (b) Brushing is completed prior to milking.
- (c) Flanks, bellies, tails and udders are clipped as often as necessary to facilitate cleaning of these areas and are free from dirt. The hair on the udders shall be of such length that it is not incorporated with the teat in the inflation during milking.
- (d) Udders and teats of all milking cows are cleaned and treated with a sanitizing solution and are relatively dry just prior to milking.
- (e) Wet hand milking is prohibited.

§ 2.22 MILKING-SURCINGLES, MILK STOOLS AND ANTIKICKERS-Item 15r.

The milking equipment cited here shall meet these requirements:

- (a) Milk stools are not padded and are constructed to be easily cleaned.
- (b) Milk stools, surcingles and antikickers are kept clean and are stored above the floor in a clean place in the milking barn, stable, parlor or milk house, when not in use.

§ 2.23 PROTECTION FROM CONTAMINATION - Item 16r.

Protection from contamination requires compliance with the following:

- (a) Equipment and operations are so located within the milking barn and milk house as to prevent overcrowding and contamination of cleaned and sanitized containers, equipment, and utensils by splash, condensation, or manual contact.
- (b) During processing, pipelines and equipment used to contain or conduct milk and milk products shall be effectively separated from tanks or circuits containing cleaning and/or sanitizing solutions.
- (c) All milk which has overflowed, leaked, been spilled, or improperly handled is discarded.
- (d) All product-contact surfaces of containers, equipment, and utensils are covered or otherwise protected to prevent the access of insects, dust, condensation and other contamination. All openings, including valves and piping attached to milk

storage and transportation tanks, pumps or vats, shall be capped or otherwise properly protected.

(e) The receiving receptacle is raised above the floor (as on a dolly or cart), or placed at a distance from the cows to protect it against manure and splash when milk is poured and/or strained in the milking barn. Such receptacle shall have a tight-fitting cover which shall be closed except when milk is being poured.

(f) Each pail or container of milk is transferred immediately from the milking barn, stable, or parlor to the milk house.

(g) Pails, cans, and other equipment containing milk are properly covered during transfer and storage.

(h) Whenever air under pressure is used for the agitation or movement of milk, or is directed at a milk-contact surface, it is free of oil, dust, rust, excessive moisture, extraneous materials, and odor and shall otherwise comply with the applicable standards of Appendix A.

(i) Antibiotics and medicinals are stored in such a manner that they cannot contaminate the milk or milk product-contact surfaces of the equipment, containers or utensils.

(j) Equipment, materials, substances and operations comply and are consistent with the applicable provisions of transmittals to the PMO bearing identification numbers M-1-88-5, M-1-88-9, M-1-88-5 (Sup 1), M-1-90-9, M-1-92-10 and M-1-92-14, more fully described in section 2.2(kk)(1),(2),(3),(11) and (12) of this Part.

§ 2.24 PERSONNEL - HAND-WASHING FACILITIES - Item 17r.

The following hand-washing facilities are required:

(a) Hand-washing facilities are located in the milk house and in or convenient to the milking barn, stable, parlor, or flush toilet.

(b) Hand-washing facilities include soap or detergent, hot and cold or warm water, individual sanitary towels, and a lavatory fixture. Utensil wash and rinse vats shall not be considered as hand-washing facilities.

(c) Such facilities are to be kept in good repair, clean, and shall not be used for storage.

§ 2.25 PERSONNEL - CLEANLINESS - Item 18r.

All persons shall meet the following requirements:

(a) Hands are washed clean and dried with an individual sanitary towel immediately before milking, before performing any milk house function, and immediately after the interruption of any of these activities.

(b) Milkers and milk haulers wear clean outer garments while milking or handling milk, milk containers, utensils or equipment.

§ 2.26 COOLING - Item 19r.

Milk shall be cooled in accordance with the following requirements:

(a) Prepasteurized milk for Grade A is cooled to 45°F (7°C) or less within two hours after milking; provided, that the blend temperatures of subsequent milkings shall not exceed 50°F (10°C). Prepasteurized milk for non-Grade A use is cooled to 55°F (13°C) or less within two hours after milking and received by the milk plant at 60°F (16°C) or less, except that morning milk need not be cooled if received by a milk plant, receiving station or transfer station before 10:00 a.m.

(b) Recirculated cooled water which is used in plate or tubular coolers or heat exchangers is from a safe source and protected from contamination. Such water shall be tested semiannually and shall comply with the bacteriological standards cited in Section 2.15 of this Part (Item 8r).

§ 2.27 VEHICLES - Item 20r.

Vehicles used to transport milk must meet the following requirements:

(a) Vehicles used to transport milk from the dairy farm to the milk plant or receiving station are constructed and operated to protect their contents from sun, freezing, and contamination.

(b) Vehicles have bodies with solid enclosures and tight, solid doors.

(c) Vehicles are kept clean, inside and out.

(d) No substance capable of contaminating the milk is transported with the milk.

(e) All openings on milk transport tanks shall be sealed after washing and sanitizing and shall be so maintained. Sealed manholes, which are opened for observation of milk level, shall be immediately resealed. Rear doors on farm tank pick-up vehicles need not be sealed between farms or from farms to receiving station if under the immediate supervision of a person licensed pursuant to section 57 of the Agriculture and Markets Law.

NOTE: See Section 2.16 and 2.17 of this Part (Items 9r and 10r) for information on the construction of milk pickup tankers.

§ 2.28 INSECT AND RODENT CONTROL - Item 21r.

Effective measures shall be taken to prevent the contamination of milk, containers, equipment and utensils by insects, rodents, and by chemicals used to control such vermin:

(a) Surroundings are kept neat, clean and free of conditions which might harbor or be conducive to the breeding of insects and rodents. During fly season, manure shall be spread directly on the fields; or stored for not more than four days in a pile on the ground surface, and then spread on the fields; or stored for not more than seven days in an impervious-floored bin, or on an impervious-curbed platform and then spread; or stored in a tight-screened and trapped manure shed; or effectively treated with larvicides; or disposed of in any other manner which controls insect breeding.

(b) Manure packs in loafing areas, stables without stanchions, pen stables, resting barns, wandering sheds, and free-stall housing are properly bedded and managed to prevent fly breeding.

(c) Milk rooms are free of insects and rodents.

(d) Milk rooms are effectively screened or otherwise protected against the entrance of vermin.

(e) Outer milk house doors are tight and self-closing. Screen doors shall open outward.

(f) Effective measures are taken to prevent the contamination of milk, containers, utensils and equipment by insects and rodents, and by chemicals used to control such vermin. Insecticides and rodenticides not approved for use in the milk house shall not be stored in the milk house.

(g) Only insecticides and rodenticides approved for use by the Commissioner and/or registered with the U.S. Environmental Protection Agency are used for insect and rodent control.

(h) Insecticides and rodenticides are used only in accordance with manufacturer's label directions and are used so as to prevent the contamination of milk, milk containers, equipment, utensils, feed and water.

SANITATION REQUIREMENTS APPLICABLE TO THE PROCESSING AND MANUFACTURING OF MILK, LOWFAT MILK, SKIM MILK, MILK PRODUCTS, GOAT MILK, GOAT MILK PRODUCTS, SHEEP MILK PRODUCTS, MELLOREAN AND FROZEN DESSERTS

§ 2.29 DEFINITIONS. The definitions set forth in section 2.2 of this Part shall apply to all of the sections of this Part, except that the definitions set forth herein shall apply to sections 2.30 through 2.65 of this Part and shall supercede the definitions for the same words set forth in section 2.2.

(a) *Milk* means milk and/or prepasteurized milk as defined in section 2.29(y) and (mm) of this Part, respectively, as the context requires.

(b) *Milk products* means milk products, goat milk products and/or sheep milk products as defined in section 2.2(bb),(r) and (vv) of this Part, respectively, as the context requires.

(c) *Pasteurized milk* means milk, lowfat milk and skim milk, goat milk and/or sheep milk as defined in section 2.2(y),(w), (ww),(q) and (uu) of this Part, respectively, as the context requires.

(d) *Raw milk*, except as used in section 2.60 of this Part, means prepasteurized milk as defined in section 2.2(mm) of this Part.

(e) *Unpasteurized milk* means prepasteurized milk as defined in section 2.2(mm) of this Part.

§ 2.30 FLOORS - WALLS AND CEILINGS-CONSTRUCTION-Items 1p and 2p.

(a) *Floors*.

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

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

(3) The floors are provided with trapped drains. Cold-storage rooms used for storing milk and milk products need not be provided with floor drains when the floors are sloped to drain to one or more exists. Storage rooms for dry

ingredients and/or packaging materials need not be provided with drains.

(b) *WALLS AND CEILINGS.*

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

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

§ 2.31 DOORS AND WINDOWS - Item 3p.

(a) All openings to the outer air are effectively protected by:

(1) Screening;

(2) Effective electric screen panels;

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

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

(5) Any effective combination of paragraph (1),(2),(3), or (4) of this subdivision, or by any other method which prevents the entrance of flies.

(b) All outer doors are tight and self-closing. Screen doors shall open outward.

(c) All outer openings are rat proofed to the extent necessary to prevent the entry of rodents.

NOTE: The evidence of insects and/or rodents in the plant shall be considered under Section 2.37 of this Part (Item 9p).

§ 2.32 LIGHTING AND VENTILATION - Item 4p.

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

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

(c) Pressurized ventilating systems, if used, have a filtered air intake.

§ 2.33 SEPARATE ROOMS- Item 5p.

(a) Pasteurizing, processing cooling and packaging are conducted in a single room(s), but not in the same room(s) used for the cleaning of milk cans, bottles and cases, or the unloading and/or cleaning and sanitizing of milk tank trucks. Provided, that in a receiving station cooling may be done in the room(s) where milk tank trucks are unloaded and/or cleaned and sanitized.

(b) All bulk milk 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, shall be considered satisfactory.

(c) Solid doors installed in required partitions are self-closing.

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

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

(f) All rooms shall be of sufficient size for their intended purposes.

§ 2.34 TOILET-SEWAGE DISPOSAL FACILITIES - Item 6p.

(a) Suitable toilet facilities shall be provided.

(b) Toilet rooms do not open directly into any room in which milk and/or milk products are processed.

(c) Toilet rooms are completely enclosed and have tight-fitting self-closing doors.

(d) Dressing rooms, toilet rooms, and fixtures are kept in a clean condition, in good repair, and are well ventilated and well lighted.

(e) Toilet tissue and easily cleanable covered waste receptacles are provided in toilet rooms.

(f) All plumbing is installed to meet the applicable provisions of the State or local plumbing code.

(g) Sewage and other liquid wastes are disposed of in a sanitary manner.

(h) Non-water carried sewage disposal facilities are not used.

(i) A durable, legible sign is conspicuously posted in each toilet and dressing room, directing employees to wash their hands before returning to work.

§ 2.35 WATER SUPPLY - Item 7p.

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

(b) The water supply shall be approved as safe by the commissioner, and in the case of individual water systems, it shall contain a MPN (most probable number of coliform organisms) of less than 1.1 per 100 ml. by the multiple tube fermentation technique or less than 1.1 per 100 ml. by the membrane filter technique or absent (less than 1 per 100 ml) by the chromogenic substrate (MMO-MUG) presence-absence method.

(c) There shall be 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 back-flow preventor, constitutes a violation of this requirement.

(d) Condensing water for milk evaporators, and water used to produce vacuum and/or to condense vapors in vacuum heat processing equipment, shall be from a source complying with subdivision (b) of this section; provided that, when approved by the Commissioner, water from sources not complying with subdivision (b) 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 include:

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

(2) Use of reliable safeguards to prevent the over-flow of condensing water from the condenser into the evaporator. Such safeguards include a barometric leg extending at least 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 will shut off the in-flowing water when the water level rises above a predetermined point in the condenser. This valve may be actuated by water, air or electricity, and shall be designed so that failure of the primary motivating power will automatically stop the flow of water into the condenser.

(e) Condensing water for all milk evaporators, complying with subdivision (b) of this section, and water reclaimed from milk or milk products, may be reused when all necessary means of

protection are afforded and such condensing water or reclaimed water has been inspected and approved by the commissioner.

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

(g) Water supplies which are otherwise found satisfactory but which are unable to meet the bacteriological standards set forth in this section shall be subjected to continuous disinfection by a method and with equipment acceptable to the commissioner.

(h) Samples for bacteriological testing of individual water supplies shall be taken upon the initial approval of the physical structure, each 6 months thereafter, and when any repair or alteration of the water supply system has been made. Bacteriological examinations shall be conducted in an officially designated laboratory.

(i) Current records of water tests shall be kept on file by the permittee.

§ 2.36 HAND-WASHING FACILITIES - Item 8p.

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

(b) Hand-washing facilities are convenient to all toilets and to all rooms in which milk plant operations are conducted.

(c) Hand-washing facilities are kept in a clean condition and in good repair.

(d) Steam-water mixing valves and vats for washing bottles, cans and similar equipment are not used as hand-washing facilities.

§ 2.37 MILK PLANT CLEANLINESS - Item 9p.

(a) Only equipment directly related to processing operations or the handling of containers, utensils, and equipment is permitted in the pasteurizing, processing, cooling, packaging and bulk milk storage rooms.

(b) All piping, floors, walls, ceilings, fans, shelves, tables, and the nonproduct-contact surfaces of other facilities and equipment are clean.

(c) No trash or solid waste is stored within the plant, except in covered containers. Waste containers at the packaging

machine or bottle washer may be uncovered during operation of such equipment.

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

§ 2.38 SANITARY PIPING - Item 10p.

(a) 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 products, consist of smooth, impervious, corrosion-resistant, non-toxic, easily cleanable material.

(b) All sanitary piping, connections and fittings consist of:

(1) stainless steel of the AISI (American Iron and Steel Institute) 300 series; or

(2) equally corrosion-resistant metal which is non-toxic and non-absorbent; or

(3) heat-resistant glass; provided, that 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 non-absorbent; which do not impart flavor or odor to the products; and which maintain their original properties under repeated use conditions, may be used for gaskets, sealing applications, and for short flexible takedown jumpers or connections where flexibility is required for essential or functional reasons.

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

(d) All interior surfaces of demountable piping, including valves, fittings, and connections are designed, constructed and installed to permit inspection and drainage.

(e) All cleaned-in-place 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 subdivision (b) of this section. If gaskets are used, they shall be self-positioning, of material meeting the specifications outlined in subdivision (b) of this section, 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, the commissioner may require that the installer provide a boroscope or other suitable inspection device to determine the acceptability of interior surfaces of welded lines. All welded surfaces shall be approved by the Commissioner.

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 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 line.

Detailed plans for welded pipeline systems shall be submitted to the Commissioner 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 Commissioner.

(f) Pasteurized milk and milk products are conducted from one piece of equipment to another only through sanitary milk piping.

(g) All stainless steel lines and vessels used to convey or store any of the products included in section 2.1 of this Part or any ingredients used in the manufacture of such products, cleaning solutions or water shall be color coded so as to provide easy identification of the material contained therein. The following color coding scheme shall be used:

Raw product lines	Red
Pasteurized product lines	Blue
Cleaning solution lines	Green
Water lines (SS only)	Yellow
Sugar and dairy food ingredients	Orange

Additional color coding of stainless steel lines to denote ingredients of special products is permitted provided it does not duplicate the color coding scheme described above.

§ 2.39 CONSTRUCTION AND REPAIR OF CONTAINERS AND EQUIPMENT -
Item 11p.

(a) All multiuse containers and equipment with which milk or milk products come into contact are of smooth, impervious, corrosion-resistant, and non-toxic material.

(b) All milk-contact surfaces of multiuse containers and equipment consist of:

- (1) stainless steel of the AISI (American Iron and Steel Institute) 300 series;

(2) equally corrosion-resistant metal which is non-toxic and non-absorbent;

(3) heat resistant glass; or

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

(c) All joints in containers, equipment, and utensils are flush and finished as smooth as adjoining surfaces. 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. 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.

(d) 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 distributor, unless a watertight joint is provided.

(e) All surfaces with which milk or milk products come into contact are easily accessible or demountable for manual cleaning or are designed for mechanical cleaning. All product-contact surfaces shall be readily accessible for inspection and shall be self-draining. Wing nuts, bayonet locks and similar devices shall be used whenever possible in lieu of bolts and nuts, to promote easy disassembly.

(f) 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.

(g) All multiuse 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.

(h) 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 function reasons inherent to the production of certain milk products, such as buttermilk, whey and dry milk products, woven material may be used where it is

impractical to use perforated metal. However, woven material parts shall be mechanically cleaned by such methods that thoroughly clean the woven material and do not contaminate the product.

(i) All single-service containers, closures, gaskets and other articles, with which milk or milk products come in contact, are non-toxic.

(j) The manufacture, packing, transportation and handling of single-service containers, closures, caps, gaskets, and similar articles are approved by the Commissioner. Inspections and tests shall be made by the Commissioner or any agency authorized by him.

(k) Copper kettles for Swiss cheese and copper evaporators and brass fillers for evaporated milk may be approved if free from corroded surfaces and kept in good condition. Wooden churns in use may be approved temporarily if maintained in good condition. Nonmetallic parts having product-contact surfaces shall be of material that is resistant to abrasion, scratching, scoring and distortion, that is nontoxic, fat-resistant, and relatively inert, nonabsorbent or insoluble, and that will not adversely affect the flavor of the products.

§ 2.40 CLEANING AND SANITIZING OF CONTAINERS AND EQUIPMENT -
Item 12p.

(a)(1) All multiuse containers and utensils are thoroughly cleaned after each use, and all equipment is thoroughly cleaned at least once each day used; provided, that storage tanks shall be cleaned when emptied and shall be emptied at least every 72 hours, except that in the case of milk plants at which frozen desserts or storable milk products are manufactured, such tanks shall be emptied at least every 96 hours. Storage tanks which are used to store raw milk longer than 24 hours and silo tanks used for the storage of raw milk, and which are installed after the adoption of this Part, shall be equipped with a seven-day temperature recording device complying with the specifications of Appendix 3 of this Title.

(2) Whenever a milk tank truck has been cleaned and sanitized, as required by the Commissioner, it shall bear a tag or a record shall be made showing the date, time, place and signature of the employee or contract operator doing the work, unless the truck delivers to only one receiving unit where responsibility for cleaning and sanitizing can be definitely established without tagging. The tag is to be removed at the first stop on the route and kept on file for the Commissioner.

(b) Pipelines and/or equipment designed for mechanical cleaning meet the following requirements:

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

(2) A temperature recording device shall be installed in the return solution line to record the temperature and time during which the line or equipment is exposed to cleaning and sanitizing.

(3) Temperature recording charts shall be identified, dated and retained for three months.

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

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

(d) In plants utilizing automatic bottle washers, such washers must 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, listing combinations of causticity, time, and temperature of equal bactericidal value, for soaker tank of soaker-type bottle washers:

COMBINATION OF CAUSTICITY, TIME AND TEMPERATURE OF EQUAL
BACTERICIDAL VALUE, FOR SOAKER TANK OF SOAKER-TYPE BOTTLE WASHERS
(Based on NSDA specifications for beverage bottles)

	<i>Temperature, degrees</i>						
	F170	160	150	140	130	120	110
	C77	71	66	60	54	49	43
<i>Time in Minutes</i>	<i>Concentration of NaOH, percent</i>						
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

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.

(e) All multiuse containers, equipment, and utensils are sanitized before use, employing one or a combination of the methods prescribed under Section 2.18 of this Part (Item 11r). Assembled equipment must be sanitized prior to each day's run.

(f) The residual bacteria count of multiuse and single-service containers used for packaging pasteurized milk and milk products shall not exceed one per milliliter of capacity, when the rinse test is used, or not over 50 colonies per 8 square inches (one per square centimeter) of product-contact surface, when the swab test is used, in 3-out-of-4 samples taken at random on a given day. All multiuse and single-service containers shall be free of coliform organisms.

(g) Plants which utilize multiuse plastic containers for pasteurized milk and milk products shall comply with the following criteria:

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

(2) The plastic material shall comply with the material specifications of section 2.39 of this Part (Item 11p).

(3) 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 commissioner.

(4) A device shall be installed in the filling line capable of detecting in each container before it is filled, volatile organic contaminants in amounts that are of public health significance. Such device must be constructed so

that it may be sealed by the Commissioner to prevent the changing of its sensitivity functioning level. Models using an air injection system and with a testing device built into the detection equipment do not have to be sealed. To assure proper functioning of the system the operator needs to be able to adjust the sensitivity. However, those models utilizing an external testing device must be sealed. Any container detected by the device as being unsatisfactory must be automatically made unusable to prevent refilling. In addition, the device must be interconnected so that the system will not operate unless the detecting device is in proper operating condition.

(5) A standard must be available for the use of the commissioner for testing the proper sensitivity functioning levels of the detection device.

(6) The Commissioner may waive the requirement for the detecting device required for in paragraph (4) of this subdivision if an alternative method of comparable sensitivity is available and has been demonstrated to be effective in milk plant operation.

(7) The containers shall comply with the applicable construction requirements of section 2.39 of this Part (Item 11p). The closure for the container shall be single-service. Screw-type closures shall not be used.

(8) The container shall not impart into the product pesticide residual levels or other chemical contaminants in excess of those considered acceptable under the Federal Food, Drug and Cosmetic Act, as amended and regulations issued thereunder.

§ 2.41 STORAGE OF CLEANED CONTAINERS AND EQUIPMENT - Item 13p.

(a) All multiuse containers, equipment and utensils, after cleaning, are transported and/or stored on metal racks or in clean cases elevated above the floor. Containers shall be stored inverted on racks or in cases constructed of relatively non-absorbent, corrosion-resistant, non-toxic materials, or otherwise protected from contamination.

(b) Floors are not flushed or washed when crates of clean bottles are stacked on them.

§ 2.42 STORAGE OF SINGLE-SERVICE CONTAINERS, UTENSILS AND MATERIALS - Item 14p.

(a) Single-service caps, cap stock, parchment paper, containers, gaskets and other single-service articles for use in contact with milk and 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.

(b) 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.

(c) Tubes or cartons are not refilled with spilled caps, gaskets or parchment papers.

(d) Cartons or boxes from which contents have been partially removed are kept closed.

(e) 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.

§ 2.43 PROTECTION FROM CONTAMINATION - Item 15p.

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

(b) During processing, pipelines and equipment used to contain or conduct milk and milk products shall be effectively separated from tanks or circuits containing cleaning and/or sanitizing solutions.

(c) All milk and milk products which have overflowed, leaked, been spilled or improperly handled are discarded. Milk and milk products drained from processing equipment at the end of

a run, or collected from a defoamer system and milk 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 45°F (7°C) or less. When the handling and/or refrigeration of such milk and milk products are not in compliance with this requirement, they shall be discarded. Returned packaged milk and milk products, frozen desserts or melloream shall not be repasteurized for Grade A milk products, frozen desserts or melloream use; provided, that the repasteurization of milk and milk products shipped in transport tankers which have been pasteurized at another Grade A plant and have been handled in a sanitary manner and maintained at 45°F (7°C) or less is permitted.

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

(1) If the area is completely enclosed (walls and ceilings, 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.

(2) If the area is not completely enclosed or doors of the unloading area are open during unloading, a suitable filter is required for the manhole or air inlet vent and suitable protection must be provided over the filter material either by design of the filter holding apparatus or a roof or ceiling over the area. Direct connections from milk tank truck to milk tank truck must be made from valve to valve and not through the manhole and the manhole and the dust cover (dome) of the milk tank truck being filled must be closed. 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.

(e) Whenever air under pressure is used for the agitation or movement of milk, or is directed at a milk-contact surface, it is free of oil, dust, rust, excessive moisture, extraneous materials, and odor. 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 quality.

(f) Standardization is done before the pasteurization process is started, unless pasteurized milk or milk products are used for standardization. Such pasteurized milk products shall be protected against contamination. In no case shall pasteurized milk or milk products be standardized with unpasteurized milk unless the standardized product is subsequently pasteurized. Reconstituted or recombined milk and milk products shall be pasteurized after reconstitution or recombining of all ingredients. Standardization of Grade A milk and milk products with other than Grade A milk and milk products is prohibited. Standardization is done only in accordance with the provisions of section 35.2 and in plants which have received permission to standardize in accordance with section 35.3 of this Title.

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

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

(i) All ingredients and nonproduct-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.

(j) Pasteurized milk is not strained or filtered except through a perforated metal strainer.

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

(l) Those poisonous or toxic materials that are necessary are not stored in any room where milk or milk products are received, processed, pasteurized or stored, or where equipment, containers or utensils are washed or where single-service containers, closures or caps are stored.

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

(n) Only insecticides and rodenticides approved by the commissioner and/or registered with the U.S. Environmental

Protection Agency 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, containers, equipment and utensils.

§ 2.44 PASTEURIZATION - Item 16p.

(a) Pasteurization shall be performed as follows: Every particle of prepasteurized milk, milk, lowfat milk, skim milk, milk products, goat milk, goat milk product, sheep milk, sheep milk product, melloream or frozen dessert mix, with the exception of water ice mix and flavoring agents used in frozen desserts, shall be heated in properly designed and operated equipment to one of the temperatures specified in the following table and held continuously at or above that temperature for at least the time specified:

Temperature	Time
*145°F (63°C)	30 minutes
*161°F (72°C)	15 seconds
191°F (89°C)	1 second
194°F (90°C)	0.5 second
201°F (94°C)	0.1 second
204°F (96°C)	0.05 second
212°F (100°C)	0.01 second

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

<u>Temperature</u>	<u>Time</u>
155°F (69°C)	30 minutes
160°F (71°C)	15 minutes
165°F (77°C)	10 minutes
175°F (80°C)	25 seconds
180°F (83°C)	15 seconds
200°F (94°C)	3 seconds
212°F (100°C)	0.01 second

Provided further, that nothing shall be construed as barring any other pasteurization process which has been recognized by the FDA to be equally efficient and which is approved by the Commissioner.

(b) The design and the operation of pasteurization equipment and all appurtenances thereto shall comply with the applicable specifications and operational procedures set forth in sections 2.45 through 2.48 of this Part and set forth in Appendices 3-10 to this Part, except with respect to milk, lowfat milk, skim milk, milk products, goat milk, goat milk products, sheep milk sheep milk products, frozen desserts and mellocream that will be aseptically processed or ultra-pasteurized, the design and the operation of processing equipment and appurtenances thereto shall also comply with Appendix L and Item 16p(c) of the PMO.

(c) Cream for buttermaking shall be pasteurized at a temperature of not less than 165°F and held continuously in a vat at such temperature for not less than 30 minutes, or at a temperature of not less than 185°F for not less than 15 seconds, or any other temperature and holding time approved by the commissioner that will assure pasteurization and comparable keeping-quality characteristics. If the vat method of pasteurization is used, vat covers shall be kept closed during the holding and cooling periods.

(d) Every person who operates a milk plant at which frozen desserts are manufactured shall ensure that all flavoring agents added to frozen desserts after the frozen desserts have been

pasteurized are sterile, aseptically processed or otherwise treated to a temperature which will render them free of all pathogenic bacteria, or alternatively have a water activity (aw) value of 0.85 or less or have a pH level of 4.6 or less. All flavoring agents shall, insofar as possible, be completely used up during each day's manufacturing.

§ 2.45 BATCH PASTEURIZATION - Item 16p(A).

(a) All indicating and recording thermometers used in connection with the batch pasteurization of milk or milk products shall comply with the applicable specifications set forth in Appendix 3 of this Title. Specifications for test thermometers and other test equipment appear in Appendix 4 of this Title.

(b) *Time and Temperature Controls For Batch Pasteurizers.*

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

(2) Location and required readings of indicating and recording thermometers. Each batch pasteurizer shall be equipped with both an indicating and a recording thermometer. The thermometers shall read not less than the required pasteurization temperature throughout the required holding period. The plant operator shall check daily the temperature shown by the recording thermometer against the temperature shown by the indicating thermometer; 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 or milk products shall be pasteurized unless it is sufficient to cover the bulbs of both the indicating and the recording thermometers.

(3) Assurance of minimum holding periods. Batch pasteurizers shall be so operated that every particle of milk or milk product will be held at not less than the minimum pasteurization temperature continuously for at least 30 minutes. When milk 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 recorder chart shall show at least 30 minutes at not less than the minimum pasteurization temperature. When milk or milk products are preheated to pasteurization temperature before entering the vat, the recorder chart shall show a holding period of at least 30

minutes at not less than the minimum pasteurization temperature plus the time of filling from the level of the recorder bulb. When cooling is begun in the holder after the opening of the outlet valve, or is done entirely outside the holder, the chart shall show at least 30 minutes at not less than the minimum pasteurization temperature plus the time of emptying to the level of the recording thermometer bulb. When the recorder time interval on the recorder chart at the pasteurization temperature includes filling and/or emptying time, such intervals shall be indicated on the recorder chart by the operator, by removing the recording thermometer bulb from the milk for a sufficient time to depress the pen, or by turning cold water into the vat jacket at the end of the holding period, or by inscribing the holding time on the chart. The filling time and the emptying time for each holder so operated shall be determined by the commissioner, initially and after any change which may affect these times. No milk shall be added to the holder after the start of the holding period.

(c) *Airspace Heating.*

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

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

(3) The temperature shown by the airspace thermometer shall be recorded on the recording thermometer chart each time the pasteurizer is in operation.

(d) *Inlet and Outlet Valves and Connections.* The following definitions shall apply to inlet and outlet valves and connections:

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

(2) *90° stop* shall mean a stop so designed as to prevent turning the plug more than 90 degrees.

(3) *120° stop* shall mean a stop which prevents turning the plug more than 120 degrees.

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

- (5) *Valve with an irreversible plug* shall mean one in which the plug cannot be reversed in the shell.
- (6) *Single-quadrant stop* shall mean a 90-degree stop in a valve with an irreversible plug.
- (7) *The fully open position* shall mean that position of the valve seat which permits the maximum flow of milk into or out of the pasteurizer.
- (8) *The closed position* shall mean any position of the valve seat which stops the flow of milk into or out of the pasteurizer.
- (9) *The fully closed position* shall mean that closed position of the valve seat which requires the maximum movement of the valve to reach the fully open position.
- (10) *The just-closed position* shall mean that closed position of a plug-type valve in which the flow into or out of the holder is barely stopped, or any closed position within 0.078 inch thereof as measured along the maximum circumference of the valve seat.
- (11) *Leakage* shall mean the entrance of unpasteurized milk onto a batch pasteurizer during the holding or emptying period, or the entrance of unpasteurized milk into any pasteurized milk line at any time.
- (12) *Leak-protector valve* shall mean a valve provided with a leak-diverting device, which, when the valve is in any closed position, will prevent leakage of milk past the valve or, in the case of batch pasteurizers filled or emptied by suction or compressed air, will prevent leakage of milk past the valve or the leakage of milk due to the leakage of air past the suction valve or the compressed air valve, as the case may be.
- (13) *Closed-coupled valve* shall mean a valve, the seat of which is either flush with the inner wall of the pasteurizer, or so closely coupled that no milk in the valve inlet is more than 1° F (0.5° C) colder than the milk 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:
- (i) The vat outlet is so flared that the smallest diameter of the large end of the flare is not less than the diameter of the outlet line plus the depth of the flare; and
 - (ii) The greatest distance from the valve seat to the small end of the flare is not greater than the diameter of the outlet line; and

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

(e) *Design and Installation of Valves and Connections.* All valves and connections shall comply with the following requirements:

(1) Valves and pipeline connections shall meet the requirements of section 2.38 of this Part Item 10p).

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

(3) To prevent clogging, and to promote drainage, all leak-protector grooves shall be at least 0.187 inch wide, and at least 0.094 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 bindings. Washers or other parts shall not obstruct leak-protector grooves.

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

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

(6) All inlet pipelines and outlets from vat pasteurizers shall be equipped with leak-protector valves; provided, that installations not equipped with leak-protector inlet valves

shall be accepted when the piping is so arranged that only one vat can be connected to the inlet line at a time, and such piping is disconnected during the holding and emptying periods.

(7) Inlet and outlet connections other than through closed-coupled valves shall not enter or leave the pasteurizer below the level of the milk therein.

(8) In cases where the inlet line enters the holder above the milk level, and in which the inlet line may be submerged and thus prevent its complete emptying when the inlet valve is closed, the inlet line shall be provided with an automatic air-relief, or vent located either at the valve or elsewhere, and so designed as to function in every closed position of the valve. A vent may be provided by drilling a hole at least 0.125 inch in diameter in the vat pipe, below the vat cover, but above the maximum milk level.

(9) All leak-protector valves shall be installed in the proper position to insure the function of the leak-diverting device. Inlet valves shall not be located in vertical pipelines, unless they can be so installed that one of the groove systems is at the lowest level of the valve; and pipelines between the inlet valve and the pasteurizer shall be as short as practicable and shall be so sloped to drain.

(10) All outlet valves shall be kept fully closed during filling, heating and holding periods; and all inlet valves shall be kept fully closed during holding and emptying periods.

(f) *Recording Charts.* All recording thermometer charts shall comply with the applicable requirements of section 2.48 of this Part (Item 16p[D]).

§ 2.46 HIGH-TEMPERATURE-SHORT-TIME, (HTST) CONTINUOUS-FLOW PASTEURIZATION - Item 16p(B).

(a) *Indicating Thermometers and Recorder/Controller Instruments.*

All indicating thermometers and recorder/controller instruments and devices used in connections with the high-temperature-short-time, continuous-flow pasteurization of milk or milk products shall comply with the applicable specifications set forth in Appendix 3 of this Title.

(b) *Automatic Milk Controller.* Each high-temperature-short-time, 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:

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

(2) Flow-diversion devices. All flow-diversion devices used in continuous pasteurizers shall comply with the following or equally satisfactory specifications:

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

(ii) 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.

(iii) A leak escape shall be installed on the forward-flow side of the valve seat. However, when back pressure is exerted on the forward-flow side of the valve seat, while the milk-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 visual means of leak detection.

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

(v) The flow-diversion device shall be so designed and installed that failure of the primary motivating power shall automatically divert the flow of milk.

(vi) The flow-diversion device shall be located downstream from the holder. The flow-control sensor shall be located in the milk line not more than 18 inches upstream from the flow-control device.

(vii) In the case of higher-heat-shorter-time (HHST) pasteurizing systems utilizing the temperature of 191°F (89°C) and above and holding times of one second and less, the flow-diversion device may be located downstream from the regenerator and/or cooler sections; provided that, when the flow-diversion device is located downstream from the regenerator and/or cooler sections, the flow-diversion device shall be automatically prevented from assuming the forward-flow position until all product-contact surfaces between the holding tube and the flow-diversion device have been held at or above the required pasteurization temperature continuously and simultaneously for at least the required pasteurization time as set forth in section 2.44 of this Part.

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

(ix) When it is used, the pipeline from the leak detector port of the flow-diversion device shall be self-draining, and shall be free of restrictions or valves, unless such restrictions or valves are so designed that stoppage of the leak detector line cannot occur.

(3) Milk-flow controller instrumentation. The following requirements shall be met with respect to the instrumentation of the milk-flow controller:

(i) The thermal limit controller shall be set and sealed so that forward flow of product cannot start unless the temperature at the controller sensor is above the required pasteurization temperature as

defined in section 2.2(a) of this Part for the milk or milk product and the process used, nor continue during descending temperatures when the temperature is below the required pasteurization temperature. The seal shall be applied by the commissioner after testing, and shall not be removed without immediately notifying the commissioner. The system shall be so designed that no milk can be bypassed around the controller sensor which shall not be removed from its proper position during the pasteurization process. The cut-in and cut-out milk temperatures, as shown by the indicating thermometer, shall be determined at the beginning of each day's operation and entered upon the recorder chart daily by the plant operator.

(ii) In the case of the HHST pasteurization systems, utilizing the temperatures of 191°F (89°C) and above, and holding times of one second or less, with the flow-diversion device located downstream from the regenerator and/or cooler section, additional temperature controllers and timers shall be interwired with the thermal limit controller, and the control system shall be set and sealed so that forward flow of product cannot start until all product-contact surfaces between the holding tube and flow-diversion device have been held at or above the required pasteurization temperature, continuously and simultaneously for at least the required pasteurization time as set forth in section 2.44 of this Part. The control system shall also be set and sealed so that forward flow cannot continue when the temperature of the product in the holding tube is below the required pasteurization temperature. The seal shall be applied by the commissioner after test, and shall not be removed without immediately notifying the commissioner. The system shall be so designed that no product can be bypassed around the control sensors, which shall not be removed from their proper position during the pasteurization process. For these HHST systems, daily measurement by the operator of the cut-in and cut-out temperatures is not required.

(iii) Manual switches for the control of pumps, homogenizers, or other devices which produce flow through the holder, shall be wired so that the circuit is completed only when the milk is above the required pasteurization temperature as set forth in section 2.44 of this Part for the milk or milk product and the process used, or when the diversion device is in the fully diverted position.

(4) Holding tube.

(i) Holders shall be designed to provide for the holding of every particle of milk or milk product for

at least the time required in section 2.2(a) of this Part for the milk or milk product and the process used.

(ii) The holder shall be so designed that the simultaneous temperature difference between the hottest and coldest milk in any cross section of flow at any time during the holding period will not be greater than one degree Fahrenheit (one-half degree Celcius). This requirement may be assumed to have been satisfied without test in tubular holders of seven inches or smaller diameter which are free of any fittings through which the milk may not be thoroughly swept.

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

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

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

(vi) The holder shall be so designed that no portion between the inlet and the flow-control temperature sensor is heated.

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

(viii) With the steam injection processes, the holding time is reduced because the product volume increases as the steam condenses to water during heating in the injector. This surplus water is evaporated as the pasteurized product is cooled in the vacuum chamber. For example, with a 120°F (66°C) increase by steam injection, which is probably the maximum temperature rise that will be used, a volume increase of 12 percent will occur in the holding tube. The measurement of the average flow rate at the discharge of the pasteurizer

does not reflect this volume increase in the holding tube. However, this volume increase, *i.e.*, holding time decrease, must be considered in the calculations.

(ix) With the steam injection process a pressure limit indicator is needed in the holding tube to keep the heated product in the liquid phase. The instrument must have a pressure switch so that the flow-diversion device will move to the divert position if the product pressure falls below a prescribed value. For operating temperatures between 191°F (89°C) and 212°F (100°C) the pressure switch must be set at 10 pounds per square inch (psi). For units which have operating temperatures above 212°F (100°C), the pressure switch must be set at a pressure 10 psi above the boiling pressure of the product at its maximum temperature in the holding tube.

(x) With the seam injection process, a differential pressure limit indicator across the injector is needed to ensure adequate isolation of the injection chamber. The instrument must have a differential pressure switch so that the flow-diversion device will move to the divert position if the pressure drop across the injector falls below 10 psi.

(5) Indicating and recording thermometers.

(i) 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 between the two thermometers does not differ significantly in temperature.

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

(iii) The recorder/controller charts shall comply with the applicable provisions of section 2.48 of this Part (Item 16p[D]).

(6) Flow-promoting devices.

(i) The pump, or pumps, and other equipment which may produce flow through the holder shall be located upstream from the holder, provided that pumps and other flow-promoting devices may be located downstream from the holder if means are provided to eliminate negative pressure between the holder and the inlet to such

equipment. When vacuum equipment is located downstream from the holder, an effective vacuum breaker, plus an automatic means of preventing a negative pressure in the line between the flow-diversion device and the vacuum chamber, shall be acceptable.

(ii) The speed of pumps or other flow-promoting devices governing the rate of flow through the holder shall be so controlled as to insure the holding of every particle of milk for at least the time required as set forth in section 2.44 of this Part, for the milk or milk product and the process used. In all cases, the motor shall be connected to the metering pump by means of 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 without detection by the commissioner. This shall be accomplished by the application of a suitable seal(s) after tests by the commissioner and such seal shall not be broken without immediately notifying the commissioner. The provision shall apply to all homogenizers used as timing pumps. Variable speed drives used in connection with the metering pump shall be so constructed that wearing or stretching of the belt results in a slow down, rather than a speed up of the pump. The metering or timing pump shall be of the positive displacement type.

(iii) The holding time shall be taken to mean the flow time of the fastest particle of milk, at or above the required pasteurization temperature, as set forth in section 2.44 of this Part, for the milk or milk product and the process used, throughout the holder section, *i.e.*, that portion of the system that is outside of the influence of the heating medium, and slopes continuously upward in the downstream direction, and is located upstream from the flow-diversion device. Tests for holding time shall be made when all equipment and devices are operated and adjusted to provide for maximum flow. When a homogenizer is located upstream from the holder, the holding time shall be determined with the homogenizer in operation with no pressure on the homogenizer valves. Where bypass lines are provided, either upstream or downstream from the metering pump, the holding time shall be tested with both the regular and bypass line open, unless the bypass valve is so designed that both lines cannot be open at the same time. The holding time shall be tested during both forward and diverted flow. If necessary to lengthen the holding time during diverted flow, an identifiable restriction may be placed in the vertical portion of the diversion pipeline. When vacuum equipment is located downstream from the holder,

the holding time shall be tested with the metering pump operating at maximum flow, and the vacuum equipment adjusted to provide for the maximum vacuum. The holding time shall be tested in both forward and diverted flow by the regulatory agency initially, quarterly thereafter, after any alteration or replacement that may affect the holding time, and whenever the seal of the speed setting has been broken.

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

(i) The product and steam flows must be isolated from pressure fluctuations inside the injection chamber. One method of isolation is to insert supplementary orifices on the product inlet and the heated product outlet of each injector. The two supplementary orifices must be sized for at least a 10 psi 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.

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

(iii) The process should be as free as possible of noncondensable gases that may evolve from the product or be carried in the steam supply. Any two-phase flow caused by the noncondensable gases would displace the product in the holding tube, resulting in reduced residence times. In addition, these gases in the steam

supply may also markedly alter the condensation mechanism at the point of injection. Accordingly, the steam boiler shall be supplied with a deaerator. The deaerator will aid in keeping the product in the holding tube as free as possible of noncondensable gases.

(8) Prevention of product adulteration with added water.

(i) When culinary steam is introduced directly into the milk or milk product downstream from the flow-diversion device, means shall be provided to preclude the addition of steam to the product, unless the flow-diversion is in the forward-flow position. This provision may be satisfied by the use of an automatic steam control valve with 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 flow-diversion device controls that steam cannot flow unless the flow-diversion device is in the forward-flow position.

(ii) When culinary steam is introduced directly into the milk or milk product, automatic means shall be provided to maintain a proper temperature differential between incoming and outgoing milk to preclude dilution with water.

(iii) Where a water feed line is connected to a vacuum condenser and 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, automatically actuated by a control which will shut off the inflowing water, if for example, the condensate pump stops and the water level rises above a predetermined point in the vacuum condenser. This valve may be actuated by water, air or electricity, and shall be so designed that failure of the primary motivating power will automatically stop the flow of water into the vacuum condenser.

§ 2.47 PASTEURIZERS EMPLOYING REGENERATIVE HEATING - Item 16p(C).

(a) *Milk to Milk Regenerative Heating.* Pasteurizers employing milk-to-milk 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 in the regenerator will

automatically be under greater pressure than raw milk in the regenerator at all times.

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

(3) The overflow of the top rim of the constant-level raw milk tank shall always be lower than the lowest milk 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 outlet from the regenerator and the nearest downstream point open to the atmosphere.

(5) No pump shall be located between the raw milk inlet to the regenerator and the raw milk supply tank, unless it is designed and installed to operate only when milk is flowing through the pasteurized milk side of the regenerator, and when the pressure of the pasteurized milk 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:

(i) The metering pump is in operation;

(ii) The flow-diversion device is in forward-flow position; and

(iii) The pasteurized milk pressure exceeds, by at least one psi, the maximum pressure developed by the booster pump. Pressure gauges shall be installed at the raw milk inlet to the regenerator and the pasteurized milk outlet of the regenerator or the outlet of the cooler. The accuracy of 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, and such records thereof maintained as directed by the Commissioner. All electric wiring interconnections should be in permanent conduit (except that rubber covered cable may be used for final connections), with no electrical connections to defeat the purpose of any provisions of this Part.

(7) All raw milk in the regenerator will drain freely back into the constant-level raw milk tank when the raw milk

pump(s) are shut down and the raw milk outlet from the regenerator is disconnected.

(8) When vacuum equipment is located downstream from the flow-diversion device, means shall be provided to prevent the lowering of the pasteurized milk 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 inlet to the regenerator.

(9) In the case of HHST pasteurization systems utilizing the temperatures of 191°F (89°C) and above and holding times of one second or less, with the flow-diversion device located downstream from the regenerator and/or cooler section, the requirement that the pasteurized product from the outlet of the regenerator or cooler shall rise to vertical elevation of 12 inches above the highest raw product level downstream from the constant-level tank and shall be open to the atmosphere at this or a higher elevation, may be eliminated, provided that a differential pressure controller is used to monitor the highest pressure in the raw product side of the regenerator and the lowest pressure in the pasteurized side of the regenerator, and the controller is interlocked with the flow-diversion device and is set and sealed so that whenever improper pressures occur in the regenerator, forward flow of product is automatically prevented and will not start again until all product-contact surfaces between the holding tube and flow-diversion device have been held at or above the required pasteurization temperature, continuously and simultaneously for at least the required pasteurization time as defined in Section 2.2(a) of this Part.

(10) When culinary steam is introduced directly into milk or milk products, as the means of terminal heating to achieve pasteurization temperature, and vacuum equipment is located downstream from the holding tube, the requirement that a vacuum breaker be installed at the inlet to the pasteurized side of the regenerator may be eliminated, provided that the differential pressure controller is installed and wired to control the flow-diversion device as described in paragraph (9) of this subdivision.

(11) When the differential pressure controller is installed and wired to control the flow-diversion device as described in paragraph (9) of this subdivision, the raw product booster pump may be permitted to run at all times, provided that the metering pump is in operation.

(b) *Milk-to-Water-to-Milk Regenerative Heating.* Milk-to-water-to-milk regenerators with both the milk and the heat-transfer water in the raw milk 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 section will, automatically, be under greater pressure than the raw 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 12 inches, than any raw milk 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 12 inches above any raw milk 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 is present in the regenerator.

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

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

- (i) the heat-transfer water pump is in operation; and
- (ii) the heat-transfer water pressure exceeds, by at least one pound per square inch, the raw milk pressure in the regenerator. Pressure gauges shall be installed at the raw milk inlet and the heat-transfer water outlet of the regenerator. The accuracy of the required pressure gauges shall be checked by the regulatory agency on installation, quarterly thereafter, and following repair or replacement.

NOTE: See Appendix 3 for further discussion concerning methods of achieving

the required pressure relationships within the regenerator.

§ 2.48 TEMPERATURE RECORDING CHARTS, EQUIPMENT TESTS AND EXAMINATIONS - Item 16p(D).

(a) *Temperature Recording Charts.* All temperature recording charts shall be preserved for a period of three months. The use of such charts shall not exceed the time limit for which they are designed. Overlapping of recorded data shall be a violation of this item. The following information shall be entered on the charts as applicable:

(1) Batch Pasteurizers:

(i) Date

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

(iii) Extent of holding period, including filling and emptying times when required, section 2.45 of this Part (Item 16p[A]).

(iv) Reading of airspace thermometer within the holding period at a given time or reference point as indicated on the chart, section 2.45 of this Part (Item 16p[A]).

(v) Reading of indicating thermometer within the holding period at a given time or reference point as indicated on the chart, section 2.45 of this Part (Item 16p[A]).

(vi) Quarterly, the initials of the regulatory agency opposite the required readings of the indicating thermometer and airspace thermometer, section 2.45 of this Part (Item 16p[A]).

(vii) Quarterly, the time accuracy of the record, as determined by the regulatory agency (Appendix 4, *infra*, Test 3).

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

(ix) Record of unusual occurrences.

(x) Signature or initials of operator.

(xi) Name of milk plant.

(2) High-temperature-Short-Time Pasteurizers. Recording thermometer charts shall contain all the information specified in paragraph (1) of this subdivision, except,

subparagraphs (iii) and (iv) and reference to airspace thermometers in subparagraph (vi), and, in addition, shall include the following:

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

(ii) The cut-in and cut-out milk temperatures recorded daily by the operator at the beginning of the run, and initialed quarterly by the regulatory agency, section 2.46 of this Part (Item 16p[B]).

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

(3) Equipment Tests and Examination. The regulatory agency shall perform the indicated tests on the following instruments and devices initially on installation, and at least once each three months thereafter, and whenever any alteration or replacement is made which may affect the proper operation of the instrument or devices, provided that the holding time test shall be conducted at least every six months. (See table in subdivision [b] of this section)

4. Removal of regulatory seals and resumption of pasteurization. No equipment required to be sealed pursuant to section 2.46 of this Part shall be used if the regulatory seal has been broken unless the conditions set forth in subparagraphs (i) and (iii) herein are met:

(i) the commissioner is notified promptly;

(ii) the provisions of section 2.46 of this Part are otherwise continuously met and compliance therewith is documented in a form satisfactory to the commissioner; and

(iii) a sample of the milk, milk product, mellocream or frozen dessert processed or manufactured in such equipment is properly taken immediately after the resumption of pasteurization and every two hours thereafter and properly analyzed in an officially designated laboratory for the presence of phosphatase and is found to not exceed the phosphatase standard set forth in section 2.8 of this Part. No milk, milk products, mellocream or frozen dessert processed or manufactured in equipment from which a seal has been broken shall be removed from the milk plant until the processing plant superintendent determines that all of the provisions set forth in subparagraphs (i) through (iii) herein have been met.

(b) Table.

<i>Instrument or device</i>	<i>Test No.</i>	<i>Test Objective</i>
Batch pasteurizer indicating thermometer	1	Accuracy
Batch pasteurizer recording thermometer	2	Temperature accuracy
Batch pasteurizer recording thermometer	3	Time accuracy
Batch pasteurizer	4	Check reading of recording thermometer against indicating thermometer
Airspace thermometer	1	Accuracy
Valves	6	Leakage in plug type leak-protector valves and poppet-type valves
HTST indicating thermometer	1	Accuracy
HTST indicating thermometer	7	Thermometric response
HTST recording thermometer	2	Temperature accuracy
HTST recording thermometer	3	Time accuracy
HTST recorder controller	2	Temperature accuracy
HTST recorder controller	4	Check reading of recorder controller against indicating thermometer
HTST recorder controller	8	Thermometric response
HTST recorder controller	10	Confirm cut-in and cut-out temperatures.
HTST flow-diversion device	5	Assembly and function

HTST auxiliary (booster pump)	9	Function of automatic control devices.
HTST auxiliary (booster pump)	9	Accuracy of pressure gauges
HTST system	11	Check holding time
HTST system	12	Thermal limit control for sequence logic
HTST system	13	Setting of control switches for product pressure in the holding tube
HTST system	14	Setting of control switches for differential pressure across the injector.

§ 2.49 COOLING OF MILK - Item 17p.

(a) All raw milk and milk products are maintained at 45°F (7°C) or less until processed.

(b) All pasteurized milk and milk products, except those to be cultured, are cooled immediately in approved equipment prior to filling and packaging to a temperature of 45°F (7°C) or less. All pasteurized milk and milk products shall be stored at a temperature of 45°F (7°C) or less.

(c) Each refrigerator room in which milk or milk products are stored is equipped with an indicating thermometer which complies with the applicable specifications of Appendix 3 of this Title. Such thermometer shall be located in the warmest zone of the refrigerator room. Each storage tank shall be equipped with an indicating thermometer, the sensor of which shall be located to permit the registering of the temperature of the contents when the tank contains no more than 20 percent of its calibrated capacity. Such thermometer shall comply with the applicable specifications of Appendix 3 of this Title.

(d) All surface coolers comply with the following specifications:

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

(2) 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 products 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 trough, or by some other approved method.

(3) The location of supports of cooler sections shall prevent drip from entering the milk or milk products.

(4) All open-surface coolers shall be provided with tight-fitting shields which protect the milk and milk products from contamination by flies, dust, drip, splash or manual contact.

(e) Recirculated cold water which is used in coolers and exchangers, including those systems in which a freezing point depressant is used, is from a safe source and protected from contamination. Such water shall be tested semiannually and shall comply with the bacteriological standards. Recirculated water systems which become contaminated through repair work or otherwise shall be properly treated and tested before being returned to use. Freezing point depressants, when used in recirculating systems, shall be non-toxic.

§ 2.50 BOTTLING AND PACKAGING - Item 18p.

(a) All milk and milk products, including concentrated milk and milk products, are bottled and packaged at the plant where final pasteurization is performed, provided that this requirement shall not apply to frozen desserts. Such bottling and packaging shall be done without undue delay following final pasteurization.

(b) 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 in one system.

(c) Bottling or packaging machines are designed to minimize the need for adjustment during operation. All pipes, connections defoaming devices and similar appurtenances shall comply with sections 2.38 and 2.39 of this Part (Items 10p and 11p).

(d) Bottling or packaging machine supply tanks and bowls have covers which are constructed to prevent any contamination from reaching the inside of the filler tank or bowl. All covers shall be in place during operation.

(e) A drip deflector is installed on each filler valve. Such drip deflector shall be designed and adjusted to divert condensation away from the open container.

(f) Container infeed conveyers to automatic bottling or packaging machines have overhead shields to protect the bottles or packages from contamination. Such 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 infeed conveyers when the cans are fed to the filler with covers off.

(g) 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.

(h) Bottling and packaging machine floats are designed to be adjustable without removing the cover.

(i) The filler pipe of all bottling and packaging machines have an apron or other approved device as close to the filler bowl as possible to prevent condensation or drip from reaching the inside of the filler bowl.

(j) Filling cylinders on packaging machines are protected from contamination by the use of overhead shields. When any lubricant is applied to the filler pistons, cylinders or other milk-contact surfaces, the lubricant shall be non-toxic, sterile, and shall be sparingly applied in a sanitary manner.

(k) Milk and milk products from continuous defoamers are not returned directly to the filler bowl.

(l) Butter liners, before use, are completely immersed in a salt solution in a non-corrosive container for not less than 30 minutes at the boiling point and held in this solution until used. At least 15 pounds of salt shall be used for every 100 pounds of solution, and the solution shall be changed frequently to keep it clean.

§ 2.51 CAPPING - Item 19p.

(a) The capping or closing of milk and milk product containers is done in a sanitary manner using approved mechanical capping/closing equipment. The term *approved mechanical capping and/or closing equipment* shall not exclude manually operated machinery. Hand-capping shall be prohibited, provided that if suitable mechanical equipment for the capping or closing of specific container(s) of three gallons or more is not available, other methods which eliminate all possibility of contamination may be approved by the regulatory agency.

(b) All *mechanical capping or closure mechanisms* are designed to minimize the need for adjustment during operation.

(c) Bottles and packages which 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 45°F (7°C) or less, and subsequently repasteurized or discarded.

(d) All caps and closures are designed and applied in such a manner that the pouring lip is protected to at least its largest diameter and, with respect to fluid product containers, removal cannot be made without detection. Single-service containers are

so constructed that the product and the pouring and opening areas are protected from contamination during handling, storage and when the containers are initially opened.

(e) Caps and closures are handled in a sanitary manner. The first cap from each tube, the first cap(s) from each roll of cap or cover stock, and the first sheet of parchment or cover paper shall be discarded. The subsequent use of loose caps which are left in the cappers at the end of an operating period after removal from the cap tubes shall be a violation of this item.

§ 2.52 PERSONNEL - CLEANLINESS - Item 20p.

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

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

(c) All persons while engaged in the processing, pasteurization, handling, storage, or transportation of milk, milk products, containers, equipment and utensils wear clean outer garments.

(d) Tobacco is not used by any person while engaged in the processing of milk or milk products and adequate head coverings are worn.

§ 2.53 VEHICLES - Item 21p.

(a) All vehicles used for transportation of pasteurized milk and milk products shall be constructed and operated so that the milk and milk products are maintained at 45°F (7°C) or less, and are protected from sun, from freezing and from contamination.

(b) This item is deemed to be satisfied when:

(1) All vehicles are kept clean.

(2) Material which is capable of contaminating milk or milk products is not transported with milk or milk products.

(3) Vehicles have fully enclosed bodies with well-fitted solid doors.

§ 2.54 SURROUNDINGS - Item 22p.

(a) 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.

(b) 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 the U.S. Environmental Protection Agency shall be used for insect and rodent control.

§ 2.55 RECEIVING STATION REQUIREMENTS.

A receiving station shall comply with each of the items required for a milk plant as set forth in this Part which are applicable to a receiving station's activities. The partitioning requirement of Item 5p and the requirements of Items 16p, 18p, 19p, and 21p shall not apply.

§ 2.56 TRANSFER STATION REQUIREMENTS.

A transfer station shall comply with each of the items required for a milk plant as set forth in this Part which are applicable to its activities. Items 5p, 13p, 16p-19p, and 21p shall not apply.

§ 2.57 TANK TRUCK CLEANING AND SANITIZING FACILITIES REQUIREMENTS.

Facilities for cleaning and sanitizing of milk tank trucks shall comply with items required for such purposes in milk plants as set forth in this Part. Items 13p, 16p - 19p and 21p shall not apply.

§ 2.58 ANIMAL HEALTH.

(a) All milk for manufacturing or processing shall be from herds which are located in an accredited or modified accredited tuberculosis area as determined by the U.S. Department of Agriculture; provided, that herds located in an area that fails to maintain such accredited status shall have been accredited by said department as tuberculosis-free, or shall have passed an annual tuberculosis 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 state, 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 Department of Agriculture and Markets may require such physical, chemical or bacteriological tests as it 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 Agriculture and Markets. Any diseased animal disclosed by such test(s) shall be disposed of as the Department directs.

§ 2.59 RESERVED.

§ 2.60 ANIMAL HEALTH REQUIREMENTS FOR RAW MILK SALES FOR PERMITTEES SELLING RAW MILK.

(a) Permittees selling raw cow or goat milk shall be in compliance with regulations for the detection and control of tuberculosis contained in Section 2.58 of this Part.

(b) Permittees selling raw cow milk shall participate in the Division of Animal Industry milk ring testing program. Individual blood agglutination tests shall be performed on all animals in the herd following a positive reaction to the ring test.

(c) Permittees selling raw goat milk shall have individual blood agglutination tests made on each adult animal each year.

(d) Whenever any milking animal is found to be infected with brucellosis as indicated by the blood agglutination test, all distribution of raw milk from that herd shall be immediately suspended. The permittee shall comply with the procedures and directives of the Division of Animal Industry regarding infected animals and shall not offer any further raw milk for distribution from that herd until again authorized to do so by the Department of Agriculture and Markets.

(e) Persons holding a permit to sell raw milk shall enroll and remain in a milk sampling program conducted by Quality Milk Promotion Services for detection of pathogenic bacteria.

§ 2.61 TRANSFERRING; DELIVERY CONTAINERS; COOLING.

(a) Except as permitted in this section, no milk producer, milk hauler or distributor shall transfer milk or milk products from one container or milk tank truck to another on the street, in any vehicle, store or in any place except a milk plant, receiving station, transfer station, or milk house especially

used for that purpose. The dipping or ladling of milk or fluid milk products is prohibited.

(b) No one shall sell or serve any milk or fluid milk product except in the individual, original container received from the distributor, or from an approved bulk dispenser, provided that this requirement shall not apply to milk for mixed drinks requiring less than a half-pint of milk, or to cream, whipped cream, or half-and-half which is consumed on the premises and which may be served from the original container of not more than half-gallon capacity, or from a bulk dispenser approved for such service by the regulatory agency.

(c) *Bulk Dispensers.* Bulk dispensers, approved by the regulatory agency, shall satisfy the following sanitary design, construction, and operation requirements:

(1) All dispensers shall comply with the applicable requirements of this Part.

(2) Product-contact surfaces shall be inaccessible to manual contact, droplet infection, dust or flies; but the delivery orifice may be exempted from this requirement.

(3) All parts of the dispensing device with which milk or milk products come into contact, including any measuring device, shall be thoroughly cleaned and sanitized at the milk plant; provided, that dispensing valves which are applied to the dispenser subsequent to its delivery to the retail vendor may be cleaned and sanitized at such establishments.

(4) The dispensing container shall be filled at the milk plant and shall be so sealed that it is impossible to withdraw any part of its contents, or to introduce any substance without breaking the seal(s).

(5) The milk or milk products shall be thoroughly and automatically mixed with each dispensing operation, except for milk or milk products which remain homogeneous.

(6) All cans shall be thoroughly cleaned and sanitized. Milk and milk products shall be kept at or below 45°F (7°C) at all times. The dispenser tube shall be integral with the dispensing container, shall be protected, and shall be under adequate refrigeration during transportation and storage.

§ 2.62 RESERVED.

§ 2.63 RESERVED.

§ 2.64 EQUIPMENT INSTALLER PERMIT.

(a) Any person who commercially constructs, reconstructs, or extensively renovates a milkhouse, milking barn, stable or parlor in a dairy farm or who constructs or extensively renovates a transfer station, receiving station or milk plant, and any person who commercially installs or modifies milk handling equipment on dairy farms or in milk plants, transfer stations or receiving stations shall file an application for a permit upon a blank prepared under the direction of the commissioner and shall set forth the information deemed necessary by the commissioner for the administration of this Part. The commissioner may decline to grant a permit, or may suspend or revoke a permit, upon due notice and opportunity for a hearing, when he is satisfied by substantial evidence that the applicant or permit holder does not have the qualifications to properly install equipment or has not complied with the provisions of subdivision (b) of this section. A permit holder shall inform the commissioner when any information set forth in his application is no longer accurate.

(b) Every equipment installer shall submit plans for the construction, reconstruction or extensive renovation of a milkhouse, milking barn, stable or parlor in a dairy farm or for the construction, reconstruction or extensive renovation of a transfer station, receiving station, or milk plant, or for the installation or modification of milk handling equipment on dairy farms or in milk plants, transfer stations or receiving stations in a form approved by the Commissioner and shall set forth and describe the equipment to be installed and the manner of installation. No work shall be done unless the plans therefor are submitted to the commissioner and the commissioner determines that the work to be done will not cause the dairy farm, milk plant, transfer station or receiving station, as the case may be, to be in noncompliance with the provisions of this Part. If the commissioner approves plans, all work shall substantially conform to the approved plans.

(c) Failure to comply with the requirements of this section shall subject such persons to the penalties authorized in Section 40 of the Agriculture and Markets Law and/or registration, suspension or revocation.

§ 2.65 PERSONNEL HEALTH.

(a) No person affected with any disease in a communicable form, or while a carrier of such disease, shall work at any dairy farm or milk plant 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 or milk plant 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, or in whose milk plant 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 regulatory agency immediately.

(b) 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 regulatory agency 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; and

(3) Adequate medical and bacteriological examination of the person, of his associates, and of his and their body discharges.