United States Department of Agriculture

Agricultural Marketing Service

Dairy Programs

Milk for Manufacturing Purposes and its Production and Processing

Recommended Requirements

Effective July 21, 2011

Subpart A - Sample State Enabling Act

An act to provide for the establishment of requirements for milk for manufacturing purposes and its production and processing.

SECTION 1. It is the intent of the Act to encourage the sanitary production of good quality milk, to promote the sanitary processing of milk for manufacturing purposes, and to assure wholesome, stable, and high-quality dairy products.

Sec. 2. The (regulatory agency of the State)[1] shall administer the provisions of this Act and is hereby authorized: to establish and promulgate rules and regulations for milk for manufacturing purposes, its production, transportation, grading, use, processing, and the packaging, labeling and storage of dairy products made therefrom; to inspect dairy farms and dairy plants; to certify dairy farms for the production and sale of milk for manufacturing purposes and to license dairy plants to handle and process milk for manufacturing purposes, in conformity with basic requirements and specifications prescribed by such rules and regulations as may be issued hereunder in effectuation of the intent hereof; to require the keeping of appropriate books and records by plants licensed hereunder; and to license qualified milk graders and bulk milk collectors.

Sec. 3. The (regulatory agency of the State)[1] may for good cause, after notice and opportunity for hearing, suspend or revoke certification and licenses issued hereunder. Provided, that nothing in this Act shall be construed to prevent the suspension of the operation of any plant prior to a hearing, when such action is authorized by any applicable and valid law or regulation.

Sec. 4. Twenty-four months from and after the effective date of the rules and regulations issued pursuant to this Act, no person, firm, or corporation shall produce, sell, offer for sale, or process milk for the manufacture of human food except in accordance with the provisions of this Act and the rules and regulations issued pursuant hereto.

Sec. 5. Any person, firm, or corporation that willfully violates any provision of this Act or the rules and regulations issued pursuant hereto shall be fined not more than $___, and each and every violation shall constitute a separate offense.

Sec. 6. This Act shall become effective _____.

[1]Insert name of appropriate regulatory agency, official, or department.

Subpart B - Definitions

SECTION B1. *Meaning of words*. Words used in the singular form shall be deemed to import the plural, and vice versa, as the case may demand.

Sec. B2. *Terms defined*. Unless the context otherwise requires, the following terms shall be construed, respectively, to mean:

(a) *Act*. (The State Act to provide for the establishment of Requirements for Milk for Manufacturing Purposes and Its Production and Processing.)[1]

(b) *Regulatory agency*. (Insert the name of the State agency, official, or department) is authorized by law to administer the Act.

(c) *Rules and regulations*. The provisions of Subpart B to F herein.

(d) *License*. A license issued under the Act by (the regulatory agency).

(e) *Fieldperson*. A person qualified and trained in the sanitary methods of production and handling of milk as set forth herein, and generally employed by a processing or manufacturing plant for the purpose of making dairy farm surveys and doing quality control work.

(f) *Fieldperson, approved*. A fieldperson qualified, trained, and approved by the (regulatory agency) to perform farm inspections and raw milk grading.

(g) *Inspector*. A qualified, trained person employed by (the regulatory agency) to perform dairy farm or plant inspections and raw milk grading.

(h) *Milk grader or bulk milk collector*. A person licensed by (the regulatory agency) as described in F 2.4(b) who is qualified and trained for the grading of raw milk in accordance with the quality standards and procedures of Subparts C and F.

(i) *Producer*. The person or persons who exercise control over the production of the milk delivered to a plant, and who receives payment for this product. A "new producer" is one who is initiating the shipment of milk from a farm. A "transfer producer" is one whose shipment of milk from a farm is shifted from one plant to another plant. A "producer/processor" is one who manufactures dairy products on the dairy farm entirely from his own milk, or from his own milk combined with milk from one or more other producers.

(j) *Dairy farm or farm*. A place or premise where one or more lactating animals are kept, and from which all or a portion of the milk produced thereon is delivered, sold, or offered for sale to a manufacturing plant.

(k) *Dairy plant or plant*. Any place, premise, or establishment where milk or dairy products are received or handled for processing or manufacturing and/or prepared for

distribution. When "plant" is used in connection with the production, transportation, grading, or use of milk, it means any plant that handles or purchases milk for manufacturing purposes; when used in connection with requirements for plants or licensing of plants, it means only those plants that manufacture dairy products.

(l) *Milk*. The term "milk" shall include the following.

(1) Milk is the lacteal secretion practically free from colostrum obtained by the complete milking of one or more healthy cows.

(2) Goat milk is the lacteal secretion practically free from colostrum obtained by the complete milking of one or more healthy goats. Goat milk shall only be used to manufacture dairy products that are legally provided for in 21 CFR or recognized as non-standardized traditional products normally manufactured from goat milk.

(3) Sheep milk is the lacteal secretion practically free from colostrums obtained by the complete milking of one or more healthy ewes. Sheep milk shall be produced according to the sanitary standards of this ordinance.

(4) Water buffalo milk is the normal lacteal secretion practically free of colostrums, obtained by the complete milking of one or more healthy water buffalo. Water buffalo milk shall be produced according to the sanitary standards of this ordinance.

(5) Lactating animals are cows, goats, sheep, and water buffalo producing milk for manufacturing purposes.

(6) The word "milk" used herein includes only milk, goat's milk, sheep's milk, and water buffalo milk for manufacturing purposes.

(m) *Milk for manufacturing purposes*. Milk produced for processing and manufacturing into products for human consumption but not subject to Grade A or comparable requirements.

(n) *Acceptable milk*. Milk that qualifies under sec. C2 as to sight and odor and that is classified No. 1 or No. 2 for sediment content (sec. C3.).

(o) *Probational milk*. Milk classified No. 3 for sediment content that may be accepted by plants for not over 10 days (sec. C3.).

(p) *Rejected milk*. Milk rejected from the market according to the provisions of sec. C5.

(q) *Excluded milk*. All of a producer's milk excluded from the market by the provisions of sec. C7.

(r) *Dairy products*. Butter, cheese (natural or processed), dry whole milk, nonfat dry milk, dry buttermilk, dry whey, evaporated milk (whole or skim), condensed whole milk and condensed skim milk (plain or sweetened), and such other products, for human consumption, as may be otherwise designated.

(s) *Farm certification*. Certification by an inspector or approved fieldperson that a producer's herd or flock, milking facility and housing, milking procedure, cooling, milkhouse or

milkroom, utensils and equipment and water supply have been found to meet the applicable requirements of subpart D for the production of milk to be used for manufacturing purposes.

(t) *Official methods*. "Official Methods of Analysis of the Association of Official Analytical Chemists"(AOAC), a publication of the Association of Official Analytical Chemists International, 481 North Frederick Avenue, Suite 500, Gaithersburg, MD 20877-2417.

(u) *Standard methods*. "Standard Methods for the Examination of Dairy Products", a publication of the American Public Health Association, 1015 Fifteenth Street, NW, Washington, D.C.20005.

(v) *3-A Sanitary Standards*. The latest standards for dairy equipment and accepted practices formulated by the 3-A Sanitary Standards Committees representing the International Association of Food Protection, the Federal Food and Drug Administration, and the Dairy Industry Committee. These standards are published by the International Association of Food Protection, 6200 Aurora Avenue, Suite 200 W, Des Moines, IA 50322-2863.

(w) *C-I-P or cleaned-in-place*. The procedure by which sanitary pipelines or pieces of dairy equipment are mechanically cleaned in place by circulation.

(x) *Atmosphere relatively free from mold*. No more than 10 mold colonies per cubic foot of air as determined in Standard Methods.

(y) *Sanitizing treatment*. Subjection of a clean surface to steam, hot water, hot air, or an acceptable sanitizing solution for the destruction of most human pathogens and other vegetative microorganisms to a level considered safe for product production. Such treatment shall not adversely affect the equipment, the milk, the milk product or the health of consumers. Sanitizing solutions shall comply with 21 CFR 178.1010.

Subpart C - Quality Requirements for Milk for Manufacturing Purposes

Sec. C1. *Basis*. The quality classification of raw milk for manufacturing purposes from each producer shall be based on an organoleptic examination for appearance and odor, a drug residue test and quality control tests for sediment content, bacterial estimate and somatic cell count.

Sec. C2. *Appearance and odor*. The appearance of acceptable raw milk shall be normal and free of excessive coarse sediment when examined visually or by an acceptable test procedure. The milk shall not show any abnormal condition (including but not limited to curdles, ropy, bloody or mastitic condition), as indicated by sight or other test procedures. The odor shall be fresh and sweet. The milk shall be free from objectionable feed and other off-odors that would adversely affect the finished product.

Sec. C3. *Sediment content classification*. Milk shall be classified for sediment content, regardless of the results of the appearance and odor examination described in Sec. C2. as follows:

The USDA Sediment Standard

No. 1 (acceptable) - not to exceed 0.50 mg. or equivalent.

No. 2 (acceptable) - not to exceed 1.50 mg. or equivalent.

No. 3 (probational, not over 10 days) - not to exceed 2.50 mg. or equivalent.

No. 4 (reject) - over 2.50 mg. or equivalent.

(a) *Method of testing*. Methods for determining the sediment content of the milk of individual producers shall be those described in the latest edition of Standard Methods for the Examination of Dairy Products. Sediment content shall be based on comparison with applicable charts of the United States Sediment Standards for Milk and Milk Products. These charts are available from the Dairy Standardization Branch, Dairy Programs, Agricultural Marketing Service, U.S. Department of Agriculture, Room 2746-South, P.O. Box 96456, Washington, D.C. 20090-6456.

(b) *Frequency of test*. At least once each month, at irregular intervals, the milk from each producer shall be tested as follows:

(1) *Milk in cans*. One or more cans of milk selected at random from each producer.

(2) *Milk in farm bulk tanks*. A sample shall be taken from each farm bulk tank.

(c) *Acceptance or rejection of milk*. If the sediment disc is classified as No. 1, No. 2, or No. 3, the producer's milk may be accepted. If the sediment disc is classified No. 4 the milk shall be rejected: *Provided*, That if the shipment of milk is commingled with other milk in a transport tank the next shipment shall not be accepted until its quality has been determined at the farm before being picked up; however, if the person making the test is unable to get to the farm before the next shipment it may be accepted but no further shipments shall be accepted unless the milk meets the requirements of No. 3 or better. In the case of milk classified as No. 3 or No. 4, if in cans, all cans shall be tested. Producers in No. 3 or No. 4 milk (cans or bulk) shall be notified immediately and shall be furnished applicable sediment discs and the next shipment shall be tested.(d) *Retests*.

(1) On test of the next shipment (if in cans, all cans shall be tested) milk classified as No. 1, No. 2, or No. 3, may be accepted, but No. 4 milk shall be rejected. Retests of bulk milk classified as No. 4 shall be made at the farm before pickup. The producers of No. 3 or No. 4 milk shall be notified immediately, furnished applicable sediment discs and the next shipment tested.

This procedure of retesting successive shipments and accepting probational (No. 3) milk and rejecting No. 4 milk may be continued for not to exceed 10 calendar days. If at the end of this time all of the producer's milk does not meet the acceptable sediment content classification (No. 1 or No. 2) it shall be excluded from market.

Sec. C4. *Bacterial estimate classification*.

(a) A laboratory examination to determine the bacterial estimate shall be made on each producer's milk at least once each month at irregular intervals. Samples shall be analyzed at a laboratory approved by the State regulatory agency.

(b) Milk shall be tested for bacterial estimate by using one of the following methods or by any other method approved by "Standard Methods for the Examination of Dairy Products":

(1) Direct microscopic clump count
(2) Standard plate count
(3) Plate loop count
(4) Pectin gel plate count
(5) Petrifilm™ aerobic count
(6) Spiral plate count
(7) Hydrophobic grid membrane filter count
(8) Impedance/conductance count

(c) Whenever the bacterial estimate indicates the presence of more than 500,000 bacteria per ml., the following procedures shall be applied:

(1) The producer shall be notified with a warning of the excessive bacterial estimate.

(2) Whenever two of the last four consecutive bacterial estimates exceed 500,000 per ml., the appropriate regulatory authority shall be notified and a written warning notice given to the producer. The notice shall be in effect so long as two of the last four consecutive samples exceed 500,000 per ml.

(d) An additional sample shall be taken after a lapse of 3 days but within 21 days of the notice required in paragraph (c) (2) of this section. If this sample also exceeds 500,000 per ml., subsequent milkings shall be excluded from the market until satisfactory compliance is obtained. Shipment may be resumed and a temporary status assigned to the producer by the appropriate State regulatory agency when an additional sample of herd or flock milk is tested and found satisfactory. The producer shall be assigned a full reinstatement status when three out of four consecutive bacterial estimates do not exceed 500,000 per ml. The samples shall be taken at a rate of not more than two per week on separate days within a 3-week period.

Sec. C5. *Rejected milk*. A plant shall reject specific milk from a producer if the milk fails to meet the requirements for appearance and odor (sec. C2.), if it is classified No. 4 for sediment content (sec. C3.), or if it tests positive for drug residue (sec. C12.).

Sec. C6. All reject milk shall be identified with a reject tag and colored with harmless food coloring.

Sec. C7. *Excluded milk*. A plant shall not accept milk from a producer if:

(a) The producer's initial milk shipment to a plant is classified as No. 3 for sediment content;

(b) The milk has been in a probational (No. 3) sediment content classification for more than 10 calendar days (sec. C3.);

(c) Three of the last five milk samples have exceeded the maximum bacterial estimate of 500,000 per ml. (sec. C4);

(d) Three of the last five milk samples have exceeded the maximum somatic cell count level of 750,000 per ml. (1,500,000 per ml. for goat milk) (sec. C11);

(e) The producer's milk shipments to either the Grade A or the manufacturing grade milk market currently are not permitted due to a positive drug residue test (sec. C12.).

Sec. C8. *Quality testing of milk from producers*.

(a) *New producers*.

(1) An examination and tests shall be made on the first shipment of milk from a new producer or from a producer resuming shipment after a period of non-shipment. The milk shall meet the requirements for:

(i) "Acceptable milk" (secs. C2. and C3.);

(ii) Bacterial estimate (sec. C4.);

(iii) Somatic cell count (sec. C11.); and

(iv) Drug residue level (sec. C12.).

(2) Thereafter, each milk shipment shall meet the requirements of sec. C2., and shall be tested in accordance with the provisions of secs. C3., C4., C11., and C12.

(b) *Transfer producers*.

(1) An examination and test shall be made by the new buyer on the first shipment of milk from a transfer producer. The milk shall meet the requirements for:

(i) "Acceptable milk" (secs. C2. and C3.);

(ii) Bacterial estimate (sec. C4.);

(iii) Somatic cell count (sec. C11.); and

(iv) Drug residue level (sec. C12.).

(2) Thereafter, each milk shipment shall meet the requirements of sec. C2., and shall be tested in accordance with the provisions of secs. C3., C4., C11., and C12.

(3) In addition, the new buyer shall determine from the producer's records that:

(i) The milk is currently classified "acceptable" for sediment;

(ii) Three of the last five consecutive milk samples do not exceed the maximum bacterial estimate;

(iii) Three of the last five consecutive milk samples do not exceed the maximum somatic cell count level requirements;

(iv) The last shipment of milk received from the producer by the former plant did not test positive for drug residue; and

(v) Milk shipments currently are not excluded from the market due to a positive drug residue test.

(4) When a producer discontinues milk delivery at one plant and begins delivery at another plant for any reason, the new buyer shall not accept the first milk delivery until he has requested from the previous buyer a copy of the record of:

(i) The producer's milk quality tests covering the preceding 90 days;

(ii) The producer's drug residue test results for the preceding 12-month period; and

(iii) A statement of the farm certification status and date of certification, if so provided under State regulations.

(5) The previous buyer shall furnish the new buyer with such information within 24 hours after receipt of the request. A new buyer may accept a transfer producer's milk after making the request for records, but before receiving them, if he first confirms the producer's records verbally from the previous buyer. If verbal communication is used to ascertain the status of quality records, the new buyer shall send to the previous buyer, as soon as possible, a written confirmation of the conversation.

(6) If the new buyer fails to receive the quality records from the previous buyer, he shall report this fact to the appropriate State regulatory agency. The new buyer may then, alternatively, obtain from the producer a copy of the test results for sediment content, bacterial estimate, and somatic cell count for the preceding 90-day period and a copy of the drug residue test results for the preceding 12-month period. A farm inspection shall then be made to confirm or establish certification of the transfer producer's farm.

Sec. C9. *Record of tests*.

Accurate records of the results of the milk quality and drug residue tests for each producer shall be kept on file for a period of not less than 12 months. The records shall be available for examination by the regulatory agency.

Sec. C10. *Field service*.

A representative of the plant shall arrange to promptly visit the farm of each producer whose milk tests positive for drug residue, exceeds the maximum somatic cell count level, exceeds the maximum bacterial estimate, or does not meet the requirements for acceptable milk. The purpose of the visit shall be to inspect the milking equipment and facilities, to offer assistance to improve the quality of the producer=s milk, and to eliminate any potential cause of drug residue. A review of the “Milk and Dairy Beef Quality Assurance Program” is one method that can be used to educate the producer in practices that are effective in eliminating the occurrence of drug residues in the milk. A representative of the plant should routinely visit each producer as often as necessary to assist and encourage the production of high-quality milk.

Sec. C11. *Somatic cell count*.

(a) A laboratory examination to determine the level of somatic cells shall be made on each producer's milk at least four times in each 6-month period at irregular intervals. Samples shall be analyzed at a laboratory approved by the State regulatory agency.

(b) A screening test may be conducted on goat herd milk. When a goat herd screening sample exceeds either of the following screening test results, a confirmatory test shall be conducted.

(1) California Mastitis Test - Weak Positive (CMT 1).

(2) Wisconsin Mastitis Test - WMT value of 18 mm.

(c) Milk shall be tested for somatic cell content by using one of the following procedures (confirmatory test for somatic cells in goat milk):

(1) Direct Microscopic Somatic Cell Count (Single Strip Procedure). Pyronin Y-Methyl green stain or "New York" modification shall be used for goat milk.

(2) Electronic Somatic Cell Count.

(3) Flow Cytometry/Opto-Electronic Somatic Cell Count.

(4) Membrane Filter DNA Somatic Cell Count.

(d) The results of the confirmatory test on goat milk for somatic cells shall be the official results.

(e) Whenever the official test indicates the presence of more than 750,000 somatic cells per ml. (1,500,000 somatic cell per ml. for goat milk), the following procedures shall be applied:

(1) The producer shall be notified with a warning of the excessive somatic cell count.

(2) Whenever two of the last four consecutive somatic cell counts exceed 750,000 per ml. (1,500,000 per ml. for goat milk), the appropriate regulatory authority shall be notified and a written warning notice given to the producer. The notice shall be in effect so long as two of the last four consecutive samples exceed 750,000 per ml. (1,500,000 per ml. for goat milk).

(f) An additional sample shall be taken after a lapse of 3 days but within 21 days of the notice required in paragraph (e) (2) of this section. If this sample also exceeds 750,000 per ml. (1,500,000 per ml. for goat milk), subsequent milkings shall be excluded from the market until satisfactory compliance is obtained. Shipment may be resumed and a temporary status assigned to the producer by the appropriate State regulatory agency when an additional sample of herd or flock milk is tested and found satisfactory. The producer shall be assigned a full reinstatement status when three out of four consecutive somatic cell count tests do not exceed 750,000 per ml. (1,000,000 per ml. for goat milk). The samples shall be taken at a rate of not more than two per week on separate days within a 3-week period.

Sec. C12. *Drug residue level*.

(a) *Industry responsibilities*.

(1) *Sampling and testing program*.

(i) All milk shipped for processing or intended to be processed on the farm where it was produced shall be sampled and tested, prior to processing, for beta lactam drug residue. Collection, handling and testing of samples shall be done according to procedures established by the appropriate State regulatory agency.

(ii) When so specified by the U.S. Food and Drug Administration (FDA), all milk shipped for processing, or intended to be processed on the farm where it was produced, shall be sampled and tested, prior to processing, for other drug residues under a random drug sampling program. The random drug sampling program shall include at least four samples collected in at least 4 separate months during any consecutive 6-month period.

(iii) When the Commissioner of the FDA determines that a potential problem exists with an animal drug residue or other contaminant in the milk supply, a sampling and testing program shall be conducted, as determined by the FDA. The testing shall continue until such time that the Commissioner of the FDA determines with reasonable assurance that the potential problem has been remedied.

(iv) The dairy industry shall analyze samples for beta lactams and other drug residues by methods which have been independently evaluated or evaluated by FDA and accepted by FDA as effective to detect drug residues at current safe or tolerance levels. Safe and tolerance levels for particular drugs are established by the FDA

(v) All sample test results for milk that does not test positive shall be recorded, and test result records shall be retained for a period of six months.

(2) *Individual producer sampling*.

(i) *Bulk milk*.

A milk sample for beta lactam drug residue testing shall be taken at each farm and shall include milk from each farm bulk tank.

(ii) *Can milk*.

A milk sample for beta lactam drug residue testing shall be formed separately at the receiving plant for each can milk producer included in a delivery, and shall be representative of all milk received from the producer.

(iii) *Producer/processor*.

A milk sample for beta lactam drug residue testing shall be formed separately according to paragraphs (a)(2)(i) and (ii) of this section for milk produced or received by a producer/processor.

3) *Load sampling and testing*.

(i) *Bulk milk*.

A load sample shall be taken from the bulk milk pickup tanker after its arrival at the plant and prior to further commingling.

(ii) *Can milk*.

A load sample representing all of the milk received on a shipment shall be formed at the plant, using a sampling procedure that includes milk from every can on the vehicle. iii) *Producer/processor*.

A load sample shall be formed at the plant using a sampling procedure that includes all milk produced and received.

(4) *Sample and record retention*.

A load sample that tests positive for drug residue shall be retained according to guidelines established by the appropriate State regulatory agency. The records of all positive sample test results shall be retained for a period of not less than 12 months.

(5) *Industry follow-up*.

(i) When a load sample tests positive for drug residue, industry personnel shall notify the appropriate State regulatory agency immediately, according to State policy, of the positive test result and of the intended disposition of the shipment of milk containing the drug residue. All milk testing positive for drug residue shall be disposed of in a manner that removes it from the human or animal food chain, except when acceptably reconditioned under FDA compliance policy guidelines.

(ii) Each individual producer sample represented in the positive-testing load sample shall be singly tested as directed by the appropriate State regulatory agency to determine the producer of the milk sample testing positive for drug residue. Identification of the producer responsible for producing the milk testing positive for drug residue, and details of the final disposition of the shipment of milk containing the drug residue, shall be reported immediately to the appropriate agency, according to State policy.

(iii) Milk shipment from the producer identified as the source of milk testing positive for drug residue shall cease immediately and may resume only after a sample from a subsequent milking does not test positive for drug residue.

(b) *Regulatory agency responsibilities*.

(1) *Monitoring and surveillance*.

The appropriate State regulatory agency shall monitor the milk industry's drug residue program by conducting unannounced on-site inspections to observe testing and sampling procedures and to collect samples for comparison drug residue testing. In addition, the regulatory agency shall review industry records for compliance with State policy. The review shall seek to determine that:

(i) Each producer is included in a routine, effective drug residue milk monitoring program utilizing methods evaluated and found acceptable by FDA to test samples for the presence of drug residue;

(ii) The regulatory agency receives prompt notification from industry personnel of each occurrence of a sample testing positive for drug residue, and of the identity of each producer identified as a source of milk testing positive for drug residue;

(iii) The regulatory agency receives prompt notification from industry personnel of the intended and final disposition of milk testing positive for drug residue, and that disposal of the load is conducted in a manner that removes it from the human or animal food chain, except when acceptably reconditioned under FDA compliance policy guidelines; and

(iv) Milk shipment from a producer identified as a source of milk testing positive for drug residue completely and immediately ceases until a milk sample taken from the dairy herd or flock does not test positive for drug residue.

(2) *Enforcement*.

(i) Any time milk is found to test positive for drug residue, the regulatory agency shall immediately take action to suspend the producer’s milk shipping privileges to prevent the sale of milk from the producer shipping milk testing positive for drug residue.

(ii) The producer’s milk shipping privileges may be reinstated when a representative sample taken from the producer’s milk, prior to commingling with any other milk, is no longer positive for drug residue.

(iii) A penalty sanctioned by the State regulatory agency shall be imposed on the producer for each occurrence of shipping milk testing positive for drug residue.

(iv) Whenever a drug residue test is positive, an investigation shall be made to determine the cause. Action shall be taken to prevent future occurrences.

(v) If a producer ships milk testing positive for drug residue three times within a 12-month period, the appropriate State agency shall initiate administrative procedures to suspend the producer's milk shipping privileges according to State policy.

Sec. C13. *Radionuclides*.

Composite milk samples from selected areas in each State should be tested for biologically significant radionuclides at a frequency which the regulatory agency determines to be adequate to protect the consumer.

Sec. C14. *Pesticides and herbicides*.

Composite milk samples should be tested for pesticides and herbicides at a frequency which the regulatory agency determines is adequate to protect the consumer. The test results from the samples shall not exceed established FDA limits.

Sec. C15. *Added water*.

Milk samples from each producer should be tested for added water at a frequency which the regulatory agency determines is adequate to prevent the addition of water to the milk.

Subpart D - Farm Requirements for Milk for Manufacturing

Sec. D1. *Health of herd* or flock.

(a) *General health*. All animals in the herd or flock shall be maintained in a healthy condition, and shall be properly fed and kept.

(b) *Tuberculin test*. The lactating animals shall be located in a Modified Accredited Area, an Accredited Free State, or an Accredited Free Herd or Flock as determined by the U.S. Department of Agriculture. The goats or sheep shall be located in States meeting the current USDA Uniform Methods and Rules and for Bovine Tuberculosis Eradication or an Accredited Free Goat Herd. If the animals are not located in such areas, they shall be tested annually under the jurisdiction of the aforesaid program. All additions to the herd or flock shall be from an area or from herds or flocks meeting those same requirements.

(c) *Brucellosis test*. The lactating animals shall be located in States meeting Class B status, or Certified-Free Herds, or shall be involved in a milk ring test program or blood testing program under the current USDA Brucellosis Eradication Uniform Methods and Rules. All additions to the herd or flock shall be from a State or from herds or flocks meeting these same requirements.

(d) *Abnormal milk*. Abnormal milk is milk which is ropy, stringy, clotted, thick, or abnormal in any way. It includes milk containing pesticides, insecticides, or medicinal agents. Regular equipment may be used but not until all other animals are milked.

Sec. D2. *Milking facility and housing*.

(a) A milking barn or milking parlor of adequate size and arrangement shall be provided to permit normal sanitary milking operations. It shall be well lighted and ventilated, and the floors and gutters in the milking area shall be constructed of concrete or other impervious material maintained free of breaks or depressions. The facility shall be kept clean, the manure removed daily and stored to prevent access of lactating animals to accumulation thereof; and no swine or fowl shall be permitted in any part of the milking area.

(b) Floors for a sheep milking facility shall be constructed of concrete or equally impervious material maintained free of breaks or depressions. They must be sloped to drain properly. Joints between floor and wall shall be water tight.

Ramps and platforms used to elevate goats or sheep must be constructed of an impervious material such as steel (wooden platforms and ramps are not allowed). Rubber cow mats may be used as long as they are not placed over a wooden platform. Sheep are generally housed in a loose house building near the milking parlor. This area should be kept reasonably clean. No excessive accumulation of manure is allowed. Complete separation between the sheep housing area and the sheep milking parlor is required if sheep milker units are stored in the parlor. Hogs and fowl shall not be housed with sheep.

(c) If milk is exposed during straining or transferring in the milking areas it shall be protected from falling particles from areas above milk facility.

(d) The yard or loafing area shall be of ample size to prevent overcrowding, shall be drained to prevent forming of standing water pools, insofar as practicable, and shall be kept clean.

Sec. D3. *Milking procedure*.

(a) The udders and flanks of all lactating animals shall be kept clean. The udders and teats shall be washed or wiped immediately before milking with a clean, damp cloth or paper towel moistened with a sanitizing solution and wiped dry, or by any other sanitary method.

(b) The milker's outer clothing shall be clean and his hands clean and dry. No person with an infected cut or open sores on their hands or arms shall milk lactating animals, or handle milk or milk containers, utensils or equipment.

(c) Lactating animals which secrete abnormal milk shall be milked last or with separate equipment. This milk shall be excluded from the supply as required in section D 1.

(d) Milking equipment used for handling abnormal milk must be washed and sanitized after each use.

(e) Abnormal milk must not be squirted on the floor, on the platform or in the producer’s hand. Producer should also wash their hands after handling such equipment and handling the teats and udders of animals producing abnormal milk.

(f) Milk stools, surcingles and antikickers shall be kept clean and properly stored. Dusty operations should not be conducted immediately before or during milking. Strong flavored feeds should only be fed after milking.

Sec. D4. *Cooling* and storage.

(a) Milk in cans shall be cooled immediately after milking (to 50°F . or lower) [2] unless delivered to the plant within 2 hours after milking. The cooler, tank, or refrigerated unit shall be kept clean.

(b) Milk in farm bulk tanks shall be cooled to 40 º F. or lower within 2 hours after milking and maintained at 50 º F. or lower until transferred to the transport tank.

(c) Milk in plastic bags shall be cooled to 40º F or lower within two hours of milking. Sheep milk shall be cooled to 45 º F or lower within (2) hours of milking. Cooling water used in bulk tanks in which bags of sheep milk are cooled shall be chlorinated. If milk is cooled by pouring into plastic bags and then floating the bags of milk in cooling water, the process must preclude contamination of the milk by the water. All water must be safe and of sanitary quality in accordance to Sec D7.

(d) Bags used to store frozen sheep milk shall be constructed of plastic that is listed under the NCIMS Certified Manufacturers of Single-Service Containers and Related Products.

(e) Bags may be up to 5 gallons in size. Each bag shall be numbered, dated, and identified with a patron name or number.

(f) Frozen Milk should remain frozen at 0°F or less for a period not to exceed 12 months.

Sec. D5. *Milkhouse or milkroom*.

(a) A milkhouse or milkroom must be provided for storage and cooling of milk and proper cleaning and storage of equipment. Other products shall not be handled in the milkroom which would be likely to contaminate milk, or otherwise create a public health hazard The milkhouse area is the area that needs to be modified to meet the particular needs of sheep milking operations. The following requirements apply to a milkhouse whether or not a bulk tank is used: milk may not be placed directly in the freezer prior to cooling.

Natural and/or artificial light shall be provided in all working areas for conducting milkhouse operations. At least 20 foot candles of artificial light are required in a milking parlor. Parlors must be properly ventilated in order to prevent excessive condensation and odors. Light fixtures shall not be installed directly above bulk milk tanks, areas where milk may be strained, or areas where equipment is stored.

(b) A double compartment wash sink with hot and cold running water plumbed to the sink is required. It shall be equipped with utensil rack, milk cooling facilities and have an adequate supply of hot water available for cleaning milking equipment. Each compartment must be large enough to accommodate the largest piece of equipment. Hot water heaters or hot water supply systems for use in the milkhouse or milk room shall have a capacity of at least 30 gallons

[2]Until 3 years after adoption, the temperature requirement for milk placed in cans will be 60□F.

for the manual washing of equipment. Clean in place washing of pipelines, units, and bulk tanks requires the capacity of 75 gallons. Water under pressure must be piped into the milkhouse to perform cleaning of the equipment. If a part of the barn or other building, it shall be partitioned, screened, and sealed to prevent the entrance of dust, flies, or other contamination. A milking parlor used strictly as a milking facility in combination with a milkhouse or milkroom, when properly equipped, arranged and maintained, need not be partitioned. Concentrates and feed, if stored in the building, shall be kept in a tightly covered box or bin. The floor of the building shall be of concrete or other impervious material and graded to provide proper drainage. Walls and ceilings must be reasonably smooth and be painted or whitewashed or have other acceptable finish; it shall be kept in good repair and surfaces shall be finished whenever wear or discoloration is evident. Ceilings must be dust tight. Hay or straw chutes must have dust-tight doors that must be kept closed during milking. All outside doors shall open outward and be self-closing, unless they are provided with tight-fitting screen doors that open outward or unless other effective means are provided to prevent the entrance of flies.

(c) If a farm bulk tank is used, it shall be properly located in the milkhouse or milkroom for access to all areas for cleaning and servicing. It shall not be located over a floor drain or under a ventilator.

(d) A small platform or slab constructed of concrete or other impervious material shall be provided outside the milkhouse, properly centered under a suitable port opening in the wall for milkhouse connections. The opening shall be fitted with a tight, self-closing door. The truck approach to the milkhouse or milkroom shall be properly graded and surfaced to prevent mud or pooling of water at point of loading.

(e) The milkhouse or milkroom shall be kept clean and free of trash. Animals and fowl shall not be allowed access to the milkhouse or milkroom at any time.

(f) *Farm chemicals and animal drugs*.

(1) Animal biologics and other drugs intended for treatment of animals, and insecticides approved for use in dairy operations, shall be clearly labeled and used in accordance with label instructions, and shall be stored in a manner which will prevent accidental contact with milk and milk contact surfaces.

(2) Only drugs that are approved by the FDA or biologics approved by the USDA for use in dairy animals that are properly labeled according to FDA or USDA regulations shall be administered to such animals.

(3) When drug storage is located in the milkroom, milkhouse, or milking area, the drugs shall be stored in a closed, tight-fitting storage unit. Such drugs shall further be segregated in such a way so that drugs labeled for use in lactating dairy animals are separated from drugs labeled for use in non-lactating dairy animals.

(4) Drugs labeled for use in non-dairy animals shall not be stored with drugs labeled for use in dairy animals. When drugs labeled for use in non-dairy animals are stored in the barn, the drugs shall be located in an area of the barn separate from the milking area.

(5) Herbicides, fertilizers, pesticides, and insecticides that are not approved for use in dairy operations shall not be stored in the milkhouse, milkroom, or milking area.

Sec. D6. *Utensils and equipment*.

(a) Utensils, milk cans, milking machines (including pipeline systems), and other equipment used in the handling of milk shall be maintained in good condition, shall be free from rust, open seams, milkstone, or any unsanitary condition, and shall be washed, rinsed, and drained after each milking, stored in suitable facilities, and sanitized immediately before use with at least 50 p.p.m. chlorine solution or its equivalent. New or replacement can lids shall be umbrella type. All new utensils and equipment shall comply with applicable 3-A Sanitary Standards. Milk contact surfaces shall be made of stainless steel of the 300 series, equally corrosion-resistant non-toxic metals or heat-resistant glass. Plastic or rubber-like material must be relatively inert and resistant to scoring, chipping, or decomposition and it must be non-toxic and not impair flavor or odor to the product. All milk contact material must be easily cleaned and must be cleaned after each use. Sanitizers must be an approved type with full label directions. Syringes and bolus guns shall be stored in a manner to preclude any contamination of milk or milk contact surfaces. All containers and utensils must be free from breaks and corrosion, and points must be free from pits or cracks. Bulk tank and freezer thermometers should be accurate within 2 degrees Fahrenheit. All milk containers and equipment, including milking machine vacuum hoses, must be stored in the milkhouse. Milking equipment must be stored to assure complete drainage. Filters and single-service plastic bags shall be stored in the original container inside a protective box. Bags for milk storage must be stored in a manner which protects them from contamination. It is recommended they be stored in an enclosed cabinet.

(b) Farm bulk tanks shall meet 3-A Sanitary Standards for construction at the time of installation and shall be installed in accordance with regulations of the regulatory agency.

(c) Single service articles shall be properly stored and shall not be reused.

Sec. D7. *Water supply*. The dairy farm water supply shall be properly located, protected, and operated, and shall be easily accessible, ample, and of safe, sanitary quality for the cleaning of dairy utensils and equipment. The water supply shall come from a source which is approved by the State regulatory authority; or from a spring, dug well, driven well, bored well, or drilled well, the water from which complies with the standards of the State regulatory authority. A source that does not conform with the construction requirements of the State regulatory authority, but is tested annually by an approved laboratory and found to be safe and of sanitary quality shall be satisfactory: *Provided*, That after adoption of this regulation any new sources of water supply or any farm water supply requiring repairs or reconstruction or any source from which tested samples have been found unsatisfactory shall meet the construction requirements of the State regulatory authority.

Sec. D8. *Sewage disposal*. House, milkhouse or milkroom and toilet wastes shall be disposed of in a manner that will not pollute the soil surface, contaminate any water supply, or be exposed to insects.

Sec. D9. *Qualifications for farm certification*. Farm certification requires satisfactory compliance with the requirements in Subpart D.

Subpart E---Requirements for Licensed Dairy Plants

Sec. E1. *General Requirements*.

Sec E 1.1. *Premises.*

(a) The premises shall be kept in a clean and orderly condition, and shall be free from strong or foul odors, smoke, or excessive air pollution. Construction and maintenance of driveways and adjacent plant traffic areas shall be of concrete, asphalt, or similar material to keep dust and mud to a minimum.

(b) Surroundings: The adjacent surroundings shall be free from refuse, rubbish, and waste materials to prevent harborage of rodents, insects and other vermin.

(c) Drainage: A suitable drainage system shall be provided which will allow rapid drainage of all water from plant buildings and driveways, including surface water around the plant and on the premises, and all such water shall be disposed of in such a manner as to prevent a nuisance or health hazard.

E 1.2. *Buildings.* The building or buildings shall be of sound construction and shall be kept in good repair to prevent the entrance or harboring of rodents, birds, insects, vermin, dogs, and cats. All service pipe openings through outside walls shall be effectively sealed around the opening or provided with tight metal collars.

(a) *Outside doors, windows, openings, etc.* All openings to the outer air including doors, windows, skylights, and transoms shall be effectively protected or screened against the entrance of flies and other insects, rodents, birds, dust, and dirt. All outside doors opening into processing rooms shall be in good condition and fit properly. All hinged, outside screen doors shall open outward. All doors and windows shall be kept clean and in good repair. Outside conveyor openings and other special-type outside openings shall be effectively protected to prevent the entrance of flies and rodents, by the use of doors, screens, flaps, fans, or tunnels. Outside openings for sanitary pipelines shall be covered when not in use. On new construction, window sills should be slanted downward at a 45^0 angle.

(b) *Walls, ceilings, partitions, and posts.* The walls, ceilings, partitions, posts of rooms in which milk or dairy products are processed, manufactured, handled, packaged, or stored (except dry storage of packaged finished products and supplies) or in which utensils are washed and stored, shall be smoothly finished with a suitable material of light color, which is substantially impervious to moisture and kept clean. They shall be refined as often as necessary to maintain a neat, clean surface.

(c) *Floors*.

(1) The floors of all rooms in which milk or dairy products are processed, manufactured, packaged, or stored or in which utensils are washed shall be constructed of tile properly laid with

impervious joint material, concrete, or other equally impervious material. The floors shall be smooth, kept in good repair, graded so that there will be no pools of standing water or milk products after flushing, and all openings to the drains shall be equipped with traps properly constructed and kept in good repair. On new construction bell-type traps shall not be used. The plumbing shall be so installed as to prevent the backup of sewage into the drain lines and to the floor of the plant.

(2) Sound, smooth wood floors which can be kept clean, may be used in rooms where new containers and supplies and certain packaged finished products are stored.

(d) *Lighting and ventilation*.

(1) Light shall be ample, natural or artificial, or both, of good quality and well distributed. All rooms in which dairy products are manufactured or packaged or where utensils are washed shall have at least 30 foot-candles of light intensity on all working surfaces and at least 50 foot-candles of light intensity in areas where dairy products are graded or examined for condition and quality. In all other rooms there shall be provided at least 5 foot-candles of light intensity when measured at a distance of 30 inches from the floor. Where contamination of product by broken glass is possible, light bulbs, fluorescent tubes, fixtures, skylight, or other glass suspended over the product shall be protected against breakage.

(2) There shall be adequate heating, ventilation, or air conditioning for all rooms and compartments to permit maintenance of sanitary conditions. Exhaust or inlet fans, vents, hoods, or temperature and humidity control facilities shall be provided where and when needed, to minimize or eliminate undesirable room temperatures, objectionable odors, moisture condensation, or mold. Inlet fans should be provided with an adequate air filtering device to eliminate dirt and dust from incoming air. Ventilation systems shall be cleaned periodically as needed and maintained in good repair. Exhaust outlets shall be screened or provided with self-closing louvers to prevent the entrance of insects when not in use.

(e) *Rooms and compartments*. Rooms and compartments in which any raw material, packaging, ingredient supplies, or dairy products are handled, manufactured, packaged, or stored shall be so designed, constructed, and maintained as to assure desirable room temperatures and clean and orderly operating conditions free from objectionable odors and vapors. Enclosed bulk milk receiving rooms when present shall be separated from the processing rooms by a partition. Rooms for receiving can milk shall be separated from the processing rooms by a partition (partial or complete) by suitable arrangement of equipment or by allowing enough distance between receiving and processing operations to avoid possible contamination of milk or dairy products during manufacturing and handling. Processing rooms shall be kept free from equipment and materials not regularly used.

(1) *Coolers and freezers.* Coolers and freezers where dairy products are stored shall be clean, reasonably dry and maintained at the proper uniform temperature and humidity to adequately protect the product, and minimize the growth of mold. Adequate circulation of air shall be maintained at all times. They shall be free from rodents, insects, and pests. Shelves shall be kept clean and dry. Refrigeration units shall have provisions for collecting and disposing of condensate.

(2) *Supply Room*. The supply rooms used for the storing of packaging materials, containers, and miscellaneous ingredients shall be kept clean, dry, orderly, free from insects, rodents, and mold and maintained in good repair. Such items stored therein shall be adequately protected from dust, dirt, or other extraneous matter and so arranged on racks, shelves, or pallets to permit access to the supplies and cleaning and inspection of the room. Insecticides, rodenticides, cleaning compounds, and other nonfood products shall be properly labeled and segregated, and stored in a separate room or cabinet away from milk, dairy products, ingredients, or packaging supplies.

(3) *Boiler and tool rooms*. The boiler and tool rooms shall be separated from other rooms where milk and dairy products are processed, manufactured, packaged, handled, or stored. Such rooms shall be kept orderly and reasonably free from dust and dirt.

(4) *Toilet and dressing* rooms. Adequate toilet and dressing room facilities shall be conveniently located.

(i) Toilet rooms shall not open directly into any room in which milk or dairy products are processed, manufactured, packaged, or stored; doors shall be self-closing; ventilation shall be provided by mechanical means or screened openings to the outer air; fixtures shall be kept clean and in good repair.

(ii) All employees shall be furnished with a locker or other suitable facility and the lockers and dressing rooms shall be kept clean and orderly. Adequate hand-washing facilities shall be provided and curable, legible signs shall be posted conspicuously in each toilet or dressing room directing employees to wash their hands before returning to work.

(5) *Laboratory*. Consistent with the size and type of plant and the volume of dairy products manufactured, an adequately equipped laboratory shall be maintained and properly staffed with qualified and trained personnel for quality control and analytical testing. A central laboratory serving more than one plant may be acceptable if conveniently located to the dairy plants and if samples and results can be transmitted without undue delay.

(6) *Starter facilities.* Adequate sanitary facilities shall be provided for the handling of starter cultures.

E 1.3 *Facilities.*

(a) *Water* supply.

(1) There shall be an ample supply of both hot and cold water of safe and sanitary quality, with adequate facilities for its proper distribution throughout the plant, and protection against contamination and pollution. Water from other facilities, when officially approved, may be used for boiler feed water and condenser water provided that such waterlines are completely separated from the waterlines carrying the sanitary water supply, and the equipment is so constructed and controlled as to preclude contamination of product contact surfaces. There is no cross connection between the safe water supply and any unsafe or questionable water supply, or any other source of pollution through which contamination of the safe water supply is possible. Bacteriological examination shall be made of the sanitary water supply at least twice a year, or as often as necessary to determine purity and suitability for use in manufacturing dairy products. Such tests shall be made by the State regulatory agency except for supplies that are regularly tested for purity and bacteriological quality, and approved by the appropriate regulatory officer. The results of all water tests shall be kept on file at the plant for which the test was performed.

(2) The location, construction and operation of any well shall comply with regulations of the appropriate agency.

(b) *Drinking water facilities.* Drinking water facilities of a sanitary type shall be provided in the plant and shall be conveniently located.

(c) *Hand-washing facilities.* Convenient hand-washing facilities shall be provided, including hot and cold running water, soap or other detergents, and sanitary single-service towels or air dryers. Such accommodations shall be located in or adjacent to toilet and dressing rooms and also at such other places in the plant as may be essential to the cleanliness of all personnel handling products. Vats for washing equipment or utensils shall not be used as handwashing facilities. Self-closing metal or plastic containers shall be provided for used towels and other wastes.

(d) *Steam*. Steam shall be supplied in sufficient volume and pressure for satisfactory operation of each applicable piece of equipment. Culinary steam used in direct contact with milk or dairy products shall be free from harmful substances or extraneous material and only nontoxic boiler compounds shall be used, or a secondary steam generator shall be used in which soft water is converted to steam and no boiler compounds are used. Steam traps, strainers, and condensate traps shall be used wherever applicable to insure a satisfactory and safe steam supply. Culinary steam shall comply with the recommended practices for "Producing Culinary Steam for Processing Milk and Milk Products" as published by the National Association of Dairy Equipment Manufacturers, Washington, D.C., April 1963 or latest revision thereof.

(e) *Air under pressure*. The method for supplying air under pressure which comes in contact with milk or dairy products or any product contact surface shall comply with the 3-A Accepted Practices for Supplying Air Under Pressure. The air used at the point of application shall be free from volatile substances, volatiles which may impart any flavor or odor to the products, and extraneous or harmful substances.

(f) *Disposal of wastes.* Dairy wastes shall be properly disposed of from the plant and premises. The sewer system shall have sufficient slope and capacity to readily remove all waste from the various processing operations. Where a public sewer is not available, all wastes shall be properly disposed of so as not to contaminate milk equipment or to create a nuisance or public health hazard. Containers used for the collection and holding of wastes shall be constructed of metal, plastic, or other equally impervious material and kept covered with tightfitting lids and placed outside the plant on a concrete slab or on a rack raised at least 12 inches. Alternatively waste containers may be kept inside a suitably enclosed, clean and flyproof room. Solid wastes shall be disposed of regularly and the containers cleaned before reuse. Accumulation of dry wastepaper and cardboard shall be kept to a minimum. The paper shall be burned at the plant in a properly constructed incinerator, or compressed or bagged and hauled away.

E 1.4 *Equipment and utensils.*

(a) *General construction, repair, and installation*.

(1) The equipment and utensils used for the processing of milk and manufacture of dairy products shall be constructed to be readily demountable where necessary for cleaning and sanitizing. The product contact surfaces of all utensils and equipment such as holding tanks, pasteurizers, coolers, vats, agitators, pumps, sanitary piping, and fittings or any specialized equipment shall be constructed of stainless steel, or other equally corrosion-resistant material. Nonmetallic parts other than glass having product contact surfaces shall meet 3-A Sanitary Standards for Plastic or Rubber and Rubberlike Materials.

(2) All equipment and piping shall be designed and installed so as to be easily accessible for cleaning, and shall be kept in good repair, free from cracks and corroded surfaces. New or rearranged equipment shall be set away from any wall or spaced in such a manner as to facilitate proper cleaning and to maintain good housekeeping. All parts or interior surfaces of equipment, pipes (except certain piping cleaned in place) or fittings, including valves and connections, shall be accessible for inspection. Milk and dairy product pumps shall be of a sanitary type and easily dismantled for cleaning or shall be of specially approved construction to allow effective cleaning in place.

(3) All CIP systems shall comply with the 3-A Sanitary Practices for Permanently Installed Sanitary Product, Pipelines, and Cleaning Systems.

(b) *Weigh cans and receiving tanks.* Weigh cans and receiving tanks shall meet the 3-A Sanitary Standards and shall be easily accessible for cleaning both inside and outside and shall be elevated above the floor and protected sufficiently with the necessary covers or baffles to prevent contamination from splash, condensate, and drippage. Where necessary to provide easy access for cleaning of floors and adjacent wall areas, the receiving tank shall be equipped with wheels or casters to allow easy removal.

(c) *Can washers.* Can washers shall have sufficient capacity and ability to discharge a clean, dry can and cover and shall be kept properly timed in accordance with the instructions of the manufacturer. The water and steam lines supplying the washer shall maintain a reasonably uniform pressure and if necessary be equipped with pressure regulating valves.

(d) *Product storage tanks or vats.* Storage tanks or vats shall be fully enclosed or tightly covered and well insulated. The entire interior surface, agitator and all appurtenances shall be accessible for thorough cleaning and inspection. Any opening at the top of the tank or vat including the entrance of the shaft shall be suitably protected against the entrance of dust, moisture, insects, oil, or grease. The sight glasses, if used, shall be sound, clean, and in good repair. Vats which have hinged covers shall be so designed that moisture or dust on the surface cannot enter the vat when the covers are raised. If the storage tanks or vats are equipped with air agitation, the system shall be of an approved type and properly installed in accordance with the 3-A Accepted Practices for Supplying Air Under Pressure. Storage tanks or vats intended to hold product for longer than approximately 8 hours shall be equipped with adequate refrigeration and/or have adequate insulation. All new storage tanks or vats shall meet the appropriate 3-A Sanitary Standards and shall be equipped with thermometers in good operating order.

(e) *Separators.* All product contact surfaces of separators shall be free from rust and pits and insofar as practicable shall be of stainless steel or other equally noncorrosive metals.

(f) *Coil or dome-type batch pasteurizers.* Coil or dome-type batch pasteurizers shall be stainless steel lined and if the coil is not stainless steel or other equally noncorrosive metal it shall be properly tinned over the entire surface. Sanitary seal assemblies at the shaft ends of coil vats shall be of the removable type, except that existing equipment not provided with this type gland will be acceptable if the packing glands are maintained and operated without adverse effects. New or replacement units shall be provided with removable packing glands. Dome-type Pasteurizer agitators shall be stainless steel except that any nonmetallic parts shall meet 3-A Sanitary Standards for Plastic or Rubber and Rubberlike Materials, as applicable. Each pasteurizer used for heating product at 165^0 F. or lower for 30 minutes or less shall be equipped with space heating equipment and the necessary thermometers to insure a temperature at least 5^0 F. above that required for pasteurization of the product. There shall be adequate means of controlling the temperature of the heating medium. Batch pasteurizers shall have temperature indicating and recording devices.

(g) *High-temperature, short-time pasteurizers*. When pasteurization is intended or required, an approved timing pump or device recorder-controller, automatic flow diversion valve and holding tube or its equivalent, if not a part of the existing equipment, shall be installed on all HTST equipment used for pasteurization, to assure complete pasteurization. The entire facility shall meet the 3-A Accepted Practices for the Sanitary Construction, Installation, Testing, and Operation of High-Temperature, Short-Time Pasteurizers. After the HTST unit has been tested according to the 3-A Accepted Practices, the timing pump or device and the recorder controller shall be sealed at the correct setting to assure pasteurization. Sealing of the HTST unit shall be performed by the control authority having jurisdiction. The HTST pasteurizer shall be tested initially upon installation, and whenever any alteration or replacement is made which affects the proper operation of the instrument or device. When direct steam pasteurizers are used, the steam, prior to entering the product, shall be conducted through a steam strainer and a steam purifier equipped with a steam trap and only steam meeting the requirements for culinary steam shall be used.

(h) *Thermometers and recorders.*

(l) *Indicating thermometers*.

(i) Long-stem indicating thermometers which are accurate within 0.5^0 F., plus or minus, for the applicable temperature range, shall be provided for checking the temperature of pasteurization and cooling of products in vats and checking the accuracy of recording thermometers.

(ii) Short-stem indicating thermometers, which are accurate within 0.5^0 F., plus or minus, for the applicable temperature range, shall be installed in the proper stationary position in all HTST, and dome-type pasteurizers. Storage tanks where temperature readings are required shall have thermometers which are accurate within 2.0^0 F., plus or minus.

(iii) Air-space indicating thermometers, where applicable, which are accurate within 1.0^0 F., plus or minus, for the proper temperature range shall also be installed above the

surface of the products pasteurized in vats, to make certain that the temperature of the foam and/or air above the products pasteurized also received the required minimum temperature treatment.

(2) *Recording thermometers.*

(i) HTST recording thermometers that are accurate within 1^0 F., plus or minus, for the applicable temperature range, shall be used on each heat treating, pasteurizing, or sterilizing unit to record the heating process.

(ii) Additional use of recording thermometers accurate within 2^0 F., plus or minus, may be required where a record of temperature or time of cooling and holding is of significant importance.

(i) *Surface coolers.* Surface coolers shall be equipped with hinged or removable covers for the protection of the product. The edges of the fins shall be so designed as to divert condensate on nonproduct contact surfaces away from product contact surfaces. All gaskets or swivel connections shall be leak proof.

(j) *Plate-type heat exchangers.* Plate-type heat exchangers shall meet the 3-A Sanitary Standards for Construction and Installation. All gaskets shall be tight and kept in good operating order. Plates shall be opened for inspection by the operator at sufficiently frequent intervals to determine if the equipment is clean and in satisfactory condition. A cleaning regimen shall be posted to insure proper cleaning procedures between inspection periods.

(k) *Internal return tubular heat exchangers*. Internal return tubular heat exchangers shall meet the 3-A Sanitary Standards for Construction and Installation.

(l) *Pumps*. Pumps used for milk and dairy products shall be of the sanitary type and constructed to meet 3-A Sanitary Standards. Unless pumps are specifically designed for effective cleaning in place they shall be disassembled and thoroughly cleaned after use.

(m) *Homogenizers.* Homogenizers and high pressure pumps of the plunger type shall meet the 3-A Sanitary Standards.

(n) *New equipment and replacements*. New equipment and replacements, including all plastic parts and rubber and rubberlike materials for parts and gaskets having product contact surfaces, shall meet the then current 3-A Sanitary Standards. If 3-A Sanitary Standards are not available, such equipment and replacements shall meet the general requirements of this section.

(o) *Vacuum chamber*. The vacuum chamber, as used for flavor control, shall be made of stainless steel or other equally noncorrosive metal. The unit shall be constructed to facilitate cleaning and all product contact surfaces shall be accessible for inspection. It shall be equipped with a vacuum breaker and a check valve at the product discharge line. Only steam which meets the requirements for culinary steam shall be used. The incoming steam supply shall be regulated by an automatic solenoid valve which will cut off the steam supply in the event the flow

diversion valve of the HTST pasteurizer is not in the forward flow position. Condensers when used shall be equipped with a water level control and an automatic safety shutoff valve.

E 1.5 *Personnel cleanliness.* All employees shall wash their hands before beginning work and upon returning to work after using toilet facilities, eating, smoking, or otherwise soiling their hands. They shall keep their hands clean and follow good hygienic practices while on duty. Expectorating or use of tobacco in any form shall be prohibited in each room and compartment where any milk, dairy product, or supplies are prepared, stored, or otherwise handled. Clean white or light-colored washable outer garments and caps (paper caps or hair nets acceptable) shall be worn by all persons engaged in receiving, testing, processing milk, manufacturing, packaging, or handling dairy products.

E 1.6 *Personnel health.* No person afflicted with a communicable disease shall be permitted in any room or compartment where milk and dairy products are prepared, manufactured, or otherwise handled. No person who has a discharging or infected wound, sore or lesion on hands, arms, or other exposed portion of the body shall work in any dairy processing rooms or in any capacity resulting in contact with milk or dairy products. Each employee whose work brings him in contact with the processing or handling of dairy products, containers, or equipment shall have a medical and physical examination by a registered physician or by the local department of health at the time of employment. In addition an employee returning to work following illness from a communicable disease shall have a certificate from the attending physician to establish proof of complete recovery. Medical certificates attesting the fact that the employee when last examined was free from communicable disease shall be kept on file at the plant office.

E 1.7 *Protection and transport of raw milk and cream.*

(a) *Equipment and facilities.*

(l) *Milk cans*. Cans used in transporting milk from dairy farm to plant shall be of such construction (preferably seamless with umbrella lids) as to be easily cleaned, and shall be inspected, repaired, and replaced as necessary to exclude substantially the use of cans and lids with open seams, cracks, rust milkstone, or any unsanitary condition.

(2) *Farm bulk tanks*. New farm bulk tanks shall meet 3-A Sanitary Standards for construction and shall be installed in accordance with the requirements of the regulatory agency in jurisdiction.

(b) *Transporting milk or cream.*

(1) *Vehicles.* Vehicles used for the transportation of can milk or cream shall be of the enclosed type, constructed and operated to protect the product from extreme temperature, dust, or other adverse conditions and they shall be kept clean. Decking boards or racks shall be provided where more than one tier of cans is carried. Cans or bulk tanks on vehicles, used for the transportation of milk from the farm to the plant shall not be used for any other purpose.

(2) *Transport tanks*. The exterior shell shall be clean and free from open seams or cracks which would permit liquid to enter the jacket. The interior shell shall be stainless steel and so constructed that it will not buckle, sag, or prevent complete drainage. All product contact

surfaces shall be smooth, easily cleaned, and maintained in good repair. The pump and hose cabinet shall be fully enclosed with tight fitting doors and the inlet and outlet shall be provided with dust covers to give adequate protection from road dust. New and replacement transport tanks shall meet 3-A Sanitary Standards for Milk Transport Tanks.

(c) *Facilities for cleaning and sanitizing*. Enclosed or covered facilities shall be available for washing and sanitizing of transport tanks, piping and accessories, at central locations or at all plants that receive or ship milk or milk products in transport tanks.

(d) *Transfer of milk to transport tank*. Milk shall be transferred under sanitary conditions from farm bulk tanks through stainless steel piping or approved tubing. The sanitary piping and tubing shall be capped when not in use.

E 1.8 *Raw product storage.*

(a) All milk shall be held and processed under conditions and at temperatures that will avoid contamination and rapid deterioration. Drip milk from can washers or any other source shall not be used for the manufacture of dairy products. Bulk milk in storage tanks within the dairy plant shall be handled in such a manner as to minimize bacterial increase and shall be maintained at 45^0 F. or lower until processing begins. This does not preclude holding milk at higher temperatures for a period of time, where applicable to particular manufacturing or processing practices.

(b) The bacteriological estimate of commingled milk in plant storage tanks shall be 1 million per milliliter or lower.

(c) During any consecutive six months, at least four (4) samples of commingled raw milk for processing shall be taken by the regulatory agency from each plant.

(d) A laboratory test of these samples to determine the bacterial estimate shall be performed at a laboratory approved by the regulatory agency.

(e) Whenever a bacterial estimate of commingled milk in a plant indicates the presence of more than 1 million per milliliter, the following procedures shall be applied:

(1) The regulatory agency shall notify plant management with a warning of excessive bacterial estimate, and recommend that appropriate action be taken to eliminate the bacterial problem.
(2) Whenever two of the last four consecutive commingled milk bacterial estimates exceed 1 million per milliliter, the regulatory agency shall notify plant management with a written warning notice. The notice shall be in effect so long as two of the last four consecutive samples exceed 1 million per milliliter. Plant management should continue to work to eliminate the bacterial problem.
(3) An additional sample shall be taken by the regulatory agency after a lapse of 3 days but within 21 days of the notice required in paragraph (e) (1) of this section.

If this sample also exceeds 1 million per milliliter, the plant license shall be suspended. A temporary status may be assigned to the plant by the appropriate regulatory agency when an additional sample of commingled milk is tested and found satisfactory. The plant shall be assigned a full reinstatement status when three out of four consecutive commingled bacterial estimates do not exceed 1 million per milliliter. The samples shall be taken at a rate of not more than two per week on separate days within a 3-week period.

(4) If a plant remains in temporary status in excess of 60 days, administrative procedures to suspend the plant's license will be taken by the appropriate regulatory authority until the plant complies with the bacteriological requirements.

E 1.9 Heat treated cream. Heat treated cream is cream in which the product may be heated to less than 160 degrees Fahrenheit in a continuing heating process and immediately cooled to 45 degrees Fahrenheit or less for a functional reason.

E 1.10 *Pasteurization or sterilization*. When pasteurization or sterilization is intended or required, or when a product is designated "pasteurized" or "sterilized" every particle of the product shall be subjected to such temperatures and holding periods as will assure proper pasteurization or sterilization of the product. The heat treatment by either process shall be sufficient to insure public health safety and to assure adequate keeping quality, yet retaining the most desirable flavor and body characteristics of the finished product. The phenol value of test samples of pasteurized finished product shall be no greater than the maximum specified for the particular product as determined and specified by the phosphatase test method prescribed in the latest edition of "Official Methods of Analysis of the Association of Official Agricultural Chemists."

E 1.11 *Composition and wholesomeness.* All necessary precautions shall be taken to prevent contamination or adulteration of the milk or dairy products during manufacturing. All substances and ingredients used in the processing or manufacturing of any dairy product shall be subject to inspection and shall be wholesome and practically free from impurities. The finished product shall comply with the requirements of the Federal Food, Drug, and Cosmetic Act as to their composition and wholesomeness.

E 1.12 *Cleaning and sanitizing treatment.*

(a) *Equipment and utensils*.

(1) The equipment, sanitary piping and utensils used in receiving and processing of the milk, and manufacturing and handling of the product shall be maintained in a sanitary condition. Sanitary seal assemblies shall be removable on all agitators, pumps and vats, and shall be inspected at regular intervals and kept clean. Unless other provisions are recommended in the following supplemental sections, all equipment not designed for C.1.P. cleaning shall be disassembled after each day's use for thorough cleaning. Dairy cleaners, detergents, wetting agents, sanitizing agents or other similar materials which will not contaminate or adversely affect the products may be used. Steel wool or metal sponges shall not

be used in the cleaning of any dairy equipment or utensils. All product contact surfaces shall be subjected to an effective sanitizing treatment immediately prior to use, except where dry cleaning is permitted. Utensils and portable equipment used in processing and manufacturing operations shall be stored above the floor in clean, dry locations and in a self draining position on racks constructed of impervious corrosion resistant material.

(2) C.I.P. cleaning, including sprayball systems shall be used only on equipment and pipeline systems which have been designed and engineered for that purpose. When such cleaning is used, careful attention shall be given to the proper procedures to assure satisfactory cleaning. All C.I.P. installations and cleaning procedures shall be in accordance with 3-A Suggested Methods for the Installation and Cleaning of Cleaned-In-Place Sanitary Milk Pipelines for Milk and Milk Products Plants. The established cleaning procedure shall be posted and followed. Following the circulation of the cleaning solution the equipment and lines shall be thoroughly rinsed with lukewarm water and checked for effectiveness of cleaning. All caps, plugs, special fittings, valve seats, cross ends, pumps, plates, and tee ends shall be opened or removed and brushed clean. Immediately prior to starting the product flow, the product contact surfaces shall be given bactericidal treatment.

(b) *Milk cans and can washers.*

(1) Milk cans and lids shall be cleaned, sanitized, and dried before returning to producers. Inspection, repair, or replacement of cans and lids shall be adequate to substantially exclude from use cans and lids showing open seams, cracks, rust condition, milkstone or any unsanitary condition.

(2) Washers shall be maintained in a clean and satisfactory operating condition and kept free from accumulation of scale or debris which will adversely affect the efficiency of the washer.

(c) *Milk transport tanks*. A covered or enclosed wash dock and cleaning and sanitizing facilities shall be available to all plants that receive or ship milk in tanks. Milk transport tanks, sanitary piping, fittings, and pumps shall be cleaned and sanitized at least once each day, after use: *Provided*, That if they are not to be used immediately after emptying a load of milk, they shall be washed promptly after use and given bactericidal treatment immediately before use. After being washed and sanitized, each tank shall be identified by a tag attached to the outlet valve, bearing the following information: Plant and specific location where cleaned, date and time of day of washing and sanitizing, and name of person who washed and name of person who sanitized the tank. The tag shall not be removed until the tank is again washed and sanitized.

(d) *Building*. All windows, glass, partitions, and skylights shall be washed as often as necessary to keep them clean. Cracked or broken glass shall be replaced promptly. The walls, ceilings, and doors shall be washed periodically and kept free from soil and unsightly conditions. The shelves and ledges shall be wiped or vacuumed as often as necessary to keep them free from dust and debris. The material picked up by the vacuum cleaners shall be disposed of by burning or other proper methods to destroy any insects that might be present.

E 1.13 *Insect and rodent control program*. In addition to any commercial pest control service, if one is utilized, a specially designated employee shall be made responsible for the performance of a regularly scheduled insect and rodent control program. Poisonous substances, insecticides, and rodenticides shall be properly labeled, and shall be handled, stored, and used in such a manner as not to create a public health hazard.

E 1.14 *Plant records*. Adequate plant records shall be maintained of all required tests on all raw milk receipts. Such records shall be available for examination at all reasonable times by the inspector. The following are the records which shall be maintained for examination at the plant or receiving station where performed.

(a) Sediment, drug residue, and bacterial test results on raw milk from each producer: Retain for 12 months.

(1) Routine tests and monthly summary of all producers showing number and percent of total in each class.

(2) Retests, if initial test places milk in probationary status.

(3) Rejections of raw milk over No. 3 in quality.

(4) Positive drug residue tests.

(b) Pasteurization recorder charts: Retain for 6 months.

(c) Water supply test certificate: Retain current copy for 6 months.

(d) Employee health certificate: Retain most recent copy until employee is no longer employed by plant.

(e) Drug residue test results for milk samples that do not test positive: Retain for 6 months.

E 1.15 *Packaging and general identification.*

(a) *Containers*.

(1) The size, style, and type of packaging used for dairy products shall be commercially acceptable containers and packaging materials which will satisfactorily cover and protect the quality of the contents during storage and regular channels of trade and under normal conditions of handling. The weights and shape within each size or style shall be as nearly uniform as is practical.

(2) Packaging materials for dairy products shall be selected which will provide sufficiently low permeability to air and vapor to prevent the formation of mold growth and surface oxidation. In addition, the wrapper should be resistant to puncturing, tearing, cracking, or breaking under normal conditions of handling, shipping, and storage. When special-type packaging is used, the instructions of the manufacturers shall be followed closely as to its application and methods of closure.

(b) *Packaging and repackaging*. Packaging dairy products or cutting and repackaging all styles of dairy products shall be conducted under rigid sanitary conditions. The atmosphere of

the packaging rooms, the equipment and packaging material shall be practically free from mold and bacterial contamination. Methods for checking the level of contamination shall be as prescribed by the latest edition of Standard Methods.

(c) *General identification*. All commercial bulk packages containing dairy products manufactured under the provisions of this subpart shall be adequately and legibly marked with the name of the product, net weight, name and address of processor or manufacturer or other assigned plant identification, lot number, and any other identiftcation as may be required. Consumer packaged product shall be legibly marked with the name of the product, net weight, name and address of packer, manufacturer, or distributor and such other identification as may be required by the regulatory agency in jurisdiction.

E 1.16 *Storage of finished product.*

(a) *Dry storage.* The product shall be stored at least 18 inches from the wall in aisles, rows, or sections and lots, in such a manner as to be orderly and easily accessible for inspection. Rooms should be cleaned regularly. Care shall be taken in the storage of any other product foreign to dairy products in the same room, in order to prevent impairment or damage to the dairy product from mold, absorbed odors, or vermin or insect infestation. Control of humidity and temperature shall be maintained at all times, consistent with good commercial practices, to prevent conditions detrimental to the product and container.

(b) *Refrigerated storage.* The finished product shall be placed on shelves, dunnage, or pallets and properly identified. It shall be stored under temperatures that will best maintain the initial quality. The product shall not be exposed to anything from which it might absorb any foreign odors or be contaminated by drippage or condensation.

E 1.17 *Qualifications for plant licensing*. Plant licensing requires satisfactory compliance with the applicable requirements in Subpart E.

Sec. E 2. *Supplemental requirements for plants manufacturing, processing and packaging instant nonfat dry milk, nonfat dry milk, dry whole milk, dry buttermilk, dry whey, and other dry milk products.*E 2.1 *Rooms and compartments.*

E 2.1.1 *Dry storage of product*. Storage rooms for the dry storage of product shall be adequate in size, kept clean, orderly, free from rodents, insects, and mold, and maintained in good repair. They shall be adequately lighted and ventilated. The ceilings, walls, beams, and floors shall be free from structural defects and inaccessible false areas which may harbor insects.

E 2.1.2 *Packaging room for bulk products*. A separate room or area shall be provided for filling bulk bins, drums, bags, or other bulk containers and shall be constructed in accordance with section 1.2 of Subpart E. The number of control panels and switchboxes in this area shall be kept to a minimum. Control panels shall be mounted a sufficient distance from the walls to facilitate cleaning or shall be mounted in the wall and provided with tight-fitting removable doors to facilitate cleaning. An adequate exhaust system shall be provided to minimize the

accumulation of product dust within the packaging room and, where needed, a dust collector shall be provided and properly maintained to keep roofs and outside areas free of dry product. Only packaging materials that are used within a day's operation may be kept in the packaging area. These materials shall be kept on metal racks or tables at least 6 inches off the floor. Unnecessary fixtures, equipment, or false areas which may collect dust and harbor insects, shall not be allowed in the packaging room.

E 2.1.3 *Hopper or dump room*. A separate room shall be provided for the transfer of bulk dry dairy products from bags or drums to the hoppers and conveyors which lead to the fillers. This room shall meet the same requirements for construction and facilities as the bulk packaging operation. Areas and facilities provided for the transfer of dry dairy products from portable bulk bins will be acceptable if gasketed surfaces or direct connections are used that appreciably eliminate the escape of product into the area.

E 2.1.4 *Repackaging room*. A separate room shall be provided for the filling of small packages and shall meet the same requirements for construction and facilities as the bulk packaging operation.

E 2.2 *Equipment and utensils.*

E 2.2.1 *General construction, repair, and installation*. All equipment and utensils necessary to the manufacture of dry milk products, including pasteurizer, timing pump or device, flow diversion valve and recorder controller, shall meet the same general requirements as outlined in section 1.4 of Subpart E. In addition, for certain other equipment the following requirements shall be met.

E 2.2.2 *Preheaters*. The preheaters shall be of stainless steel or other equally corrosion-resistant material, cleanable, accessible for inspection and shall be equipped with suitable automatic temperature controls.

E 2.2.3 *Hotwells.* The hotwells shall be enclosed or covered and equipped with indicating thermometers either in the hotwell or in the hot milk inlet line to the hotwell and if used for holding high heat products they should also have recorders.

E 2.2.4 *Evaporators and/or vacuum pans*. Open-type evaporators and/or vacuum pans shall be equipped with an automatic condenser water level control, barometric leg, or so constructed so as to prevent water from entering the product, and should meet the applicable 3-A Sanitary Standards. When enclosed-type condensers are used, no special controls are needed to prevent water from entering the product.

E 2.2.5 *Surge tanks*. If surge tanks are used for hot milk and temperatures of product including foam being held in the surge tank during processing is not maintained at a minimum of 150^0 F., then two or more surge tanks shall be installed with cross connections to permit flushing and cleaning during operation. Covers easily removable for cleaning shall be provided and used at all times.

E 2.2.6 *High pressure pumps and lines.* High pressure lines may be cleaned in place and shall be of such construction that deadends, valves and the high pressure pumps can be disassembled for hand cleaning. New high pressure pumps shall meet the 3-A Sanitary Standard Covering Homogenizers and High Pressure Pumps of the Plunger Type.

E 2.2.7 *Dryers.*

(a) *Spray dryers.* Spray dryers shall be of a continuous discharge type and all product contact surfaces shall be of stainless steel or other equally corrosion-resistant material. All joints and seams in the product contact surfaces shall be welded and ground smooth. All dryers shall be constructed so as to facilitate ease in cleaning and inspection. Sight glasses or ports of sufficient size shall be located at strategic positions. Dryers shall be equipped with suitable air intake filters and with air intake and exhaust recording thermometers. The filter system shall consist of filtering media or devices that will effectively, and in accordance with good commercial practices, prevent the entrance of foreign substances into the drying chamber. The filtering system shall be cleaned or component parts replaced as often as necessary to maintain a clean and adequate air supply. In gas-fired dryers, precautions shall be taken to assure complete combustion. Air shall be drawn into the dryer from sources free from objectionable odors and smoke, dust, or dirt.

(b) *Roller dryers.*

(1) The drums of a roller dryer shall be smooth, readily cleanable and free of pits and rusts. The knives shall be maintained in such condition so as not to cause scoring of the drums.

(2) The end boards shall have an impervious surface and be readily cleanable. They shall be provided with a means of adjustment to prevent leakage and accumulation of milk solids. The stack, hood, the drip pan inside of the hood and related shields shall be constructed of stainless steel and be readily cleanable. The lower edge of the hood shall be constructed so as to prevent condensate from entering the product zone. The hood shall be properly located and the stack of adequate capacity to remove the vapors. The stack shall be closed when the dryer is not in operation. The augers shall be of stainless steel or properly plated, and readily cleanable. The auger troughs and related shields shall be of stainless steel and be readily cleanable. All air entering the dryer room shall be filtered to eliminate dust and dirt. The filter system shall consist of filtering media or device that will effectively, and in accordance with good commercial practices, prevent the entrance of foreign substances into the drying room. The filtering system shall be cleaned or component parts replaced as often as necessary to maintain a clean and adequate air supply. All dryer adjustments shall be made and the dryer operating normally before food grade powder can be collected from the dryer.

E 2.2.8 *Collectors and conveyors*. Collectors shall be made of stainless steel or equally noncorrosive material and should be constructed to facilitate cleaning and inspection. Filter sack collectors, if used, shall be in good condition and the system shall be of such construction that all parts are accessible for cleaning and inspection. Conveyors shall be of stainless steel or equally corrosion-resistant material and shall be constructed to facilitate thorough cleaning and inspection.

E 2.2.9 *Dry dairy product cooling equipment*. Cooling equipment shall be provided with sufficient capacity to cool the product to 110^0 F. or lower immediately after removal from dryer and prior to packaging. If bulk bins are used, the product should be cooled to approximately 90^0 F. but shall be not more than 110^0 F. A suitable dry air supply with effective filtering shall be provided where air cooling and conveying is used.

E 2.2.10 *Special treatment equipment*. All special equipment such as instantizing systems, flakers, pulverizers or hammer mills used to further process dry milk products shall be of sanitary construction and all parts shall be accessible for cleaning and inspection.

E 2.2.11 *Sifters.* All newly installed sifters used for dry milk and dry milk products shall meet the 3-A Sanitary Standards for Sifters for Dry Milk and Dry Milk Products. All other sifters shall be constructed of stainless steel or other equally noncorrosive material and shall be of sanitary construction and accessible for cleaning and inspection. The mesh size of sifter screen used for various dry dairy products shall be those recommended in the appendix of the 3-A Standard for sifters.

E 2.2.12 *Portable and stationary bulk bins*. Bulk bins shall be constructed of stainless steel, aluminum or other equally corrosion resistant materials, free from cracks and seams and must have an interior surface that is relatively smooth and easily cleanable. All product contact surfaces shall be easily accessible for cleaning.

E 2.2.13 *Automatic sampling device.* If automatic sampling devices are used, they shall be constructed in such a manner as to prevent contamination of the product, and all parts must be readily accessible for cleaning.

E 2.2.14 *Dump hoppers, screens, mixers, and conveyors.* The product contact surfaces of dump hoppers, screens, mixers, and conveyors which are used in the process of transferring dry products from bulk containers to fillers for small packages or containers, shall be of stainless steel or equally corrosion resistant material and designed to prevent contamination. All parts should be accessible for cleaning. The dump hoppers shall be of such height above floor level as to prevent foreign material or spilled product from entering the hopper.

E 2.2.15 *Filler and Packaging equipment*. All filling and packaging equipment shall be of sanitary construction and all parts, including valves and filler heads, accessible for cleaning.

E 2.2.16 *Heavy duty vacuum cleaners*. Each plant handling dry milk products shall be equipped with a heavy duty industrial vacuum cleaner. Regular scheduling shall be established for its use in vacuuming applicable areas.

E 2.3 *Clothing and shoe covers.* Clean clothing and shoe covers shall be provided exclusively for the purpose of cleaning the interior of the drier when it is necessary to enter the drier to perform the cleaning operation.

E 2.4 *Operations and operating procedures.*

E 2.4.1 *Pasteurization.*

(1) All milk, buttermilk and whey used in the manufacture of dry dairy products shall be pasteurized at the plant where dried, except that condensed whey and acidified buttermilk containing 40 percent or more solids may be transported to another plant for drying without repasteurization. Milk or skim milk to be used in the manufacture of nonfat dry milk shall be heated prior to condensing to at least the minimum pasteurization temperature of 161^0 F. for at least 15 seconds or its equivalent in bacterial destruction. Condensed skim made from pasteurized skim milk may be transported to a drying plant, provided that it shall be effectively repasteurized at the drying plant, prior to drying, at not less than 175^0 F. for 25 seconds or its equivalent in bacterial destruction.

(2) All buttermilk or cream from which it is derived shall be pasteurized prior to condensing at a temperature of 185^0 F. for 15 seconds or its equivalent in bacterial destruction.

(3) All cheese whey or milk from which it is derived shall be pasteurized prior to condensing at a temperature of 161^0 F. for 15 seconds or its equivalent in bacterial destruction.

E 2.4.2 *Condensed surge supply.* Surge tanks or balance tanks if used between the evaporators and dryer shall be used to hold only the minimum amount of condensed product necessary for a uniform flow to the dryers. Such tanks holding product at temperatures below 150^0 F. shall be completely emptied and washed after each 4 hours of operation or less. Alternate tanks shall be provided to permit continuous operation during washing of tanks.

E 2.4.3 *Condensed storage tanks.*

(1) Excess production of condensed product over that which the dryer will take continuously from the pans should be bypassed through a cooler into a storage tank at 50^0 F. or lower and held at this temperature until used.

(2) Product cut-off points shall be made at least every 24 hours and the tank completely emptied, washed, and sanitized before reuse.

E 2.4.4 *Drying*. Each dryer should be operated at not more than the manufacturer's rated capacity for the highest quality dry product consistent with the most efficient operation. This does not preclude the remodeling or redesigning of dryers after installation when properly engineered and designed. The dry products shall be removed from the drying chamber continuously during the drying process.

E 2.4.5 *Cooling dry products*. Prior to packaging and immediately following removal from the drying chamber the dry product shall be cooled to a temperature not exceeding 110^0 F.

E 2.4.6 *Packaging, repackaging* and *storage.*

(a) *Containers*. Packages or containers used for the packaging of nonfat dry milk or other dry milk products shall be any clean, sound commercially accepted container or packaging

material which will satisfactorily protect the contents through the regular channels of trade, without significant impairment of quality with respect to flavor, wholesomeness or moisture content under the normal conditions of handling. In no instance will containers which have previously been used for nonfood items or food which would be deleterious to the dairy product be allowed to be used for the bulk handling of dairy products.

(b) *Filling*. Empty containers shall be protected at all times from possible contamination and containers which are to be lined shall not be prepared more than 1 hour in advance of filling. Every precaution shall be taken during the filling operation to minimize product dust and spillage. When necessary a mechanical shaker shall be provided; the tapping or pounding of containers shall be prohibited. The containers shall be closed immediately after filling and the exteriors shall be vacuumed or brushed when necessary to render them practically free of product remnants before being transferred from the filling room to the palleting or dry storage areas.

(c) *Repackaging.* The entire repackaging operation shall be conducted in a sanitary manner with all precautions taken to prevent contamination and to minimize dust. All exterior surfaces of individual containers shall be practically free of product before overwrapping or packing in shipping containers. The flow shall be kept free of dust accumulation, waste, cartons, liners, or other refuse. Conveyors, packaging and cartonmaking equipment shall be vacuumed frequently during the operating day to prevent the accumulation of dust. No bottles or glass materials of any kind shall be permitted in the repackaging or hopper room. The inlet openings of all hoppers and bins shall be of minimum size, screened and placed well above the floor level. The room and all packaging equipment shall be cleaned as often as necessary to maintain a sanitary operation. Close attention shall be given to cleaning points of equipment where residues of the dry product may accumulate. A thorough cleanup including windows, doors, walls, light fixtures, and ledges, shall be performed as frequently as is necessary to maintain a high standard of cleanliness and sanitation. All waste dry dairy products including dribble product at the fillers shall be properly identified and disposed of as animal feed.

(d) *Storage.*

(l) *Product*. The packaged dry milk product shall be stored or so arranged in aisles, rows, or sections and lots at least 18 inches from any wall and in such a manner as to be orderly, easily accessible for inspection or for cleaning of the room. All bags and small containers of product shall be placed on pallets elevated approximately 6 inches from the floor. The storage room shall be kept clean and dry and all openings protected against entrance of insects and rodents.

(2) *Supplies.* All supplies shall be placed on dunnage or pallets and arranged in an orderly manner for accessibility and cleaning of the room. Supplies shall be kept enclosed in their original wrapping material until used. After removal of supplies from their original containers they shall be kept in an enclosed metal cabinet, bins, or on shelving and if not enclosed shall be protected from powder and dust or other contamination. The room shall be vacuumed as often as necessary and kept clean and orderly.

E 2.4.7 *Product adulteration*. All necessary precautions shall be taken throughout the entire operation to prevent the adulteration of one product with another. The commingling of

one type of liquid or dry product with another shall be considered as an adulteration of that product. This does not prohibit the normal standardization of like products in accordance with good commercial practices or the production of specific products for special uses, provided applicable labeling requirements are met.

E 2.4.8 *Checking quality*. All milk, milk products, and dry milk products shall be subject to inspection and analysis by the dairy plant for quality and condition throughout each processing operation. Line samples shall be taken periodically as an aid to quality control in addition to the regular routine analysis made on the finished products.

E 2.4.9 *Requirements for instant nonfat dry milk.*

(a) *Sampling and testing.* All instant nonfat dry milk offered for sale shall be sampled and tested by the regulatory authority at least once each month for the purpose of assuring that the product meets the requirements of section E 2.4.9(b). In addition the dry milk plant shall have each sublot of approximately 4,000 pounds tested and analyzed prior to being packaged or offered for sale. Product not meeting the requirements of section E 2.4.9(b) shall not be offered as Extra Grade.

(b) *Requirements for Extra Grade instant nonfat dry milk.*

(l) *Flavor and odor*. The flavor and odor shall be sweet, pleasing and desirable but may possess the following flavors to a slight degree: Chalky, cooked, feed, flat.

(2) *Physical appearance*. The physical appearance shall possess a uniform white to light cream natural color; shall be reasonably free-flowing and free from lumps except those that readily break up with very slight pressure.

(3) *Bacterial estimate*. The standard plate count shall not be more than 30,000 per gram.

(4) *Coliform count*. The coliform count shall not be more than 10 per gram.

(5) *Milkfat content*. The milkfat shall not be more than 1.25 percent.

(6) *Moisture count*. The moisture shall not be more than 4.5 percent.

(7) *Scorched particle content*. Scorched particles shall not be more than 15 mg.

(8) *Solubility index*. The solubility index shall not be more than 1 ml.

(9) *Titratable acidity*. The titratable acidity shall not be more than 0.15 percent.

(10) Dispersibility. The dispersibility shall not be less than 85 percent by the Modified Moats-Dabbah Method.

(11) *Direct microscopic clump count*. The direct microscopic clump count shall not be more than 75 million per gram.

E 2.4.10 *Cleaning of dryers, conveyors, sifters, and storage bins*. This equipment shall be cleaned as often as is necessary to maintain such equipment in a clean and sanitary condition. The kind of cleaning procedure either wet or dry and the frequency of cleaning shall be based upon observation of actual operating results and conditions.

E 2.4.11 *Insect and rodent control program*. In addition to any commercial pest control service, if one is utilized, a specially designated employee shall be made responsible for the performance of a regularly scheduled insect and rodent control program.

Sec. E 3. *Supplemental requirements for plants manufacturing, processing and packaging butter and related products.*

E 3.1 *Rooms and compartments.*

E 3.1.1 *Coolers and freezers.* The coolers and freezers shall be equipped with facilities for maintaining proper temperature and humidity conditions, consistent with good commercial practices for the applicable product, to protect the quality and condition of the products during storage or during tempering prior to further processing. Coolers and freezers shall be kept clean, orderly, free from insects, rodents, and mold, and maintained in good repair. They shall be adequately lighted and proper circulation of air shall be maintained at all times. The floors, walls, and ceilings shall be of such construction as to permit thorough cleaning.

E 3.1.2 *Churn rooms*. Churn rooms in addition to proper construction and sanitation shall be so equipped that the air is kept free from objectionable odors and vapors and extreme temperatures by means of adequate ventilation and exhaust systems or air conditioning and heating facilities.

E 3.1.3 *Print and bulk packaging rooms*. Rooms used for packaging print or bulk butter and related products shall, in addition to proper construction and sanitation, provide an atmosphere relatively free from mold (no more than 10 mold colonies per cubic foot of air), dust, or other airborne contamination and be maintained at a reasonable room temperature.

E 3.2 *Equipment and utensils.*

E 3.2.1 *General construction, repair, and installation*. All equipment and utensils necessary to the manufacture of butter and related products shall meet the same general requirements as outlined in section 1.4 of subpart E 1. In addition for certain other equipment, the following requirements shall be met.

E 3.2.2 *Continuous churn*. All product contact surfaces shall be of noncorrosive material. All nonmetallic product contact surfaces shall comply with 3-A Standards for Plastic, Rubber, and Rubber-Like Materials. All product contact surfaces shall be readily accessible for cleaning and inspection.

E 3.2.3 *Conventional churn*. Churns shall be constructed of aluminum, stainless steel or equally corrosion resistant metal, free from cracks, and in good repair. All gasket material shall be fat resistant, nontoxic and reasonably durable. SeaIs around the doors shall be tight.

E 3.2.4 *Bulk butter trucks, boats and packers*. Bulk butter trucks, boats and packers shall be constructed of aluminum, stainless steel or equally corrosion resistant metal free from cracks, seams and must have a surface that is relatively smooth and easily cleanable.

E 3.2.5 *Butter, frozen or plastic cream melting machine*. Shavers, shredders or melting machines used for rapid melting of butter, frozen or plastic cream shall be of stainless steel or equally corrosion resistant metal, sanitary construction, and readily cleanable.

E 3.2.6 *Printing equipment*. All printing equipment shall be designed to be readily demountable for cleaning of product contact surfaces. All product contact surfaces shall be aluminum, stainless steel or equally corrosion resistant metal, or plastic, rubber and rubber like material which meet 3-A standards, except that conveyors may be constructed of material which can be properly cleaned and maintained in a satisfactory manner.

E 3.2.7 *Brine tanks.* Brine tanks used for the treating of parchment liners shall be constructed of noncorrosive material and have an adequate and safe means of heating the salt solution for the treatment of the liners. The tank shall also be provided with a satisfactory drainage outlet.

E 3.2.8 *Starter vats.* Bulk starter vats shall be of stainless steel or equally corrosion-resistant metal and constructed according to applicable 3-A Sanitary Standards. The vats shall be in good repair, equipped with tight-fitting lids, and have effective temperature controls.

E 3.3 *Operations and operating procedures.*

E 3.3.1 *Pasteurization*. The milk or cream shall be pasteurized at the plant where the milk or cream is processed into the finished product.

(a) *Cream for buttermaking.*

(1) The cream for buttermaking shall be pasteurized at a temperature of not less than 165^0 F. and held continuously in a vat at such temperature for not less than 30 minutes; or pasteurized by HTST method at a minimum temperature of not less than 185^0 F. for not less than 15 seconds; or by any other equivalent time and temperature combination. Additional heat treatment above the minimum pasteurization requirement is advisable to insure improved keeping-quality characteristics.

(2) Adequate pasteurization control shall be used and the diversion valve shall be set to divert at no less than 185^0 F. with a 15-second holding time or its equivalent in time and temperature to assure pasteurization. If the vat or holding method of pasteurization is used, vat covers shall be closed prior to holding period to assure temperature of air space reaching the minimum temperature before holding time starts. Covers shall also be kept closed during the holding and cooling period.

(b) *Cream for plastic or frozen cream.* The pasteurization of cream for plastic or frozen cream shall be accomplished in the same manner as in (a) above, except, that the temperature for the vat method shall be not less than 170^0 F. for not less than 30 minutes, or not less than 190^0 F. for not less than 15 seconds or by any other temperature and holding time which will assure adequate pasteurization and comparable keeping-quality characteristics.

E 3.3.2 *Composition and wholesomeness.* All ingredients used in the manufacture of butter and related products shall be subject to inspection and shall be wholesome and practically free from impurities. Chlorinating facilities shall be provided for butter wash water if needed and all other necessary precautions shall be taken to prevent contamination of products. All finished products shall comply with the requirements of the Federal Food, Drug, and Cosmetic Act, as to composition and wholesomeness.

E 3.3.3 *Containers.*

(a) Containers used for the packaging of butter and related products shall be commercially acceptable containers or packaging material that will satisfactorily protect the quality of the contents in regular channels of trade. Caps or covers which extend over the lip of the container shall be used on all cups or tubs containing 2 pounds or less, to protect the product from contamination during subsequent handling.

(b) *Liners and wrappers*.

(1) Supplies of parchment liners, wrappers, and other packaging material shall be protected against dust, mold, and other possible contamination.

(2) Prior to use, parchment liners for bulk butter packages shall be completely immersed in a boiling salt solution in a suitable container constructed of stainless steel or other equally noncorrosive material. The liners shall be maintained in the solution for not less than 30 minutes. The solution should consist of at least 15 pounds of salt for every 85 pounds of water and shall be strengthened or changed as frequently as necessary to keep the solution full strength and in good condition.

(3) Other liners such as polyethylene shall be treated or handled in such a manner as to prevent contamination of the liner prior to filling.

(c) *Filling bulk butter containers*. The lined butter containers shall be protected from possible contamination prior to filling.

E 3.3.4. *Printing and packaging*. Printing and packaging of consumer size containers of butter shall be conducted under sanitary conditions.

E 3.3.5. *General identiftcation*. Commercial bulk shipping containers shall be legibly marked with the name of the product, net weight, name and address of manufacturer, processor or distributor or other assigned plant identification (manufacturer's lot number, churn number, etc.) and any other identification that may be required. Packages of plastic or frozen cream shall be marked with the percent of milkfat.

E 3.3.6 *Storage of finished product in coolers.* All products shall be kept under refrigeration at temperatures of 40^0 F. or lower after packaging and until ready for distribution or shipment. The products shall not be placed directly on floors or exposed to foreign odors or conditions such as drippage due to condensation which might cause package or product damage.

E 3.3.7 *Storage of finished product in freezer.*

(a) *Sharp freezers.* Plastic cream or frozen cream intended for storage shall be placed in quick freezer rooms immediately after packaging, for rapid and complete freezing within 24 hours. The packages shall be piled or spaced in such a manner that air can freely circulate between and around the packages. The rooms shall be maintained at -10^0 F. or lower and shall be equipped to provide sufficient high-velocity air circulation for rapid freezing. After the products have been completely frozen, they may be transferred to a freezer storage room for continued storage.

(b) *Freezer storage.*

(1) The room shall be maintained at a temperature of 0^0 F. or lower. Adequate air circulation is desirable.

(2) Butter intended to be held more than 30 days shall be placed in a freezer room as soon as possible after packaging. If not frozen before being placed in the freezer, the packages shall be spaced in such a manner as to permit rapid freezing and repiled, if necessary, at a later time.

Sec. E 4. *Supplemental requirements for plants manufacturing and packaging cheese*

E 4.1 *Rooms and compartments.*

E 4.1.1 *Starter room*. Starter rooms or areas shall be properly equipped and maintained for the propagation and handling of starter cultures. All necessary precautions shall be taken to prevent contamination of starter, of the room, equipment, and the air therein.

E 4.1.2 *Make room*. The room in which the cheese is manufactured shall be of adequate size, and the vats adequately spaced to permit movement around the vats and presses for proper cleaning and satisfactory working conditions. Adequate ventilation shall be provided.

E 4.1.3 *Drying room*. If cheese is to be paraffined, a drying room of adequate size shall be provided to accommodate the maximum production of cheese during the flush period. Adequate shelving and air circulation shall be provided for proper drying. Suitable temperature and humidity control facilities shall be provided.

E 4.1.4 *Paraffining room*. For rind cheese, a separate room or compartment shall be provided for paraffining and boxing the cheese. The room or compartment shall be of adequate size and the temperature maintained near the temperature of the drying room to avoid sweating of the cheese prior to paraffining.

E 4.1.5 *Rindless block wrapping* area. For rindless blocks a suitable space shall be provided for proper wrapping and boxing of the cheese. The area shall be free from dust, condensation, mold or other conditions which may contaminate the surface of the cheese or contribute to an unsatisfactory packaging of the cheese.

E 4.1.6 *Coolers or curing rooms*. Coolers or curing rooms where cheese is held for curing or storage shall be clean and maintained at the proper uniform temperature and humidity to adequately protect the cheese. Proper circulation of air shall be maintained at all times. The rooms shall be free from rodents, insects, and pests. The shelves shall be kept clean and dry.

E 4.1.7 *Cutting and packaging rooms*. When small packages of cheese are cut and wrapped, separate rooms shall be provided for the cleaning and preparation of the bulk cheese and a separate room shall be provided for the cutting and wrapping operation. The rooms shall be well lighted, ventilated, and provided with filtered air. Air movement shall be outward to minimize the entrance of unfiltered air into the cutting and packaging room.

E 4.2 *Equipment and utensils.*

E 4.2.1 *General construction, repair, and installation*. All equipment and utensils necessary to the manufacture of cheese and related products shall meet the same general requirements as outlined in section 1.4 of Subpart E. In addition, for certain other equipment the following requirements shall be met.

E 4.2.2 *Starter vats.* Bulk starter vats shall be of stainless steel or equally corrosion-resistant metal and shall be in good repair, equipped with tight-fitting lids and have adequate temperature controls such as valves, indicating and/or recording thermometers. New vats shall be constructed according to the applicable 3-A Sanitary Standards.

E 4.2.3 *Cheese vats.*

(1) The vats used for making cheese shall be of metal construction with adequate jacket capacity for uniform heating. The inner liner shall be minimum 16-gage stainless steel or other equally corrosion-resistant metal, properly pitched from side to center and from rear to front for adequate drainage. The liner shall be smooth, free from excessive dents or creases and shall extend over the edge of the outer jacket. The outer jacket, when metal, shall be constructed of stainless steel or other metal which can be kept clean and sanitary. The junction of the liner and outer jackets shall be constructed so as to prevent milk or cheese from entering the inner jacket.

(2) The vat shall be equipped with a suitable sanitary outlet valve. Effective valves shall be provided and properly maintained to control the application of heat to the vat.

E 4.2.4 *Mechanical agitators.* The mechanical agitators shall be of sanitary construction. The carriage and track shall be so constructed as to prevent the dropping of dirt or grease into the vat. Metal blades, forks, or stirrers shall be constructed of stainless steel and of material approved in the 3-A Sanitary Standards for Plastic and Rubber or Rubberlike Materials and shall be free from rough or sharp edges which might scratch the equipment or remove metal particles.

E 4.2.5 *Curd mill and miscellaneous equipment*. Knives, hand rakes, shovels, paddles, strainers, and miscellaneous equipment shall be stainless steel or of material approved in the 3-A Sanitary Standards for Plastic and Rubberlike Material. The product contact surfaces of the curd mill shall be of stainless steel. All pieces of equipment shall be so constructed that they can be kept clean. The wires in the curd knives shall be stainless steel, kept tight and replaced when necessary.

E 4.2.6 *Hoops and followers.* The hoops, forms, and followers shall be constructed of stainless steel or heavy tinned steel. If tinned, they shall be kept tinned and free from rust. All hoops, forms, and followers shall be kept in good repair. Drums or other special forms used to press and store cheese shall be clean and sanitary.

E 4.2.7 *Press.* The cheese press shall be constructed of stainless steel and all joints welded and all surfaces, seams, and openings readily cleanable. The pressure device shall be the continuous type. Press cloths shall be maintained in good repair and in a sanitary condition. Single-service press cloths shall be used only once.

E 4.2.8 *Rindless cheese press.* The press used to heat seal the wrapper applied to rindless cheese shall have square interior corners, reasonably smooth interior surface and have controls that shall provide uniform pressure and heat equally to all surfaces.

E 4.2.9 *Paraffin tanks*. The metal tank shall be adequate in size, have wood rather than metal racks to support the cheese, have heat controls and an indicating thermometer. The cheese wax shall be kept clean.

E 4.3 *Operations and operating procedures.*

E 4.3.1 *Cheese from pasteurized milk.*

(a) If the cheese is labeled as pasteurized, the milk shall be pasteurized by subjecting every particle of milk to a minimum temperature of 161^0 F. for not less than 15 seconds.

(b) HTST pasteurization units shall be equipped with the proper controls and equipment to assure pasteurization. If the milk is held more than 2 hours between time of receipt or heat treatment and setting, it shall be cooled to 45^0 F. or lower until time of setting.

E 4.3.2 *Cheese from unpasteurized milk*. If the cheese is labeled as "heat treated", "unpasteurized", "raw milk", or "for manufacturing", the milk may be raw or heated at temperatures below pasteurization. If the milk is held more than 2 hours between time of receipt or heat treatment and setting, it shall be cooled to 45^0 F. or lower until time of setting.

E 4.3.3 *Whey disposal.*

(a) Adequate sanitary facilities shall be provided for the disposal of whey. If outside, necessary precautions shall be taken to minimize flies, insects, and development of objectionable odors.

(b) Whey or whey products intended for human food shall at all times be handled in a sanitary manner in accordance with the procedures of this subpart as specified for handling milk and dairy products.

E 5.2 *Equipment and utensils.*

E 5.2.1 *General construction, repair and installation*. The equipment and utensils used for the manufacture and handling of cottage cheese shall be as specified in section 1.4. of subpart E. In addition for certain other equipment the following requirements shall be met.

E 5.2.2 *Cheese Vats.*

(1) The vats used for making the cottage cheese shall be of stainless steel construction with adequate jacket capacity for uniform heating and cooling. The inner liner shall be minimum 16 gage stainless steel, or equally corrosion-resistant metal properly pitched from side to center and from rear to front for adequate drainage. The liner shall be smooth, free from excessive dents or creases and shall extend over the edge of the outer jacket. The outer jacket shall be constructed of stainless steel or other metal which can be kept clean and sanitary. The junction of the liner and outer jacket shall be constructed as to prevent milk or cheese from entering the inner jacket.

(a) Vats shall be equipped with valves to control the heating and cooling medium and a suitable sanitary outlet valve. Also, the vats shall be equipped with removable stainless steel or other suitable metal covers, cloth covers which can be regularly and suitably laundered, or with single service paper covers. Vats used for creaming curd shall be equipped with a refrigerated cooling medium.

E 5.2.3 *Agitators*. Mechanical agitators shall be installed on all cheese vats for stirring the milk or cheese. The carriage shall be completely enclosed or provided with a trough or drip pan to prevent condensation, oil, or dirt from dropping into the vat.

E 5.2.4 *Container fillers.* New fillers shall conform to the 3-A Sanitary Standards for Equipment for Packaging Frozen Desserts and Cottage Cheese.

E 5.2.5 *Mixers.* They shall be constructed in such a manner as to be readily cleanable. If shafts extend through the wall of the tank below the level of product, they shall be equipped with proper seals which are readily removable for cleaning and sanitizing. The mixer shall be enclosed or equipped with tight fitting covers.

E 5.2.6 *Starter vats.* Bulk starter vats shall be made of stainless steel or equally corrosion resistant metal, shall be in good repair, equipped with tight fitting lids and accurate temperature controls such as valves, indicating and/or recording thermometers. New vats shall be constructed according to applicable 3-A Sanitary Standards.

E 5.3 *Operations and operating procedures.*

E 5.3.1 *Pasteurization*.

(a) The skim milk used for the manufacture of cottage cheese shall be pasteurized not more than 24 hours prior to the time of setting by heating every particle of skim milk to a temperature of 161^0 F. for not less than 15 seconds or by any other combination of temperature and time giving equivalent results. All skim milk must be cooled promptly to setting temperature. If held more than 2 hours between pasteurization and time of setting, the skim milk shall be cooled and held at 45^0 F. or colder until set.

(b) Cream or cheese dressing shall be pasteurized at not less than 150^0 F. for not less than 30 minutes or at not less than 166^0 F. for not less than 15 seconds or by any other combination of temperature and time treatment giving equivalent results. Cream and cheese dressing shall be cooled promptly to 40^0 F. or lower after pasteurization to aid in further cooling of cottage cheese curd for improved keeping quality.

(c) Reconstituted nonfat dry milk for cottage cheese manufacture need not be repasteurized provided it is reconstituted within 2 hours prior to the time of setting. Skim milk separated from pasteurized whole milk need not be repasteurized provided it is separated in equipment from which all traces of raw milk from previous operations have been removed by proper cleaning and sanitizing.

E 5.3.2 *Reconstituting nonfat dry milk*. Nonfat dry milk shall be reconstituted in a sanitary manner, preferably by the use of a centrifugal pump and funnel arrangement. It shall be reconstituted within 2 hours of the time of setting, using water which is free from viable pathogenic or otherwise harmful microorganisms.

E 5.3.3 *Packaging and general identification.*

(a) *Containers*. Containers used for packaging cottage cheese shall be any commercially acceptable multiple use or single service container or packaging material which will satisfactorily protect the contents through the regular channels of trade without significant impairment of quality with respect to flavor or contamination under normal conditions of handling. Caps or covers which extend over the lip of the container shall be used on all cups or tubs containing 2 pounds or less to protect the product from contamination during subsequent handling.

(b) *Packaging.* The cheese shall be packaged in a sanitary manner. The containers shall be check weighed during the filling operation to assure they are filled uniformly to not less than the stated net weight on the container.

(c) *General identification*. Bulk packages containing cottage cheese shall be adequately and legibly marked with the name of the product, net weight, name and address of the manufacturer, lot number, code or date of packaging and any other identification as may be required. Consumer size packaged products shall be legibly marked with the name of the product, net weight, name and address of the manufacturer or distributor, code or date of packaging and any other identification as may be required.

E 5.3.4 *Storage of finished product*. Cottage cheese after packaging shall be promptly stored at a temperature of 45^0 F. or lower to maintain quality and condition until loaded for distribution. During distribution and storage prior to sale the product should be maintained at a temperature of 45^0 F. or lower. The product shall not be exposed to foreign odors or conditions such as drippage or condensation that might cause package or product damage. Packaged cottage cheese shall not be placed directly on floors.

Sec. E 6. *Supplemental requirements for plants manufacturing, processing and packaging pasteurized process cheese and related products.*

E 6.1 *Equipment and utensils.*

E 6.1.1 *General construction, repair, and installation*. The equipment and utensils used for the handling and processing of cheese products shall be as specified in section 1.4 of subpart E. In addition, for certain other equipment the following requirements shall be met.

E 6.1.2 *Conveyors*. Conveyors shall be constructed of material which can be properly cleaned, will not rust, or otherwise contaminate the cheese, and shall be maintained in good repair.

E 6.1.3 *Grinders or shredders.* The grinders or shredders used in the preparation of the trimmed and cleaned natural cheese for the cookers shall be adequate in size. Product contact surfaces shall be of corrosion resistant material, and of such construction as to prevent contamination of the cheese and to allow thorough cleaning of all parts and product contact surfaces.

E 6.1.4 *Cookers.* The cookers shall be the steam jacketed or direct steam type. They shall be constructed of stainless steel or other equally corrosion-resistant material. All product contact surfaces shall be readily accessible for cleaning. Each cooker shall be equipped with an indicating thermometer, and should be equipped with a temperature recording device. The recording thermometer stem may be placed in the cooker if satisfactory time charts are used; if not, the stem shall be placed in the hotwell or filler hopper. Steam check valves on direct steam type cookers shall be mounted flush with cooker wall, be constructed of stainless steel and designed to prevent the backup of product into the steam line, or the steam line shall be constructed of stainless steel pipes and fittings which can be readily cleaned. If direct steam is applied to the product only culinary steam shall be used.

E 6.1.5 *Fillers*. The hoppers of all fillers shall be covered but the cover may have sight ports. If necessary, the hopper may have an agitator to prevent buildup on side wall. The filler valves and head shall be kept in good repair, capable of accurate measurements.

E 6.2 *Operations and operating procedures.*

E 6.2.1 *Trimming and cleaning*. The natural cheese shall be cleaned free of all nonedible portions. Paraffin and bandages as well as rind surface, mold, or unclean areas or any other part which is unwholesome or unappetizing shall be removed.

E 6.2.2 *Cooking the batch*. Each batch of cheese within the cooker, including the optional ingredients shall be thoroughly commingled and the contents pasteurized at a temperature of at least 158^0 F. and held at that temperature for not less than 30 seconds. Care shall be taken to prevent the entrance of cheese particles or ingredients after the cooker batch of cheese has reached the final heating temperature. After holding for the required period of time, the hot cheese shall be emptied from the cooker as quickly as possible.

E 6.2.3 *Forming containers*. Containers either lined or unlined shall be assembled and stored in a sanitary manner to prevent contamination. The handling of containers by filler crews shall be done with extreme care and observance of personal cleanliness. Performing and

assembling of pouch liners and containers shall be kept to a minimum and the supply rotated to limit the length of time exposed to possible contamination prior to filling.

E 6.2.4 *Filling containers*. Hot fluid cheese from the cookers may be held in hot wells or hoppers to assure a constant and even supply of processed cheese to the filler or slice former. Filler valves shall effectively measure the desired amount of product into the pouch or containers in a sanitary manner and shall cut off sharply without drip or drag of cheese across the opening. An effective system shall be used to maintain accurate and precise weight control. Damaged or unsatisfactory packages shall be removed from production, and the cheese may be salvaged into sanitary containers, and added back to cookers.

Sec. E 7. *Supplemental requirements for plants manufacturing, processing, and packaging evaporated, condensed, or sterilized milk products.*

E 7.1 *Equipment and utensile.*

E 7.1.1 *General construction, repair, and installation*. The equipment and utensils used for processing and packaging evaporated, condensed, or sterilized milk products shall be as specified in section 1.4 of Subpart E. In addition, for certain other equipment, the following requirements shall be met.

E 7.1.2 *Evaporators and vacuum pans*. All equipment used in the removal of moisture from milk or milk products for the purpose of concentrating the solids should meet the requirements of the 3-A Sanitary Standards for Milk and Milk Products Evaporators and Vacuum Pans. All new or used replacements for this type of equipment shall meet the appropriate 3-A Sanitary Standards.

E 7.1.3 *Fillers*. Both gravity- and vacuum-type fillers shall be of sanitary design and all product contact surfaces, if metal, shall be made of stainless steel or equally corrosion-resistant material; except that certain evaporated milk fillers having brass parts may be approved if free from corroded surfaces and kept in good repair. Nonmetallic product contact surfaces shall meet the requirements for 3-A Sanitary Standards for Rubber and Rubberlike Materials or for Multiple-Use Plastic Materials. Fillers shall be designed so that they in no way will contaminate or detract from the quality of the product being packaged.

E 7.1.4 *Batch or continuous in-container sterilizers*. Shall be equipped with accurate temperature controls and effective valves for regulating the sterilization process. The equipment shall be maintained in such a manner as to assure control of the length of time of processing, and to minimize the number of damaged containers.

E 7.1.5 *Homogenizers*. Homogenizers where applicable shall be used to reduce the size of the fat particles and to evenly disperse them in the product. New homogenizers shall meet the applicable 3-A Sanitary Standards.

E 7.2 *Operations and operating procedures.*

E 7.2.1 *Preheat, pasteurization*. When pasteurization is intended or required by either the vat method, HTST method, or by the UHT method it shall be accomplished by systems and equipment meeting the requirements outlined in section 1.4 of Subpart E.

E 7.2.2 *Sterilization*. The complete destruction of all living organisms shall be performed in one of the following methods: (a) The complete in-container method, by heating the container and contents to a range of 212^0 F. to 280^0 F. for a sufficient time; (b) by a continuous flow UHTST process at high temperatures of 280^0 F. and above for a sufficient time, then packaged aseptically; (c) the product is first sterilized according to UHTST methods as in paragraph (b) of this section, then packaged and given further heat treatment to complete the sterilization process.

E 7.2.3 *Filling containers*.

(a) The filling of small containers with product shall be done in a sanitary manner. The containers shall not contaminate or detract from the quality of the product in any way. After filling, the container shall be hermetically sealed.

(b) Bulk containers for unsterilized product shall be suitable and adequate to protect the product in storage or transit. The bulk container (including bulk tankers) shall be cleaned and sanitized before filling, and filled and closed in a sanitary manner.

E 7.2.4 *Aseptic filling*. A previously sterilized product shall be filled under conditions which prevent contamination of the product by living organisms or spores. The containers prior to being filled shall be sterilized and maintained in a sterile condition. The containers shall be sealed in a manner that prevents contamination of the product.

E 7.2.5 *Storage*. Proper facilities shall be provided for the storage and handling of finished product.

Subpart F-Administrative Procedures

Sec. F 1. *Farm certification.*

F 1.1 *Necessity for certification.*

(a)Within 24 months from the effective date of these rules and regulations, every farm producing and selling milk for manufacturing purposes shall be inspected and certified as provided in section F 1.2, 1.3, and 1.5. On and after the effective date of these rules and regulations, a new producer's farm shall be inspected and certified as provided in sections F 1.2, 1.3, and 1.5 before his first sale of milk for manufacturing purposes. Twenty-four months from and after the effective date of these rules and regulations, no milk for manufacturing purposes produced on an uncertified farm shall be bought or sold.

(b) Certified farms shall be inspected annually after initial certification to determine eligibility for recertification. The inspection procedure for recertification shall be the same as that for initial certification.

F 1.2 *Inspection*. Each farm shall be inspected by an inspector or approved fieldsman. When evidence indicates that it is advisable to do so [the regulatory agency] may require an examination of the herd or flock by a licensed veterinarian. If the farm meets the applicable requirements for certification described in section D 1 to D 9 of subpart D, as indicated by the Farm Certification Report Form (section F 4) the farm shall be certified as described in section F 1.3. If the farm does not meet the requirements for certification, it shall be reinspected within 30 days after the initial inspection. If the farm then meets the requirements for certification, it shall be certified. If the farm does not meet the requirements for certification, it shall not be certified, and the producer's authorization to sell milk for human food from that farm shall be withheld by [the regulatory agency] until such time as the farm qualifies for certification. Provided that, if the inspector determines during any of these inspections that corrections on the farm will require some capital investment, a reasonable extension of the prescribed time limits may be granted by [the regulatory agency]. Each completed Farm Certification Report Form (section F 4) shall be kept by the regulatory agency and a copy shall be given to the producer.

F 1.3 *Certification.* An inspector or approved fieldperson shall certify farms that meet the requirements of sections D 1 to D 9 of subpart D as applicable, based upon the inspection procedure described in section F 1.2. Farm certification shall authorize the sale from that farm of milk for manufacturing purposes that meets the quality standards of section C 2 to C 4 of subpart C as determined by the procedures described in sections C 2 to C 11 of subpart C.

F 1.4 *Expiration and revocation of certification*.

(a) Farm certification shall expire and become renewable 1 year from the date of certification unless revoked earlier by [the regulatory agency] and no certification shall be transferrable.

(b) If at any time an inspector or approved fieldperson determines that a certified farm does not meet the requirements for certification [the regulatory agency] may allow a reasonable probationary period for the producer to bring his farm within the requirements for certification. If at the end of this time the farm does not meet the requirements for certification [the regulatory agency] may revoke the farm certification.F 1.5 *Reinstatement*. If, after a period of withholding, probation, or revocation of farm certification, a producer makes the necessary corrections at the farm, he may apply for reinspection. When conditions have been corrected, the farm shall be reinspected by an inspector or approved fieldperson. When the inspector or approved fieldperson determines that requirements for certification have been met, he shall certify the farm.

Sec. F 2. *Licensing plants, milk graders, and bulk milk collectors.*

F 2.1 *Necessity for plant license.*

(a) Within 12 months from the effective date of these rules and regulations, every plant receiving or processing milk for the manufacture of dairy products shall be inspected and licensed as provided in sections F 2.2, 2.3, 2.4 (a), and 2.6. On and after the effective date of these rules and regulations, a new plant shall be inspected and licensed as provided in sections F 2.2. 2.3, 2.4(a), and 2.6 before buying or processing any milk for the manufacture of dairy products. Twelve months from and after the effective date of these rules and regulations, no unlicensed plant shall handle, purchase, or receive milk or manufacture dairy products therefrom.

(b) All licensed plants shall be inspected annually after issuance of the initial license to determine eligibility for license renewal. The inspection procedure for license renewal shall be the same as that for initial licensing.

F 2.2 *Application for license.* Applications to [the regulatory agency] for a new or renewal license for dairy plants, milk graders, and bulk milk collectors shall contain the name and address of the applicant and such other pertinent information as may be required.

F 2.3 *Plant inspection*.

(a) Each plant shall be inspected by an inspector. If, upon initial inspection, the inspector finds that the plant meets the requirements for licensing described in subpart E, as indicated by the Plant Inspection Report Form (section F 5), a license shall be issued to the plant as described in section F 2.4 (a). If the plant does not meet the requirements for licensing, the plant shall be reinspected by an inspector within 30 days of the initial inspection. A longer time may be allowed if major changes or new equipment is required. If at this time the plant meets the requirements for licensing, a license shall be issued. If the plant does not meet the requirements for licensing, it shall not be licensed, and its authorization to handle, purchase, or receive milk or to manufacture dairy products therefrom shall be withheld until such time as the plant qualifies for a license.

(b) Each completed Plant Inspection Report Form (section F 5) shall be kept by [the regulatory agency], and a copy shall be given to the plant operator.

F 2.4 *Issuance of license.*

(a) *Dairy plants*. [The regulatory agency] shall license dairy plants that meet the specifications of subpart E based upon the inspection procedure described in section F 2.3. The license certificate shall be posted conspicuously at the plant. The license shall authorize the plant to test, purchase, and receive milk for manufacturing purposes and to manufacture dairy products therefrom, in compliance with the applicable provisions of the Act and the rules and regulations issued pursuant thereto.

(b) *Milk graders and bulk milk collectors.*[The regulatory agency] shall license milk graders and bulk milk collectors who meet the qualifications prescribed by [the regulatory agency]. The licenses of milk graders and bulk milk collectors shall authorize them to grade, accept, and reject raw milk in accordance with the provisions of subpart C.

F 2.5 *Expiration, suspension and revocation of license.*

(a) Licenses shall expire and become renewable 1 year from the date of issuance unless revoked earlier and no license shall be transferable.

(b) If at any time an inspector determines that a licensed plant does not meet the requirements for licensing, he may allow a reasonable probationary period for the operator to bring his plant within the requirements for licensing. If at the end of this time the plant does not meet the licensing requirements [the regulatory agency] may revoke the plant license.

(c) [The regulatory agency] may suspend or revoke licenses of milk graders and bulk milk collectors for any violation of these regulations on the Act. An opportunity for a hearing shall be provided any license before suspension or revocation of his license.

F 2.6 *Reinstatement*.

(a) If, after a period of withholding, probation or revocation of a plant license, the operator makes the necessary corrections at the plant, he may apply to [the regulatory agency] for reinspection and reinstatement. When the inspector determines that requirements for licensing have been met [the regulatory agency] shall issue a license to the plant.

(b) The reinstatement of licenses for milk graders and bulk milk collectors which have been suspended or revoked shall be made only after satisfying [the regulatory agency] of their qualifications.

Sec. F 3. *Supervision.*

F 3.1 *Regulatory agency*. [The regulatory agency] to insure compliance with the provisions of the Act and the rules and regulations shall:

(a) Make periodic examinations of milk from a representative number of producers at each plant to determine whether the milk is being graded and tested in accordance with the applicable provisions of subpart C.

(b) Examine the quality records of transfer producers at each plant periodically and when necessary, determine the acceptability of such producers= milk.

(c) Make periodic farm inspections and compare the results of such inspections with previously completed Farm Certification Report Forms filed by the inspector or approved fieldperson.

(d) Periodically examine the milk quality tests records of individual producers at each plant.

(e) Periodically inspect plant premises, buildings, equipment, facilities, operations, sanitary practices and compare the results with previously completed plant inspection forms filed by the inspector.

(f) Assist plant management and laboratory and field staffs with educational programs among producers relating to quality improvement of milk.

(g) Perform such other services and institute such other supervisory procedures as may be necessary to insure compliance with the provisions of the Act and the rules and regulations.

(h) F 4. *Farm certification report form*. The following form shall be used by inspectors or approved fieldperson in determining eligibility for farm certification: