COLORADO
Department of Public Health & Environment

Dedicated to protecting and improving the health and environment of the people of Colorado

To: Members of the State Board of Health

From: Paul Klug, Milk Program Coordinator, Division of Environmental Health and Sustainability

Cary E. Ruble, Regulation Development and Enforcement Coordinator, Division of Environmental Health and Sustainability

Through: Jeff Lawrence, Director
Division of Environmental Health and Sustainability (JL)

Date: November 16, 2016

Subject: **Rulemaking Hearing**
Proposed Amendments to 6 CCR 1010-4, *Colorado Grade "A" Pasteurized Milk and Fluid Milk Products* and repeal of 6 CCR 1010-3, *Colorado Manufactured Milk & Dairy Products Regulations*, for the rulemaking to occur in November 2016

The Division of Environmental Health and Sustainability ("division") is proposing revisions to 6 CCR 1010-4 and repeal of 6 CCR 1010-3 and is requesting that the Board of Health adopt the revised regulation and repeal 6 CCR 1010-3 at the November 16, 2016 Board of Health meeting.

6 CCR 1010-4 was last amended by the Board of Health in August 2014. The current revision proposes to update the incorporation by reference by incorporating the *Grade "A" Pasteurized Milk Ordinance, 2015 Revision* (***PMO***); *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments (NCIMS), 2015 Revision* (***Procedures***); and, *Methods of Making Sanitation Ratings of Milk Shippers and the Certifications/Listings of Single-Service Containers and/or Closures for Milk and/or Milk Products Manufacturers, 2015 Revision* (***Methods***). The PMO, Procedures, and Methods are developed by the Federal Food and Drug Administration (FDA) with the assistance of state and local milk regulatory agencies, the dairy industry and educational and research institutions for the purpose of assuring uniformity and effectiveness in state milk sanitation programs. The PMO, Procedures, and Methods also serve as the official documents setting forth the sanitation requirements that govern the processing, packaging, sale, and interstate shipment of Grade A milk and milk products. An electronic copy of these documents is on the division website:

- https://www.colorado.gov/pacific/cdphe/milk-and-dairy-regulations

Also, the 2015 PMO, Procedures, and Methods are posted and available for review on the following International Dairy Food Association (IDFA) website:

- http://www.idfa.org/news-views/headline-news/article/2016/03/31/2015-pmo-and-related-documents-now-available-online

Adoption of the updated 2015 PMO, Procedures, and Methods will ensure that Colorado's Grade "A" and manufactured milk and dairy sanitation programs are in conformance with the latest national standards, thereby permitting Colorado milk and dairy products to move freely in interstate commerce. No controversial issues, related to the adoption of these federal documents, have been identified.

In addition, the division is proposing to combine the Grade "A" rules found at 6 CCR 1010-4 with the manufactured milk and dairy rules found at 6 CCR 1010-3 into one regulation, 6 CCR 1010-4, which will be identified as the *Colorado Milk and Dairy Products Regulations.* 6 CCR 1010-3, *Colorado Manufactured Milk & Dairy Products Regulations*, which was last amended by the Board of Health in March 2003, would be repealed in its entirety. The division proposes this change because both 6 CCR 1010-4 and 6 CCR 1010-3 draw upon the same PMO, the change better aligns the rule with statute and creates parity across the division's milk and dairy program. The PMO is formally revised every two years; the incorporation by reference of the PMO into the combined regulation would align nationally accepted standards for both Grade "A" and manufactured milk and dairy producers and create significant efficiencies in the biennial rulemaking process. The division has engaged stakeholders and to date, none have expressed concern with consolidating and aligning the regulations.

The division appreciates the Board's consideration.

STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for Amendments to
6 CCR 1010-4, *Colorado Grade A Pasteurized Milk and Fluid Milk Products*
and Repeal of
6 CCR 1010-3, *Colorado Manufactured Milk & Dairy Products Regulations*

Basis and Purpose.

Revisions to *Rules and Regulations Pertaining to Colorado Grade "A" Pasteurized Milk and Fluid Milk Products,* 6 CCR 1010-4 would adopt the revised *Grade "A" Pasteurized Milk Ordinance, 2015 Revision* (***PMO***); *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments (NCIMS), 2015 Revision* (***Procedures***); and, *Methods of Making Sanitation Ratings of Milk Shippers and the Certifications/Listings of Single-Service Containers and/or Closures for Milk and/or Milk Products Manufacturers, 2015 Revision* (***Methods***), since 6 CCR 1010-4 was last amended by the Board of Health in August 2014.

Along with updating the incorporation by reference, 6 CCR 1010-4 would be revised to include the standards for manufactured milk and dairy products which are currently located in 6 CCR 1010-3, *Colorado Manufactured Milk & Dairy Products Regulations* and 6 CCR 1010-3, which was last amended by the Board of Health in March 2003, would be repealed. Rule 6 CCR 1010-4 and 6 CCR 1010-3 both rely upon the same PMO and the same incorporation by reference, as applicable, to both the Grade A and the manufactured milk and dairy industry. The result is a single regulation, 6 CCR 1010-4, *Colorado Milk and Dairy Products Regulations.*

The PMO is formally revised every two years, the incorporation by reference of the PMO into the combined regulation aligns nationally accepted standards for both Grade "A" and manufactured milk and dairy producers and create significant efficiencies in the biennial rulemaking process.

The revised *Colorado Milk and Dairy Products Regulations,* 6 CCR 1010-4*,* would recognize technological advances, milk plant environment changes, drug residue controls for food producing animals, and changes in production and processing equipment. The regulation will maintain Colorado's conformance with the requirements adopted by other states, thereby permitting freedom in the movement of milk and dairy products across state lines, to federal reservations and agencies and to certain school districts, in accordance with the terms of:

A. U.S. Department of Health and Human Services, Public Health Service/Food and Drug Administration, *Grade "A" Pasteurized Milk Ordinance, (Includes provisions from the Grade "A" Condensed and Dry Milk Products and Condensed and Dry Whey – Supplement I to the Grade "A" PMO) 2015 Revision*, including supplements, administrative procedures, appendices, and coded Food and Drug Administration Interpretative Memoranda;

B. *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments (NCIMS), 2015 Revision* (*Procedures*); and,

C. *Methods of Making Sanitation Ratings of Milk Shippers and the Certifications/Listings of Single-Service Containers and/or Closures for Milk and/or Milk Products Manufacturers, 2015 Revision* (*Methods*).

The incorporation by reference of these documents into the proposed combined regulation translates new knowledge, technology and methodologies into effective and practicable public health practices. The PMO, Procedures, and Methods are developed by FDA with assistance of state and local milk regulatory agencies and all segments of the dairy industry and educational and research institutions, for adoption by states for the purpose of assuring uniformity and effectiveness in conducting their programs.

The repeal of 6 CCR 1010-3, *Colorado Manufactured Milk & Dairy Products Regulations,* the combining of Grade "A" and manufactured milk and dairy regulations, and the adoption of the *Colorado Milk and Dairy Products Regulations* will provide effective public health protection through the regulation of the Colorado milk and dairy industry.

Specific Statutory Authority.

These rules are promulgated pursuant to the following statutes: Sections 25-1.5-104(1)(b)(I), 25-5.5-103, 25-5.5-107(5) and (6), 25-5.5-205, 25-5.5-309, and 25-5.5-310, C.R.S.

SUPPLEMENTAL QUESTIONS

Is this rulemaking due to a change in state statute?

_____ Yes, the bill number is _____; rules are ___ authorized ___ required.
__X__ No

Is this rulemaking due to a federal statutory or regulatory change?

__X__ Yes
_____ No

Does this rule incorporate materials by reference?

__X__ Yes
_____ No

Does this rule create or modify fines or fees?

_____ Yes
__X__ No

REGULATORY ANALYSIS
for Amendments to
6 CCR 1010-4, *Colorado Grade A Pasteurized Milk and Fluid Milk Products*
and Repeal of
6 CCR 1010-3, *Colorado Manufactured Milk & Dairy Products Regulations*

1. A description of the classes of persons who will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.

Producers, processors and consumers of milk and dairy products will be affected.

2. To the extent practicable, a description of the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.

At this time, there are no known or foreseen increases in cost to the Colorado milk and dairy industry or to consumers.

3. The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

The Colorado Department of Public Health and Environment, Division of Environmental Health and Sustainability, expects minimal, if any, increase in the costs to this Department. There is no increase in the inspectional time anticipated. Distribution of information and guidance relative to the combined milk and dairy regulation may result in a slight increase in the cost to CDPHE. These potential costs will be offset by the reduced burden of maintaining one regulation rather than two, as a result of repealing 6 CCR 1010-3, *Colorado Manufactured Milk & Dairy Products Regulations,* and combining the Grade "A" and manufactured milk regulations. The Department currently provides interpretations, training, and educational materials to regulated facilities, so little impact is anticipated in continuing these services with the revised regulations.

Local health agencies will not be involved with the inspection and enforcement of these facilities and, therefore, there is no associated cost to these agencies.

4. A comparison of the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.

This revised regulation will bring Colorado into conformance with the requirements adopted by other states, thereby permitting freedom in the movement of milk and dairy products across state lines, to federal reservations and agencies and to certain school districts, in accordance with the terms of the PMO, Procedures, and Methods governing Interstate Milk Shippers. The regulations translate new knowledge, technology and methodologies into effective and practicable public health practices.

Inaction would result in Colorado's milk and dairy regulations not being in conformance with the requirements of the 2015 Grade "A" PMO, Procedures, or Methods. A failure to keep Colorado's milk regulations current and in conformance with other states' requirements, would result in Colorado milk processors not being allowed to ship milk and dairy products in interstate commerce or to federal institutions.

5. A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

Adoption of the 2015 PMO, Procedures, and Methods has been determined to obtain uniformity between states, higher levels of milk and dairy sanitation practices, and the facilitation of interstate shipments of quality milk and dairy products. No less costly or intrusive method for achieving the purpose of this rule was identified.

6. Alternative Rules or Alternatives to Rulemaking Considered and Why Rejected.

Consideration was given to revising the existing manufactured milk and dairy products regulation to include the incorporation by reference of the PMO, as previously incorporated into the current Grade "A" milk regulation. As such, and for efficiency in rulemaking and implementation, the determination was made to incorporate the PMO into one regulation that combines both the Grade "A" and manufactured milk and dairy products regulations.

7. To the extent practicable, a quantification of the data used in the analysis; the analysis must take into account both short-term and long-term consequences.

Quantification of the data is not applicable.

STAKEHOLDER COMMENTS
for Amendments to
6 CCR 1010-4, *Colorado Grade A Pasteurized Milk and Fluid Milk Products*
and Repeal of
6 CCR 1010-3, *Colorado Manufactured Milk & Dairy Products Regulations*

Early Stakeholder Engagement:

The Division has been tracking opportunities to improve and modernize the manufactured milk and dairy regulations since 2003. Beginning in August 2016, the division notified stakeholders to discuss proposed changes to the Grade "A" and manufactured milk and dairy regulations and requested feedback.

The following individuals and/or entities were included in the development of these proposed rules:

- U.S. Department of Health and Human Services, Public Health Service/Food and Drug Administration (FDA)
- National Conference On Interstate Milk Shippers (NCIMS)
- CDPHE staff
  - Paul Klug, Division of Environmental Health and Sustainability, Milk Program Coordinator
  - Cary Ruble, Regulation Development and Enforcement Coordinator
  - Susan Parachini, Milk and Corrections Unit Manager
  - Sean Scott, Division of Environmental Health and Sustainability, Deputy Director
  - Jeff Lawrence, Division of Environmental Health and Sustainability, Director
  - Ben Chouaf, Laboratory Services Division, Physical Scientist
  - Jeff Groff, Laboratory Services Division, Certification Program Manager
  - Skip Gossack, Laboratory Services Division, Environmental Microbiologist
- Milk and Dairy Program Stakeholders
  - Michael Amen, Ugly Goat Milk Company, LLC
  - Rob and Amy Anderson, Mini-Moos Dairy
  - Wes Bangma, Mile High Dairy
  - Dan Boyd, Longmont Dairy Plant
  - Katie Burford, Cream Bean Berry
  - Ron Cantwell, Leprino Foods - Fort Morgan
  - Peggy Colfelt, Aurora Organic Dairy
  - Brett Corsentino, Corsentino Dairy
  - Dave Davis, Noosa Yoghurt
  - Andrea Davis, Broken Shovels Farm
  - Kathy Doty, De La Chiva Dairy, LLC
  - Steve Fritzler, Leprino Foods - Greeley
  - Caille Gash, Cozy Cow Dairy
  - Kim Geraldine, Frozen Matter
  - John Gibson, Rockin' W Cheese
  - Rob Graves, Morning Fresh Dairy
  - Karl Guderian, Safeway Stores, Inc. Milk Plant
  - Jim Heaston, Juniper Valley Farm
  - Charles Hellmer, Haystack Mountain Goat Dairy
  - Kyle Hendrix, HX Butterfield

- Tim Houck, Dairy Farmers of America
- Dan James, James Ranch Artisan Cheese
- Dawn Jump, Jumpin' Good Goat Dairy
- Jim Jung, Meadow Gold Dairy - Greeley
- Jennifer Knoblauch, Laz Ewe 2 Bar Dairy
- Ann Kurronen, AnnaVail Cheese
- Joel Lederman, Colorado Dairy Supply
- Jacob Lofgren, CDPHE - DEHS
- Chris Maes, AMCOR PET Packaging - North America
- Joe May, Meadow Gold Dairies - Englewood
- Wade Meek, Dairy Farmers Of America (Transfer Station)
- Paul Minerich, Russell Stover Candies LLC
- Wendy Mitchell, Avalanche Cheese Company
- Amanda Moore, Sinton Dairy Foods Co. LLC
- Tammie Niemoth, Rich Thompson Trucking, Inc.
- Clayton Peherson, Mountain View Foods
- Vallorie Philpott, Philpott Goat Dairy
- Robert Poland, MouCo Cheese Company, Inc.
- Sister Gertrude Read, Abbey of St. Walburga Cheese Plant
- Keith Roehr, DVM, Colorado Dept of Agriculture
- Tony Rosso, Dairy Farmers of America, Inc. Ft. Morgan Plant
- Scott Roy, Boulder Ice Cream
- Jim Smith, Hi Plains Dairy
- Randy Sorenson, Dairy Specialists
- Nick Streigel, DVM, Colorado Dept of Agriculture
- Kendall Tankersly, Third Bowl Homemade Ice Cream
- Steve Valente, Bottles Unlimited
- Juan Velez, Aurora Organic Dairy Farms
- Jimmy Warren, Fruition Farms Dairy and Creamery
- Edith Wilkin, Leprino Foods - Denver
- Terry Witt, Royal Crest Dairy
- Tom and Doris Zubal, Zubal Goat Dairy

Summarize Major Factual and Policy Issues Encountered and the Stakeholder Feedback Received. If there is a lack of consensus regarding the proposed rule, please also identify the Department's efforts to address stakeholder feedback or why the Department was unable to accommodate the request.

The stakeholder comments received have been positive, resulted in consensus on the proposed revisions, and has identified opportunities for the development of technical guidance to assist with implementation of the revised regulations. There were no major factual or policy issues encountered during the drafting of the proposed regulation.

Please identify health equity and environmental justice (HEEJ) impacts. Does this proposal impact Coloradoans equally or equitably? Does this proposal provide an opportunity to advance HEEJ? Are there other factors that influenced these rules?

No HEEJ impacts were identified during revision of the subject regulation. The revised and proposed regulation will continue to assure uniformity and effectiveness in the state milk and dairy sanitation programs and promote the full health potential of all Coloradans.

SUMMARY OF CHANGES TO THE PMO, 2015 REVISION

The following Proposals were passed or passed as amended and addressed changes to the PMO:

104. Adds consistency to the coliform requirements for Grade A bulk shipped condensed whey and/or whey products as is other bulk shipped Grade A products in Table 1 Chemical, Physical, Bacteriological, and Temperature Standards on pages 33 and 34 of the 2013 PMO.

105. Removes out dated or not needed language from 2013 PMO, page 38, Item 3r regarding the cleaning of barn floors.

112. Specifies the applicable requirements of electronic data collection and storage in Appendix H, IV and V for 18r Raw Milk Cooling.

114. Clarifies, on page 75 of the 2013 PMO, that sanitizing drying and dry product equipment is only necessary after the equipment has been wet cleaned.

119. The U.S. Department of Agriculture Animal and Plant Health Inspection Service (USDA APHIS) Programs on Tuberculosis (TB) and Brucellosis eradication were designed for cattle and bison. While there is little known risk from TB or Brucellosis in areas where the diseases have been eradicated in cattle and bison there is a concern that there is not sufficient data to prove there is no risk. This proposal follows the same options as the conference has allowed on other species for brucellosis and extends the testing requirements for TB. This includes an option that puts the specifics of each state plan into the hands of the State Veterinarian, as they are the most knowledgeable of the risks in their state.

121. From the 2013 PMO, removes the statement quoting the National Mastitis Council (NMC) on page 164, Milking Methods, paragraph 1, indicating a thirty (30) second prepare time. On page 165, paragraph 4 removed the statement of machine stripping the cow. Page 164, paragraph 6, removed the statements on number of units.

124. Clarifies language in the 2013 PMO with regard to Appendix H - Section II - Air Under Pressure -Milk Product-Contact Surfaces, final filter efficiency. This proposal also updates the 2013 PMO's "commercially sterile air" filter efficiency criteria, so that it is consistent with the current 3-A Accepted Practice (604-05) criteria.

126. Adds additional instruction options to perform high temperature/short time (HTST) test 9.2.2 on page 304. The option would allow for usage of the raw regenerator section differential pressure controller sensing element.

128. Allows equipment for testing the holding time on a pasteurization system that does not conform to equipment that has been used in the past. The start of the system is important because it uses the operation of a valve to begin the holding time test. As with other items found in the PMO alternate systems that work as well or better than existing systems have been allowed. These changes allow for equipment to be used in the testing of the holding time without the possibility of giving false tests. It simply allows equipment that is not traditional to be used and to give a very accurate test of the holding time. By allowing the use of a valve and switch to start the timing of the system

salt enters the holding tube, starts the timing sequence and then the time stops in the conventional method through the use of conductivity. We have found very similar holding times, some faster, to conventional testing methods through this method because the starting sequence is more reliable.

133. Brings the PMO Appendix J and the 2400 series forms into agreement on sample size. FDA-National Conference on Interstate Milk Shipments (NCIMS) form 2400i, Pasteurized Milk containers, rev 10-13, item 26a states one sample is 5-50 square centimeter (cm2 areas or 250 cm2 of product contact surface). A sample set is 4 times one sample or 4-250 cm areas. However, the PMO, Appendix J, repeatedly bases regulatory action on 3 out of 4 samples where a sample size is given to be 4-50 cm2 areas. Since the 2400 forms are based on science it would make sense to change the definition of a sample set for the swab test to agree with the 2400 forms.

134. Addresses concerns cited in Appendix Q-Operation of Automatic Milking Installations for the Production of Grade "A" Raw Milk for Pasteurization, Ultra pasteurization or Aseptic Processing and Packaging, Item Ir-Abnormal Milk, Item 13r-Milk – Flanks, Udders and Teats of the PMO, and provides guidance for written procedures for milk with abnormalities, computer system(s) verification, and general computer requirements for Automatic Milking Installations (AMI). With the increased use of AMIs that utilize computerized systems and new technologies on Grade "A" dairy farms, this Proposal provides general guidance for AMI computer systems and clarification as to how AMI computer systems for the detection of abnormal milk and teat preparation are to be monitored and maintained.

203. Adds the definition for "inspection/audit report" to the PMO.

207. Adds the definition of "camel milk" to the PMO.

208. Allows electronically generated or hand written inspection/audit reports of all dairy facility inspections to be provided to the establishment, operator, or other responsible person.

213. Addresses Proposal 220 from the 2013 NCIMS Conference that was assigned to the Appendix N Modification Committee addressing the procedure to follow when using a drug testing method that has NOT been evaluated and accepted by FDA and the NCIMS when there is a drug testing method AVAILABLE that has been evaluated and accepted by FDA and the NCIMS (M-a-85, latest revision, and M-I-92-11). It further addresses a request from FDA to the Appendix N Modification Committee and accepted by the Appendix N Modification Committee to develop a procedure to follow when using a drug testing method that has NOT been evaluated and accepted by FDA and the NCIMS when there is NOT a drug testing method that has been evaluated and accepted by FDA and the NCIMS available.

216. Modifies the minimum sensitivity requirement, the 50% detection level of the safe/tolerance level rule, for the acceptance of test methods for drug residue analysis by making safe levels of drugs not applicable with the exception of penicillin G. The proposal would delete the word "safe" from the 50% rule and from the text of the PMO, where appropriate. For test methods for tetracycline drugs, modify the minimum sensitivity requirement. Test methods that meet or exceed the 90/95 detection levels for oxytetracycline and tetracycline of the currently accepted test kit may be accepted for

Appendix N testing. The 90/95 detection levels for chlortetracycline for the currently accepted test kit meet the 50% rule.

219. Requires the Regulatory Agency to do the arithmetical averaging of sample results from producers shipping multiple tanks/loads of raw milk in a day. This proposal allows personnel in an Official, Commercial or Industry Laboratory approved by the Milk Laboratory Control Agency to do the arithmetical averaging.

224. Revises wording in Section 6, Laboratory Techniques, of the PMO to allow new simplified methods for bacterial detection that have been FDA-NCIMS evaluated published in M-a-98, lasted revision, and accepted into a 2400 series form.

225. Includes in Section 6, The Examination of Milk and/or Dairy Products, the appropriate somatic cell counting method and appropriate somatic cell count standard for use with camel milk.

226. Changes PMO bacteriological water standards to address EPA elimination of the maximum contaminant level (MCL) for Total Coliform and implementation of an E. coli MCL.

227. Changes the annual tank inspection to a 2-year inspection. Changing the requirement of the tank truck inspections to a 2 year cycle allows the tanks to be inspected between 1 and 2 years, which would also allow a milk hauler and the state inspector enough time to keep the inspection current. This would give an inspector a broader timeframe to inspect a milk tank truck when they have the opportunity at a plant or the milk hauler's place of business.

229. Requires records of all sample results shall be maintained for a minimum of two (2) years by the industry at the location where the tests were run, and/or another location as directed by the Regulatory Agency.

301. Provides a two (2) year extension of the NCIMS Aseptic Pilot Program (APP) to specifically address aseptically processed and packaged Grade "A" fermented high-acid milk and/or milk products. The additional two (2) years will be utilized to continue to evaluate the effectiveness of regulating and rating milk plants producing aseptically processed and packaged Grade "A" fermented high-acid milk and/or milk products under the provisions currently in place. The NCIMS Aseptic Program Committee (APC) is discontinuing their evaluation of aseptically processed and packaged Grade "A" acidified milk and/or milk products.

306. Adds to the Table of Contents of each NCIMS document a listing of abbreviations and acronyms that are used throughout the individual PMO, MMSR, Procedures and EML documents.

309. Develops listing and withdrawal of listing criteria for Single Service Containers and Closures (SSCC) manufacturers. Develops qualifications, authorization, certification/recertification procedures, etc. for consultants that currently certify or wish to certify SSCC manufacturers located outside the geographical boundaries of NCIMS Member States.

JC1. Addresses the PMO, with Appendices, and the supporting milk plant-specific

procedures required herein, shall constitute a milk plant's food safety plan as required by 21 CFR 117.126 to the extent that the procedures address all the hazards identified by the milk plant as applicable for that milk plant. A milk plant shall have a written Hazard Analysis for each kind or group of milk and/or milk product processed.

JC3. Addresses food allergen control and a written food recall plan that shall include procedures as described in 21 CFR Part 7 (Subpart A and C).

JC4. Addresses environmental monitoring.

JC5. Addresses a supplier control program.

JC7. Addresses prerequisite and other program procedures as described in 21 CFR Part 7 (Subpart A and C) in Appendix K-HACCP Program of the PMO.

The following Proposals were passed or passed as amended and addressed changes to the Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments (Procedures):

306. See above.

307. Clarifies that drug residue summary data shall be collected by Third Party Certifiers (TPCs) and reported to the third party database. Collection and reporting of drug residue summary data by Third Party Certifiers aligns the requirements of the voluntary International Certification Program with the domestic NCIMS program.

308. Reduces the number of bulk milk hauler/samplers evaluated during Sampling Surveillance Officer re-certification. This will make the re-Certification process similar to the current re-delegation to state regulatory personnel process as established by the 2007 NCIMS found in the 'Procedures Governing the Cooperative State-Public Health Service I Food and Drug Administration Program of the National Conference on Interstate Milk Shipments (2013 Revision) " document.

309. See above.

The following Proposals were passed or passed as amended and addressed changes to the Methods of Making Sanitation Ratings of Milk Shippers (MMSR Methods):

306. See above.

309. See above.

The following Proposals were passed or passed as amended and addressed the formation or continuation of Pilot Programs:

211. Charges the Appendix N Modification Committee to develop a pilot program establishing a regulatory framework by which testing raw milk for veterinary drugs would be *required for drugs other than beta-lactams*.

301. See above.

The following Proposals were passed or passed as amended and are of significance to the Grade "A" Milk Safety Program:

JC1, JC3, JC4,
JC5, and JC7:

All Proposals seek to align the PMO with the requirements of the Food Safety Modernization Act (FSMA) Proposed Rule for Prevention Controls for Human Foods. See above.

211, 213, and 216:

Address testing for non-Beta lactam animal drugs on bulk milk pickup tankers and/or all raw milk supplies that have not been transported in bulk milk pickup tankers.

211. See above.

213. Establishes a protocol when utilizing a drug test method that has not been evaluated by FDA and accepted by the NCIMS for initial screening followed by a drug test method that has been evaluated by FDA and accepted by the NCIMS (M-a-85, latest revision, and M-I-92-11) for determining a screening test positive (load and/or raw milk supply that has not been transported in bulk milk pickup tankers confirmation). It also established a protocol when utilizing a drug test method that has not been evaluated by FDA and accepted by the NCIMS for initial screening and determining a verified screening positive load and/or raw milk supply that has not been transported in bulk milk pickup tankers when a drug test method that has been evaluated by FDA and accepted by the NCIMS (M-a-85, latest revision, and M-I-92-11) is not available.

216. Identifies a "target testing" level instead of the previously used "safe" level for individual animal drugs. It also states that new drug test methods, which are submitted to NCIMS, from FDA, for acceptance, shall not detect drug residues at less than 50% of the tolerance level or 25% of the target testing level* for individual drugs, with the exception of penicillin G and tetracyclines.

226. See above.

309. See above.

219. See above.

226. See above.

227. See above.

COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Division of Environmental Health and Sustainability

6 CCR 1010-4

COLORADO ~~GRADE A PASTEURIZED~~ MILK AND ~~FLUID MILK~~ DAIRY PRODUCTS REGULATIONS

COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Division of Environmental Health and Sustainability

6 CCR 1010-4

COLORADO ~~GRADE A PASTEURIZED~~ MILK AND ~~FLUID MILK~~ DAIRY PRODUCTS REGULATIONS

Adopted by the Board of Health on _____; effective, _____

4.1 Authority

This regulation is adopted pursuant to ~~the authority in~~ Section 25-1.5-104(1)(b)(I), 25-5.5-103, 25-5.5-107(5), and (6), 25-5.5-205, 25-5.5-309, and 25-5.5-310, Colorado Revised Statute (C.R.S.) and is consistent with the requirements of the State Administrative Procedures Act, Section 24-4-101, *et seq.*, C.R.S.

4.2 Scope and Purpose

A. This regulation ~~establishes provisions governing~~ shall govern:

1. ~~d~~ Dairy sanitation, the processing, packaging, transportation and sale of Grade "A" milk and milk products, and represents the state and federal standard for Grade "A" milk sanitation~~.~~;

2. Sanitary production of milk for manufacturing purposes including its transportation, grading, use, processing, and the packaging, labeling and storage of dairy products made there from;

3. Licensure and inspection of dairy farms and dairy plants for the production and sale of milk or dairy products for manufacturing purposes;

4. Retention of appropriate documentation and records by plants licensed hereunder; and

5. Licensure of qualified milk or dairy product samplers and testers.

~~B. This regulation does not apply to milk and dairy products as defined under the Colorado Manufactured Milk & Dairy Products Regulations, 6 CCR 1010-3.~~

B. Section 4.7 of this regulation incorporates by reference the *Grade "A" Pasteurized Milk Ordinance 2013~~3~~5 Revision*, including supplements, provisions, administrative procedures and appendices (PMO), *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments 2013~~3~~5 Revision* (Procedures), and *Methods of Making Sanitation Ratings of Milk Shippers 2013~~3~~5 Revision* (Methods), in effect as of this date.

4.3 Applicability

A. Pursuant to the provisions of Section 25-1.5-104(1)(b)(I), C.R.S., this regulation shall

apply to dairy plants, dairy farms, processing plants, receiving stations and other facilities or establishments handling, transporting or selling any Grade "A" milk and dairy ~~milk~~ products for human consumption.

B. The PMO shall apply to ~~regulate~~ dairy sanitation and the labeling and grading of milk pursuant to the provisions of Section 25-1.5-104(1)(b)(I), C.R.S., in so far as it is consistent with Colorado statutes and regulations, except that: In the PMO as indicated, "State of Colorado" shall be inserted in all footnotes numbered (2).

C. The PMO shall apply to the production of raw milk and cream for manufacturing purposes, butter, raw aged cheeses, pasteurized cheese and cheese products, frozen desserts, ice cream, pasteurized ice cream, dry whole milk, nonfat dry milk, dry buttermilk, dry whey, evaporated milk (whole or skim), condensed whole milk (excluding sweetened condensed milk), condensed skim milk, cottage cheese, dry curd cottage cheese, low fat cottage cheese, and other such products for human consumption, as may be otherwise designated. These products may be produced from cow, goat, sheep, camel or other milk producing animals.

D. The PMO shall apply to the production, transportation, processing, handling, sampling, examination, labeling, and sale of milk and dairy products; the inspection of dairy farms, milk tank trucks, milk plants, receiving stations, transfer stations, milk tank truck cleaning facilities, and bulk milk hauler/samplers.

E. The PMO shall apply to the issuing and revocation of licenses to milk and dairy producers, dairy farms, bulk milk hauler/samplers, milk tank trucks, milk transportation companies, milk plants, receiving stations, transfer stations, milk tank truck cleaning facilities, haulers, and distributors; and the fixing of penalties.

F. The department shall utilize the PMO or other department approved methods as appropriate to assure that non-Grade "A" manufactured milk and dairy products are in compliance with Section 25-5.5-101, *et seq.*, C.R.S.

4.4 Definitions

A. For the purpose of these rules and regulations:

1. ~~2.~~Jurisdiction~~,~~ (as used in the PMO)~~, shall~~ means the State of Colorado.

2. ~~3.~~ Ordinance~~,~~ (as used in the PMO)~~, shall~~ means the ~~rules and~~ regulations of the State of Colorado.

~~4. Cottage cheese, dry curd cottage cheese, and low fat cottage cheese, as defined in the Code of Federal Regulations, Title 21, Sections 133.128 and 133.129, manufactured or sold in the State of Colorado, shall meet the applicable requirements of the PMO.~~

3. ~~1.~~Regulatory Agency~~, as defined in the PMO, shall~~ means the Colorado Department of Public Health and Environment and its authorized representative.

4. Sale means the transfer of manufactured milk and dairy products from one individual, partnership, or corporation to another individual, partnership, or corporation in exchange for cash or any other contractual obligation to pay for the product.

4.5 License Requirements

Any person desiring to operate a dairy farm, milk or dairy plant or receiving station or to sample or test milk or cream for the purpose of payment in this state, before undertaking such operation, shall make application to and, if approved, be licensed by the Department in accordance with Section 25-5.5-107, C.R.S.

4.6 Denial and Suspension of Licenses

All denials, suspensions or revocations of licenses shall be conducted in accordance with the provisions of Sections 24-4-104 and 24-4-105, C.R.S.

4.7 Incorporation by Reference

A. Throughout these regulations, standards and requirements of outside organizations have been adopted and incorporated by reference. The material incorporated by reference cited herein includes only those versions that were in effect as of 2013~~5~~, and not later amendments to the incorporated materials. These rules incorporate by reference:

1. U.S. Department of Health and Human Services, Public Health Service/Food and Drug Administration, *Grade "A" Pasteurized Milk Ordinance (Includes provisions from the Grade "A" Condensed and Dry Milk Products and Condensed and Dry Whey – Supplement I to the Grade "A" PMO 2013~~5~~ Revision)*, including supplements, administrative procedures, appendices, and coded Food and Drug Administration Interpretative Memoranda (PMO);

2. U.S. Department of Health and Human Services, Public Health Service/Food and Drug Administration and the National Conference On Interstate Milk Shipments, *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments 2013~~5~~ Revision* (Procedures); and,

3. U.S. Department of Health and Human Services, Public Health Service/Food and Drug Administration, *Methods of Making Sanitation Ratings of Milk Shippers 2013~~5~~ Revision* (Methods).

B. The Division of Environmental Health and Sustainability shall maintain certified copies of the complete text of the incorporated materials, which shall be available for public inspection during regular business hours, and shall provide certified copies of the materials at cost upon request. For information regarding how the incorporated materials may be obtained or examined, contact:

Division Director
Division of Environmental Health and Sustainability

Colorado Department of Public Health and Environment
4300 Cherry Creek Drive South
Denver, Colorado 80246-1530

C. ~~Materials incorporated by reference have been submitted to the State Publications Depository and Distribution Center and may be examined at any state publications depository library.~~The incorporated materials are available at:

www.colorado.gov/pacific/cdphe/milk-and-dairy-regulations

~~**DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT**~~

~~**Division of Environmental Health and Sustainability**~~

~~**COLORADO MANUFACTURED MILK AND DAIRY PRODUCTS**~~

~~**6 CCR 1010-3**~~
~~*[Editor's Notes follow the text of the rules at the end of this CCR Document.]*~~

~~**INTRODUCTION**~~

~~The Colorado Department of Public Health and Environment shall administer the provision of these Regulations under authority of §25-1-107(1)(o) (I, IV) and 25-5.5-107 (1,2,3) C.R.S. It is the intent of these Regulations to: encourage the sanitary production of good quality milk for manufacturing purposes including its transportation, grading, use, processing, and the packaging, labeling and storage of dairy products made there from; require the licensure and inspection of dairy farms and dairy plants for the production and sale of milk for manufacturing purposes; require the keeping of appropriate documentation and records by plants licensed hereunder; and require the licensure of qualified milk samplers and testers.~~

~~These Regulations include, but are not limited to, the production of raw milk and cream for manufacturing purposes, raw aged cheeses, pasteurized cheese and cheese products, frozen desserts, dry whole milk, nonfat dry milk, dry buttermilk, dry whey, evaporated milk (whole or skim), condensed whole milk, condensed skim milk and other such products, for human consumption, as may be otherwise designated.~~

~~These products may be produced from cow, goat, sheep, or other milk producing animal. Milk and milk products produced under the~~ 1999 Colorado Grade A Pasteurized Fluid Milk and Milk Products Regulations ~~are excluded from these Regulations. These Regulations shall become effective one year from adoption by the Colorado State Board of Health at which time 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 provision of these Regulations.~~

~~Sections 2 through 12 list the requirement(s) for the section following the section and/or item title. The requirement may be followed by the "Public Health Reason" and/or the "Administrative Procedures." The public health reason explains the significance of the item to public health and is for informational purposes rather than a regulatory requirement. The administrative procedures explain the regulatory requirement(s). In Section 7, when items are designated by an "r" the item refers to a raw milk requirement. Those designated by a "p" refer to dairy plant requirements.~~

~~A regulation which defines: "milk" and certain "dairy products", "milk producer", "pasteurization", etc.; prohibits the sale of adulterated and misbranded milk and dairy products; requires permits for the sale of milk and dairy products; regulates the inspection of dairy farms and dairy plants, the examination, labeling, pasteurization, aseptic processing and packaging and distribution and sale of milk and dairy~~

products; provides for the construction of future dairy farms and dairy plants; and includes the enforcement of these Regulations and the fixing of penalties.

SECTION 1. DEFINITIONS

Terms used in this document not specifically defined herein are defined within Title 21, Code of Federal Regulations (CFR) 1999, parts 100–169 and 170–199, and/or the *Federal Food, Drug, and Cosmetic Act* (1998).

The following additional definitions shall apply in the interpretation and the enforcement of these Regulations:

A. **BULK MILK HAULER/SAMPLER.** A bulk milk hauler/sampler is any person who collects official samples and may transport raw milk from a farm and/or raw dairy products to or from a dairy plant, receiving station or transfer station and has in their possession a permit from any state to sample such products.

B. **BULK MILK PICKUP TANKER.** A bulk milk pickup tanker is a vehicle, including the truck, tank and those appurtenances necessary for its use, used by a milk hauler to transport bulk raw milk for pasteurization from a dairy farm to a dairy plant, receiving station, or transfer station.

C. **CHANGE OF OWNERSHIP** means a transfer of the ownership/license of the business to a person, partnership, or corporation different from the ownership/license of the business on or after the effective date these regulations.

D. **CONCENTRATED DAIRY PRODUCTS.** Concentrated dairy products shall be taken to mean and to include homogenized concentrated milk, concentrated nonfat milk, concentrated reduced fat milk, and similar concentrated products made from concentrated milk or concentrated non-fat milk, and which, when combined with potable water in accordance with instructions printed on the container, conform with the definitions of the corresponding dairy products in this section C.

E. **CONCENTRATED MILK.** Concentrated milk is a fluid product, unsterilized and unsweetened, resulting from the removal of a considerable portion of the water from the milk, which, when combined with potable water in accordance with instructions printed on the container, results in a product conforming with the milkfat and milk solids not fat levels of corresponding dairy products as defined in this section.

F. **DAIRY FARM.** A dairy farm is any place or premises where one or more lactating animals (cows, goats, sheep, etc.) are kept, and from which a part or all of the milk or dairy product(s) is provided, sold or offered for sale to a receiving station, transfer station or dairy plant.

G. **DAIRY PLANT.** A dairy plant is any place, premises or establishment where milk or dairy products are collected, handled, processed, stored, pasteurized, aseptically processed, aged, packaged, or prepared for distribution.

H. **DAIRY PLANT SAMPLER.** A person responsible for the collection of official samples for regulatory purposes outlined in Section 6 of these Regulations. This person is an employee of the regulatory agency and is evaluated at least once every two-year period by the State Sampling Surveillance Officer.

I. **DAIRY PRODUCTS.** Dairy products also include those dairy foods made by modifying the federally standardized products listed in this Section in accordance with 21 CFR 133 & 135 (1999).

This definition is intended to include but not limited to ice cream and other desserts, butter, and cheese.

J. **DRY MILK AND WHEY PRODUCTS.** Dry milk and whey products are products which have been produced for use in pasteurized or aseptically processed dairy products.

K. **EXEMPTED GOAT DAIRY.** means a goat dairy which is not required to meet the pasteurization requirements of Section 7, Item 16p of these regulations and includes only the following goat operations:

Le-Platt Hi-Country Goat Dairy, 21604 County Rd. 41.6, Trinidad, Co. 81082Philpott Goat Dairy, P.O. Box 113, Hoehne, Co. 81046Provost Goat Dairy, 2227 41-1/2 Lane Olsen, Avondale, Co. 81022Zubal Goat Dairy, P.O. Box 71, Hoehne, Co. 81046

L. **FROZEN MILK CONCENTRATE.** Frozen milk concentrate is a frozen dairy product with a composition of milkfat and milk solids not fat in such proportions that when a given volume of concentrate is mixed with a given volume of water the reconstituted product conforms to the milkfat and milk solids not fat requirements of whole milk. In the manufacturing process, water may be used to adjust the primary concentrate to the final desired concentration. The adjusted primary concentrate is pasteurized, packaged, and immediately frozen. This product is stored, transported and sold in the frozen state.

M. **GOAT MILK.** Goat milk is the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one or more healthy goats. Goat milk sold in retail packages shall contain not less than 2.5 percent milkfat and not less than 7.5 percent milk solids not fat. Goat milk shall be produced according to the sanitary standards of these Regulations. The word "milk" shall be interpreted to include goat milk.

N. **MILK DISTRIBUTOR.** A milk distributor is any person who offers for sale or sells to another any manufactured milk or dairy products.

O. **MILK PRODUCER.** A milk producer is any person who operates a dairy farm and provides, sells or offers milk for sale to a dairy plant, receiving station or transfer station.

P. **MILK TANK TRUCK CLEANING FACILITY.** Any place, premise, or establishment, separate from a dairy plant, receiving or transfer station, where a milk tank truck is cleaned and sanitized.

Q. **MILK TANK TRUCK DRIVER.** A milk tank truck driver is any person who transports raw or pasteurized dairy products to or from a dairy plant, receiving station or transfer station. Any transportation of a direct farm pickup requires the milk tank truck driver to have responsibility for accompanying official samples.

R. **MILK TANK TRUCK.** A milk tank truck is the term used to describe both a bulk milk pickup tanker and a milk transport tank.

S. **MILK TRANSPORT TANK.** A milk transport tank is a vehicle, including the truck and tank, used by a milk hauler to transport bulk shipments of milk from a dairy plant, receiving station or transfer station to another dairy plant, receiving station or transfer station.

T. **MILK TRANSPORTATION COMPANY.** A milk transportation company is the person responsible for a milk tank truck(s).

U. **OFFICIAL LABORATORY.** An official laboratory is a biological, chemical or physical laboratory which is under the direct supervision of the State or a local regulatory agency.

V. **OFFICIALLY DESIGNATED LABORATORY.** An officially designated laboratory is a commercial laboratory authorized to do official work by the regulatory agency, or a milk industry laboratory officially designated by the regulatory agency for the examination of producer samples of raw milk

for pasteurization and commingled milk tank truck samples of raw milk for drug residues and bacterial limits.

W. **PERSON.** The word "person" shall include any individual, plant operator, partnership, corporation, company, firm, trustee, association or institution.

X. **PASTEURIZATION.** The terms "pasteurization", "pasteurized" and similar terms shall mean the process of heating every particle of milk or dairy product, in properly designed and operated equipment, to one of the temperatures given in the following chart and held continuously at or above that temperature for at least the corresponding specified time:

Temperature	**Time**
*63°C (145°F)	30 minutes
*72°C (161°F)	15 seconds
89°C (191°F)	1.0 second
90°C (194°F)	0.5 second
94°C (201°F)	0.1 second
96°C (204°F)	0.05 second
100°C (212°F)	0.01 second
*If the fat content of the dairy product is 10 percent or more, or if it contains added sweeteners, the specified temperature shall be increased by 3°C (5°F). Provided, that ice cream mixes shall be heated to at least the following temperature and time specifications:	
69°C (155°F)	30 minutes
80°C (175°F)	25 seconds
83°C (180°F)	15 seconds
Provided further, that nothing shall be construed as barring any other pasteurization process which has been recognized by the Food and Drug Administration to be equally efficient and which is approved by the regulatory agency.	

Y. **RECEIVING STATION.** A receiving station is any place, premises or establishment where raw milk is received, collected, handled, stored or cooled and prepared for further transporting.

Z. **RECONSTITUTED OR RECOMBINED MILK AND DAIRY PRODUCTS.** Reconstituted or recombined milk and/or dairy products shall mean milk or dairy products defined in this section which result from reconstituting or recombining of milk constituents with potable water when appropriate.

AA. **REGULATORY AGENCY.** The regulatory agency shall mean the Colorado Department of Public Health and Environment (CDPHE), or authorized representative The term, "regulatory agency", whenever it appears in these Regulations shall mean the appropriate agency having jurisdiction and control over the matters embraced within these Regulations.

BB. **SHEEP MILK.** Sheep milk is the normal lacteal secretion practically free of colostrum, obtained by the complete milking of one or more healthy sheep. Sheep milk shall be produced according to the sanitary standards of these Regulations. The word "milk" shall be interpreted to include sheep milk.

CC. **TRANSFER STATION.** A transfer station is any place, premises or establishment where milk or dairy products are transferred directly from one milk tank truck to another.

DD. **SALE.** means the transfer of manufactured milk and dairy products from one individual, partnership, or corporation to another individual, partnership, or corporation in exchange for cash or any other contractual obligation to pay for the product. The sale of undivided shares or

~~interests in a dairy herd is considered to constitute the sale of raw milk, which is prohibited under state law.~~

~~SECTION 2. ADULTERATED OR MISBRANDED MILK OR DAIRY PRODUCTS~~

~~No person shall, within the State of Colorado, or its jurisdiction, produce, provide, sell, offer, or expose for sale or have in possession with intent to sell any milk or dairy product which is adulterated or misbranded.~~

~~Any adulterated or misbranded milk or dairy product may be embargoed by the regulatory agency and disposed of in accordance with applicable laws or regulations.~~

~~ADMINISTRATIVE PROCEDURES~~

~~This section of these Regulations shall be used when embargoing the products of, or preferring charges against, persons who adulterate or misbrand their milk or dairy products, or label them with any grade designation not authorized by the regulatory agency under the terms of these Regulations or who sell or deliver ungraded milk or dairy products.~~

~~SECTION 3. PERMITS~~

~~It shall be unlawful for any person who does not possess a permit or a license from a regulatory agency outside of the State of Colorado to bring into, send into or receive into the State of Colorado or its jurisdiction, for sale, or to sell, or offer for sale therein or to have in storage any milk or dairy products defined in these Regulations. Provided, that similar retail food establishments where milk or dairy products are served or sold at retail, but not processed, may be exempt from the requirements of this section.~~

~~Only a person who complies with the requirements of these Regulations shall be entitled to receive and retain such a permit. Permits shall not be transferable with respect to persons and/or locations.~~

~~The regulatory agency shall suspend such permit, whenever it has reason to believe that a public health hazard exists; or whenever the permit holder has violated any of the requirements of these Regulations; or whenever the permit holder has interfered with the regulatory agency in the performance of its duties. Provided, that the regulatory agency shall, in all cases except where the milk or dairy product involved creates, or appears to create, an imminent public health hazard; or in any case of a willful refusal to permit authorized inspection, serve upon the holder a written notice of intent to suspend permit. The notice shall specify with particularity the violation(s) in question and afford the holder such reasonable opportunity to correct such violation(s) as may be agreed to by the parties, or in the absence of agreement, fixed by the regulatory agency before making any order of suspension effective. A suspension of permit shall remain in effect until the violation(s) has been corrected to the satisfaction of the regulatory agency.~~

~~Upon notification, acceptable to the regulatory agency, by any person whose permit has been suspended, or upon application within 48 hours of any person who has been served with a notice of intention to suspend, and in the latter case before suspension, the regulatory agency shall within 72 hours proceed to a hearing to ascertain the facts of such violation(s) or interference and upon evidence presented at such hearing shall affirm, modify or rescind the suspension or intention to suspend.~~

~~Upon repeated violation(s), the regulatory agency may revoke such permit following reasonable notice to the permit holder and an opportunity for a hearing. This section is not intended to preclude the institution of court action as provided in Sections 5 and 6.~~

~~ADMINISTRATIVE PROCEDURES~~

~~ISSUANCE OF PERMITS.—~~ ~~Every milk producer, milk distributor, bulk milk hauler/sampler, milk transportation company and each dairy plant, receiving station, milk tank truck cleaning facility and transfer station operator shall hold a valid permit. The permit for one or more milk tank trucks may be~~

issued to the milk transportation company. The following will not be required to possess a bulk milk haulers/samplers permit: milk producers who transport milk or dairy products only from their own dairy farms; employees of a milk distributor or dairy plant operator who possesses a valid permit; and employees of a milk transportation company that possesses a valid permit and transports milk from a dairy plant, receiving station or transfer station. Retail food establishments where milk and dairy products are served or sold but not processed, may be exempt from the requirements of this section.

SUSPENSION OF PERMIT.—When any requirement(s) of these Regulations is violated, the permit holder is subject to the suspension of his permit. The regulatory agency may forego suspension of the permit, provided the product or products in violation are not sold or offered for sale.

HEARINGS.—If a State or municipal administrative procedure act, which provides procedures for administrative hearings and judicial review of administrative determinations, is available, the act shall be made applicable by reference to the hearings provided for in these Regulations. If such administrative procedures act is not available, appropriate procedures, including provision for notice, hearing officer, his authority, record of hearing, rules of evidence and court review shall be established by appropriate authority.

REINSTATEMENT OF PERMITS.—Any producer, distributor, bulk milk hauler/sampler, milk transportation company or dairy plant operator whose permit has been suspended may make written application for the reinstatement of his permit.

When the permit suspension has been due to a violation of any of the bacterial, coliform or cooling-temperature standards (see Section 7). the regulatory agency, within one week after the receipt of notification for reinstatement of permit, shall issue a temporary permit after determining by an inspection of the facilities and operating methods that the conditions responsible for the violation have been corrected. When a permit suspension has been due to a violation of the somatic cell count standard (see Section 7), the regulatory agency may issue a temporary permit whenever a resampling of the herd's milk supply indicates the milk supply to be within acceptable limits as prescribed in Section 7. Samples shall then be taken at the rate of not more than two per week on separate days within a 3-week period and the regulatory agency shall reinstate the permit upon compliance with the appropriate standard as determined in accordance with Section 6 of these Regulations.

Whenever the permit suspension has been due to a violation of a requirement other than bacteriological, coliform, somatic cell count, drug residue test or cooling-temperature standards, the notification shall indicate that the violation(s) has been corrected. Within one week of the receipt of such notification, the regulatory agency shall make an inspection of the applicant's establishment, and as many additional inspections thereafter as are deemed necessary, to determine that the applicant's establishment is complying with the requirements. When the findings justify, the permit shall be reinstated.

When a permit suspension has been due to positive drug residues, the permit shall be reinstated in accordance with the provisions of Appendix N.

SECTION 4. LABELING

All bottles, containers and packages enclosing milk or dairy products defined in Section 1 of these Regulations shall be labeled in accordance with the applicable requirements of the *Federal Food, Drug, and Cosmetic Act* (1998) as amended, the *Nutrition Labeling and Education Act* of 1990, and regulations developed thereunder, 21 CFR 101 (1999), and in addition, shall comply with applicable requirements of this section as follows:

All bottles, containers and packages enclosing milk or dairy products, except milk tank trucks, storage tanks and cans of raw milk from individual dairy farms, shall be conspicuously marked with:

1. The identity of the dairy plant where aged, pasteurized, ultra-pasteurized or aseptically processed.2. The words “keep refrigerated after opening” in the case of aseptically processed milk and dairy

products.3. The name of the lactating animal (i.e. sheep, goat, etc.) shall precede the name of the milk or dairy product, with the exception of products manufactured from cow milk.4. The word "reconstituted" or "recombined" if the product is made by reconstitution or recombination.

All vehicles and milk tank trucks containing milk or dairy products shall be legibly marked with the name and address of the dairy plant or hauler in possession of the contents.

Milk tank trucks transporting raw, heat treated or pasteurized milk and dairy products to a dairy plant from another dairy plant, receiving or transfer station are required to be marked with the name and address of the dairy plant or hauler and shall be sealed; in addition, for each such shipment, a shipping statement shall be prepared containing at least the following information:

1. Shipper's name, address and permit number2. Permit identification of hauler, if not an employee of the shipper.3. Point of origin of shipment.4. Tanker identity number.5. Name of product.6. Weight of product.7. Temperature of product.8. Date of shipment.9. Name of supervising regulatory agency at the point of origin.10. Whether the contents are raw, pasteurized, or in the case of cream, reduced fat or lowfat or nonfat (skim) milk, whether it has been heat-treated.

Each bulk milk pickup tanker load of milk shall be accompanied by documentation (weigh ticket or manifest) which shall include the BTU numbers or Identification Number(s) or the Plant Number (for farm groups listed with a plant).

ADMINISTRATIVE PROCEDURES

IDENTITY LABELING.— "Identity", as used in this section, is defined as the name and address of the dairy plant at which the aging, pasteurization, ultra-pasteurization or aseptic processing takes place.

In cases where several plants are operated by one firm, the common firm name may be utilized on containers. Provided, that the location of the plant at which the contents were aged, pasteurized, ultra-pasteurized or aseptically processed is also shown, either directly or by a code. This requirement is necessary in order to enable the regulatory agency to identify the source of the aged, pasteurized, ultra-pasteurized or aseptically processed milk. The street address of the dairy plant need not be shown when only one dairy plant of a given name is located within the municipality and listed in the local telephone directory.

The identity labeling requirement may be interpreted as permitting plants and persons to purchase and distribute, under their own label, milk and dairy products processed and packaged at another dairy plant, provided, that the label reads, "Processed at ... (name and address)", or that the processing and packaging plant is identified by a proper code.

MISLEADING LABELS.— The regulatory agency shall not permit the use of any misleading marks, words or endorsements upon the label. They may permit the use of registered trade designs or similar terms on the label when, in their opinion, they are not misleading and are not so used as to obscure the labeling required by these Regulations.

SECTION 5. INSPECTION OF DAIRY FARMS AND DAIRY PLANTS

Each dairy farm, dairy plant, receiving station, milk tank truck cleaning facility and transfer station whose milk or dairy products are intended for consumption within the State of Colorado or it's jurisdiction, and each bulk milk hauler/sampler who collects samples of raw milk for processing, for bacterial, chemical or temperature standards and hauls milk from a dairy farm to a dairy plant, receiving station or transfer station and his bulk milk pickup tank and its appurtenances shall be inspected by the regulatory agency prior to the issuance of a permit. Following the issuance of a permit, the regulatory agency shall:

1. Inspect each milk tank truck and its appurtenances used by a bulk milk hauler/sampler who collects samples of raw milk for processing for bacterial, chemical or temperature standards and hauls

~~milk from a dairy farm to a dairy plant, receiving station or transfer station, at least once every 12 months;~~

~~2. Inspect each such bulk milk hauler/sampler pickup and sampling procedures at least once every 24 months;~~

~~3. Inspect each dairy plant and receiving station at least once every six months.~~

~~4. Inspect each milk tank truck cleaning facility and transfer station at least once every six months; and~~

~~5. Inspect each dairy farm at least once every six months.~~

~~Should the violation of any requirement set forth in Section 7, or in the case of a milk hauler also Section 6, be found to exist on an inspection, a second inspection shall be required after the time deemed necessary to remedy the violation, but not before 3 days. This second inspection shall be used to determine compliance with the requirements of Section 7 or in the case of a bulk milk hauler/sampler or milk tank truck milk hauler also Section 6. Any violation of the same requirement of Section 7, or in the case of a bulk milk hauler/sampler or milk tank truck also Section 6 on such second inspection, shall call for permit suspension in accordance with Section 3 and/or court action. Provided, that when the regulatory agency finds that a critical processing element violation involving:~~

~~1. Proper pasteurization, whereby every particle of milk or dairy product may not have been heated to the proper temperature and held for the required time in properly designed and operated equipment; or~~

~~2. A cross-connection exists whereby direct contamination of pasteurized milk or dairy product is occurring; or~~

~~3. Conditions exist whereby direct contamination of pasteurized milk or dairy product is occurring; or~~

~~4. When raw milk is used for an aged product and the aging process does not meet the requirements set forth in 21 CFR 133 (1999); the regulatory agency shall take immediate action to prevent further processing of such milk or dairy product until such violations of critical processing element(s) have been corrected. Should correction of such critical processing element(s) not be accomplished immediately, the regulatory agency shall take prompt action to suspend the permit as provided for in Section 3 of these Regulations. Provided, that in the case of dairy plants producing aseptically processed milk and dairy products, when an inspection of the dairy plant and its records reveal that the process used has been less than the required scheduled process, it shall be considered an imminent hazard to public health and the regulatory agency shall take immediate action to suspend the permit of the plant for the sale of aseptically processed milk and dairy products in conformance with Section 3 of these Regulations.~~

~~One copy of the inspection report shall be handed to the person in charge or be posted in a conspicuous place in the establishment. Said inspection report shall not be defaced and shall be made available to the regulatory agency upon request. An identical copy of the inspection report shall be filed with the records of the regulatory agency. Every milk producer, bulk milk hauler/sampler, milk transportation company or milk tank truck driver, distributor or plant operator shall, upon request of the regulatory agency, permit access of officially designated persons to all parts of their establishment or facilities to determine compliance with the provisions of these Regulations. A distributor or plant operator shall furnish the regulatory agency, upon request, for official use only, a true statement of the actual quantities of milk and dairy products purchased and sold, a list of all sources of such milk and dairy products, records of inspections, tests and pasteurization time and temperature records, and /or aging records.~~

It shall be unlawful for any person who, in an official capacity, obtains any information under the provisions of these Regulations which is entitled to protection as a trade secret (including information as to the quantity, quality, source or disposition of milk or dairy products, or results of inspections or tests thereof) to use such information to their own advantage or to reveal it to any unauthorized person.

ADMINISTRATIVE PROCEDURES

INSPECTION FREQUENCY.—For the purposes of determining the inspection frequency for dairy farms, dairy plants, receiving stations, and transfer stations the interval shall include the designated six month period plus the remaining days of the month in which the inspection is due.

One milk tank truck inspection every 12 months, or bulk milk hauler/sampler pickup and sampling procedures inspection each 24 months, or one producer inspection every six months or one plant inspection every six months is a legal minimum. Bulk milk hauler/samplers, milk tank trucks, dairy farms and dairy plants experiencing difficulty meeting requirements should be visited more frequently. Inspections of dairy farms shall be made at milking time as often as possible and of dairy plants at different times of the day in order to ascertain if the processes of equipment assembly, sanitizing, pasteurization, cleaning and other procedures comply with the requirements of these Regulations.

ENFORCEMENT PROCEDURE.—This section provides that a dairy farm, bulk milk hauler/sampler, milk tank truck, milk tank truck driver or dairy plant, except those processing aseptically processed milk and dairy products, shall be subject to suspension of permit and/or court action, if two successive inspections disclose a violation of the same requirement.

The penalties of suspension or revocation of permit, and/or court action, are provided to prevent continued violation of the provisions of these Regulations, but are worded to protect the dairy industry against unreasonable or arbitrary action. When a condition is found which constitutes an imminent health hazard, prompt action is necessary to protect the public health; therefore, the regulatory agency is authorized, in Section 3, to suspend the permit immediately. However, except for such emergencies, no penalty is imposed on the producer, responsible person for the milk tank truck, bulk milk hauler/sampler, milk tank truck driver or distributor upon the first violation of any of the sanitation requirements listed in Section 7. A producer, milk transportation company, bulk milk hauler/sampler, milk tank truck driver or distributor found violating any requirement must be notified in writing and given a reasonable time to correct the violation(s) before a second inspection is made, but not before three days. The requirement of giving written notice shall be deemed to have been satisfied by the handing to the operator or by the posting of an inspection report, as required by this section. After receipt of a notice of violation, but before the allotted time has elapsed, the producer, milk transportation company, bulk milk hauler/sampler, milk tank truck driver or distributor shall have an opportunity to appeal the inspector's interpretation to the regulatory agency or for an extension of the time allowed for correction.

ENFORCEMENT PROCEDURES—ASEPTIC PROCESSING DAIRY PLANTS.—Because aseptically processed milk and dairy products are stored at room temperature and are not refrigerated after processing they must be considered an imminent hazard to public health whenever it is revealed by an inspection or a review of the processing records that the process is less than the required scheduled process and the products produced have not maintained their commercial sterility. Prompt action by the regulatory agency to suspend the permit must be initiated in order to protect the public health. The regulatory agency shall stop the sale of all under-processed product and follow at least the minimum requirements of 21 CFR 113.89 (1999) before releasing any product.

SECTION 6. THE EXAMINATION OF MILK AND DAIRY PRODUCTS

It shall be the responsibility of the bulk milk hauler/sampler to collect a representative sample of milk from each farm bulk tank prior to transferring milk from a farm bulk tank, truck or other container. All samples shall be collected and delivered to a dairy plant, receiving station, transfer station or other location

~~approved by the regulatory agency. All milk and dairy products shall be sampled and examined as determined by the Colorado Department of Public Health and Environment.~~

~~Samples of milk and dairy products shall be taken while in the possession of the producer or distributor at any time prior to delivery to the store or consumer.~~

~~Raw milk for processing may be tested for bacterial counts, somatic cell counts, cooling temperature checks, and drug residues. Processed milk and dairy products may be tested for bacterial counts, drug residues, coliform determinations, phosphatase and cooling temperature. Required drug residue tests may be performed on aseptically processed milk and dairy products (see Section 7 for all chemical, bacteriological, and temperature standards).~~

~~Whenever a sample for bacterial counts (except those for aseptically processed milk and dairy products), somatic cell count, coliform determinations, or cooling temperatures, exceeds the limit of the standard (see Section 7) for the milk and/or dairy products, the regulatory agency shall send a written notice thereof to the person concerned. An additional sample shall be taken within 21 days of the sending of such notice, but not before the lapse of three days. If this second sample exceeds the set limits, a third sample shall be taken within 21 days of sending the second notice, but not before the lapse of three days. Immediate suspension of permit, in accordance with Section 3, and/or court action shall be instituted whenever the standard is violated by three (3) consecutive bacterial counts (except those for aseptically processed milk and dairy products), coliform determinations, cooling temperatures or somatic cell counts.~~

~~Whenever a phosphatase test is positive, the cause shall be determined. Where the cause is improper pasteurization, it shall be corrected and any milk or dairy product involved shall not be offered for sale.~~

~~Whenever a pesticide residue test is positive, an investigation shall be made to determine the cause and the cause shall be corrected. An additional sample shall be taken and tested for pesticide residues and no milk or dairy products shall be offered for sale until it is shown by a subsequent sample to be free of pesticide residues or below the actionable levels established for such residues.~~

~~Whenever a drug residue test is positive, an investigation shall be made to determine the cause, and the cause shall be corrected in accordance with the provisions of Appendix N.~~

~~Whenever a container or containers of aseptically processed milk or dairy product is found to be unsterile, due to under-processing, the regulatory agency shall consider this to be an imminent hazard to public health and shall suspend the permit of the dairy plant for the sale of aseptically processed milk and dairy products. No aseptically processed milk and dairy product shall be sold until it can be shown that the processes, equipment and procedures used are suitable for consistent production of a sterile product. All product from the lot that was found to contain one or more unsterile units shall be recalled and disposed of as directed by the regulatory agency.~~

~~Samples shall be analyzed at a Federal or state accredited milk laboratory. All sampling procedures and required laboratory examinations shall comply with the 16th Edition of *Standard Methods for the Examination of Dairy Products* or, the FDA 2400 series. Other methods found acceptable by FDA or USDA may be used.~~

~~ADMINISTRATIVE PROCEDURES~~

~~**ENFORCEMENT PROCEDURES.—**All violations of bacteria, coliform, confirmed somatic cell counts and cooling temperature standards (see Section 7) should be followed promptly by inspection to determine and correct the cause.~~

~~Aseptically processed milk and dairy products packaged in hermetically sealed containers are exempt from the refrigerated storage requirements of these Regulations. Therefore, whenever a breakdown in the processing or packaging of these products occurs, an imminent hazard to public health exists. Dairy~~

~~plants aseptically processing milk and dairy products in hermetically sealed containers should perform bacterial and other quality tests on each lot of aseptically processed milk and dairy product produced in order to ascertain that these products have been properly processed and have not been rendered non-sterile after aseptic processing and packaging. The regulatory agency may utilize industry records, of each lot of aseptically processed milk and dairy products, to determine when lots can be released for sale after a violation of the bacterial standards has existed.~~

~~**LABORATORY TECHNIQUES.—**Procedures for the collection and holding of samples; the selection and preparation of apparatus, media and reagents; and the analytical procedures, incubation, reading and reporting of results, shall be in substantial compliance with the 16th edition of *Standard Methods for the Examination of Dairy Products.* The procedures shall be those specified therein for:~~

~~1. Standard plate count at 32°C (agar or petrifilm method).~~

~~2. Alternate methods, including Plate Loop Count with petrifilm, for viable counts for raw milk, and the petrifilm method, for pasteurized milk and dairy products, at 32°C.~~

~~3. Coliform test with solid media or petrifilm method at 32°C for all milk and dairy products, and Petrifilm High Sensitivity Coliform count method for all milk and dairy products.~~

~~4. Beta lactam methods which have been independently evaluated or evaluated by FDA and have been found acceptable by FDA for detecting drug residues in raw milk, or pasteurized milk, or that particular type of pasteurized dairy product at current safe or tolerance levels shall be used for each drug of concern.~~

~~Regulatory action shall be taken on all positive results (see Appendix N). A result shall be considered positive if it has been obtained by using a method which has been evaluated and deemed acceptable by FDA at levels established in memoranda transmitted periodically by FDA as required by Section III of Appendix N.~~

~~5. Screening and confirmatory methods for the detection of abnormal milk.~~

~~6. 16th edition of *Standard Methods for the Examination of Dairy Products* or the FDA 2400 series phosphatase tests.~~

~~7. Any other tests which have been approved by the Food and Drug Administration to be equally accurate and precise.~~

~~8. All standards used in the development and use of drug residue detection methods designed for monitoring programs will be referenced to a United States Pharmacopeia (USP) standard when available. When a USP standard is not available, then the original method must define the standard to be used.~~

~~The phosphatase test is an index of the efficiency of the pasteurization process. In the event the laboratory phosphatase test is positive, the cause shall be determined immediately. Where the cause is improper pasteurization, it shall be corrected. When a laboratory phosphatase test is positive, and doubt should exist as to the compliance of the equipment, standards or methods outlined in Section 7., Item 16p., the regulatory agency should immediately conduct another phosphatase test.~~

~~The Wisconsin Mastitis Test or California Mastitis Test may be used for screening raw milk samples, to indicate a range of somatic cell levels, as long as the somatic cell standard for cow milk remains 750,000/ml. and other species at 1,000,000/ml.~~

~~Any of the following confirmatory or screening tests shall be used: Direct Microscopic Somatic Cell Counting Single Strip Procedure, Electronic Somatic Cell Counting, Flow Cytometry/Opto-Electronic~~

Somatic Cell Counting or Membrane Filter DNA Somatic Cell Counting. Pyronine Y-Methyl green stain or 'New York modification' shall be used in the confirmatory test for Direct Microscopic Somatic Cell Counts in milk.

Laboratories using the Wisconsin Mastitis Test, Modified Whiteside or California Mastitis Test for milk shall confirm samples of herd milk which exceeds 18mm, or a value of one (1), respectively.

The results of the screening test or confirmatory test shall be recorded on the official records of the dairy farm and a copy of the results sent to the milk producer.

When a warning letter has been sent, because of excessively high somatic cell counts, an official inspection of the dairy should be made by regulatory personnel or certified industry personnel. This inspection should be made during milking time.

SAMPLING PROCEDURES. The 16th edition of *Standard Methods for the Examination of Dairy Products* contains guidance for sampling of products. See Appendix C for a reference to drug residues in milk and the conditions under which a positive phosphatase reaction may be encountered in properly pasteurized milk or cream.

SECTION 7. STANDARDS FOR MANUFACTURED MILK AND DAIRY PRODUCTS

All dairy products shall be produced, processed and pasteurized, ultra-pasteurized, aseptically processed, or properly aged to conform with the following chemical, bacteriological and temperature standards and the sanitation requirements of this section.

No process or manipulation other than pasteurization, ultra-pasteurization or proper aging; and appropriate refrigeration shall be applied to milk and dairy products for the purpose of removing or deactivating microorganisms. Provided, that in the bulk shipment of cream, nonfat (skim) milk or reduced fat or lowfat milk, the heating of the raw milk, one time, to temperatures greater than 52°C (125°F) but less than 72°C (161°F), for separation purposes, is permitted when the resulting bulk shipment(s) of cream, nonfat (skim) milk or reduced fat or lowfat milk are labeled heat-treated. In the case of heat-treated cream, the cream may be further heated to less than 75°C (166°F) in a continuing heating process and immediately cooled to 7°C (45°F) or less when necessary for enzyme deactivation (such as lipase reduction) for a functional reason. In the case of a properly aged product culturing, coagulating and salting are permitted during the process.

Table 1. Chemical Bacteriological and Temperature Standards

RAW MILK AND DAIRY PRODUCTS FOR PASTEURIZATION, ULTRAPASTEURIZATION, ASEPTIC PROCESSING OR PROPER AGING	Temperature	Cooled to 7°C (45°F) or less within two hours after milking. Provided, that the blend temperature after the first and subsequent milkings does not exceed 10°C (50°F).
	Bacterial limits	Individual producer milk not to exceed 100,000 per ml prior to commingling with other producer milk. Not to exceed 300,000 per ml as commingled milk prior to pasteurization.
	Drugs	No positive results on drug residue detection methods as referenced in Section 6 - Laboratory Techniques

	Somatic Cell Count*	Individual producer milk: Not to exceed 750,000 per ml.
PASTEURIZED MILK AND DAIRY PRODUCTS, PROPERLY AGED RAW DAIRY PRODUCTS, AND BULK SHIPPED HEAT-TREATED DAIRY PRODUCTS	Temperature	Cooled to 7°C (45°F) or less and maintained thereat.
	Bacterial limits**	50,000 per ml., or gm.***
	Coliform****	Not to exceed 20 per ml. Provided, that in the case of bulk milk transport tank shipments, shall not exceed 100 per ml.
	Phosphatase****	Less than 350 milliunits/L for fluid products and less than 500 for other dairy products by the Fluorometer or Charm ALP or equivalent.
	Drugs**	No positive results on drug residue detection methods as referenced in Section 6 - Laboratory Techniques which have been found to be acceptable for use with pasteurized and heat-treated milk and dairy products.
ASEPTICALLY PROCESSED MILK AND DAIRY PRODUCTS	Temperature	None.
	Bacterial limits	Refer to 21 CFR 113.3(e)(1) (1999)*****
	Drugs**	No positive results on drug residue detection methods as referenced in Section 6 - Laboratory Techniques which have been found to be acceptable for use with aseptically processed milk and dairy products.

* Goat Milk 1.000.000 and other lactating animals.
** Not applicable to cultured products.
*** Results of the analysis of dairy products which are weighed in order to be analyzed will be reported in # per gm (See the 16th Edition of the *Standard Methods for the Examination of Dairy Products*).
**** Not applicable to bulk shipped heat-treated dairy products. Phosphatase Test is also not applicable to aged raw dairy products.

***** **21 CFR 113.3(e)(1) (1999) contains the definition of "COMMERCIAL STERILITY"**

STANDARDS FOR RAW MILK FOR PRODUCTION OF MANUFACTURED DAIRY PRODUCTS

ITEM 1r. ABNORMAL MILK

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

PUBLIC HEALTH REASON.—The health of the animal is a very important consideration because a number of diseases of lactating animals, including salmonellosis, staphylococcal infection and streptococcal infection, may be transmitted to man through the medium of milk. The organisms of most of these diseases may get into the milk either directly from the udder or indirectly through infected body discharges which may drop, splash or be blown into the milk.

Bovine mastitis is an inflammatory and, generally, highly communicable disease of the bovine udder. Usually, the inciting organism is a streptococcus of bovine origin (type B), but the disease is often caused by a staphylococcus or other infectious agent. Occasionally animal's udders become infected with hemolytic streptococci of human origin, which may result in milkborne epidemics of scarlet fever or septic

~~sore throat. The toxins of staphylococci, and possibly other organisms in milk, may cause severe gastroenteritis. Some of these toxins are not destroyed by pasteurization.~~

~~ADMINISTRATIVE PROCEDURES~~

~~This item is deemed to be satisfied when:~~

~~1. Milk from lactating animals being treated with medicinal agents, which are capable of being secreted in the milk, is not offered for sale for such a period as is recommended by the attending veterinarian or as indicated on the package label of the medicinal agent.~~

~~2. Milk from lactating animals treated with or exposed to insecticides, not approved for use on dairy animals by the U.S. Environmental Protection Agency, is not offered for sale.~~

~~3. The regulatory agency requires such additional tests for the detection of abnormal milk as they deem necessary.~~

~~4. Bloody, stringy, off-colored milk, or milk that is abnormal to sight or odor, is so handled and disposed of as to preclude the infection of other lactating animals and the contamination of milk utensils.~~

~~5. Lactating animal secreting abnormal milk are milked last or in separate equipment which effectively prevents the contamination of the wholesome supply. Abnormal milking equipment is maintained clean to reduce the possibility of re-infecting or cross infection of the dairy animal.~~

~~6. Equipment, utensils and containers used for the handling of abnormal milk are not used for the handling of milk to be offered for sale, unless they are first cleaned and effectively sanitized.~~

~~7. Processed animal waste derivatives, used as a feed ingredient for any portion of the total ration of the lactating dairy animal, have been:~~

~~A. Properly processed in accordance with the requirements of the Colorado Department of Agriculture; and~~

~~B. Do not contain levels of deleterious substances, harmful pathogenic organisms or other toxic substances which are secreted in the milk at any level which may be deleterious to human health.~~

~~8. Unprocessed poultry litter and unprocessed recycled animal body discharges are not fed to lactating dairy animals.~~

~~ITEM 2r. MILKING BARN, STABLE OR PARLOR - CONSTRUCTION~~

~~A milking barn, stable or parlor shall be provided on all dairy farms in which the milking herd shall be housed during milking time operations. The areas used for milking purposes shall:~~

~~1. Have floors constructed of concrete or equally impervious materials. Provided, convalescent (maternity) pens located in milking areas of stanchion-type barns may be used when they comply with the guidelines specified in Appendix A.~~

~~2. Have walls and ceilings which are smooth, painted or finished in an approved manner; in good repair, ceiling dust-tight;~~

~~3. Have separate stalls or pens for horses, calves and bulls, and not be overcrowded;~~

~~4. Be provided with natural and/or artificial light, well distributed, for day and/or night milking;~~

5. Provide sufficient air space and air circulation to prevent condensation and excessive odors

PUBLIC HEALTH REASON. — When milking is done elsewhere than in a suitable place provided for this purpose, the milk may be contaminated. Floors constructed of concrete or other impervious materials can be kept clean more easily than floors constructed of wood, earth or similar materials and are; therefore, more apt to be kept clean. Painted, or properly finished walls and ceilings encourage cleanliness. Tight ceilings reduce the likelihood of dust and extraneous material getting into the milk. Adequate light makes it more probable that the barn will be clean and that the animals will be milked in a sanitary manner.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. A milking barn, stable or parlor is provided on all dairy farms.

2. Gutters, floors and feed troughs are constructed of good quality concrete or equally impervious material. Floors shall be easily cleaned (brushed surfaces permitted), be graded to drain, maintained in good repair and free of excessive breaks or worn areas that may create pools.

3. Gravity flow manure channels in milking barns, if used, shall be constructed in accordance with the specifications of Appendix A.

4. Stall barns, when used with gutter grates over manure storage pits, are designed and constructed in accordance with the specifications of Appendix A.

5. Walls and ceilings are finished with wood, tile, smooth-surfaced concrete, cement plaster, brick or other equivalent materials with light colored surfaces. Walls, partitions, doors, shelves, windows and ceilings shall be kept in good repair, and surfaces shall be refinished whenever wear or discoloration is evident.

Whenever feed is stored overhead, ceilings shall be constructed to prevent the sifting of chaff and dust into the milking barn, stable or parlor. If a hay opening is provided from a loft which is open into the milking portion of the barn, such openings shall be provided with a dust-tight door which shall be kept closed during milking operations.

6. Bull pens, maternity and stalls for non-lactating animals are partitioned from the milking portion of the barn. Such portions of the barn that are not separated by tight partitions shall comply with all the requirements of this item.

7. Overcrowding is not evidenced by the presence of young animals, lactating animals or other barnyard animals in walks or feed alleys. Inadequate ventilation and excessive odors may also be evidence of an overcrowded barn.

8. The milking barn is provided with natural and/or artificial light to insure that all surfaces and particularly the working areas will be plainly visible. The equivalent of at least ten (10) foot-candles of light in all working areas shall be provided.

9. Air circulation is sufficient to minimize odors and to prevent condensation upon walls and ceilings.

10. A dust-tight partition, provided with doors that are kept closed except when in actual use, shall separate the milking portion of the barn from any feed room or silo in which feed is ground or mixed, or in which sweet feed is stored.

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

ITEM 3r. MILKING PARLOR CLEANLINESS

The interior shall be kept clean. Floors, walls, ceilings, windows, pipelines and equipment shall be free of filth and/or litter and shall be clean. Swine and fowl shall be kept out of the milking area.

Feed shall be stored in a manner that will not increase the dust content of the air or interfere with the cleaning of the floor.

Surcingles, milk stools and antikickers shall be kept clean and stored above the floor.

PUBLIC HEALTH REASON.—A clean interior reduces the chances of contamination of the milk or milk pails during milking. The presence of other animals increases uncleanliness and the potential for the spread of disease.

Clean milk stools and surcingles (or belly straps) reduce the likelihood of contamination of milker's hands between the milking of one animal and the milking of another.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. The interior of the milking barn, stable or parlor is kept clean.

2. Leftover feed in feed mangers appears fresh and is not wet or soggy.

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

4. Outside surfaces of pipeline systems located in the milking barn, stable or parlor are clean.

5. Gutter cleaners are clean.

6. All pens and stalls, if not separated from the milking barn, stable or parlor, are clean.

7. Swine and fowl are kept out of the milking area.

8. Milk stools are not padded and are constructed to be easily cleaned. Milk stools, surcingles and antikickers are kept clean and are stored above the floor in a clean place in the milking barn, stable parlor or milkhouse, when not in use.

9. Gravity flow manure channels in milking barns, if used, shall be maintained in accordance with Appendix A.

10. Stall barns, when used with gutter grates over manure storage pits, are operated and maintained in accordance with the specifications of Appendix A.

The method of cleaning is immaterial. Dairymen whose barns are provided with water under pressure should scrub the floors after each milking with a stiff-bristled brush. In barns in which water under

~~pressure is not available, the floors may be brushed dry and limed. In the latter event, care should be exercised to prevent caking of the lime. When lime or phosphate is used, it shall be spread evenly on the floor as a thin coating. If clean floors are not maintained by this method, the inspector should require cleaning with water.~~

~~ITEM 4r. LACTATING ANIMAL YARD~~

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

~~PUBLIC HEALTH REASON.~~ ~~The lactating animal yard is interpreted to be that enclosed or unenclosed area in which the lactating animals are apt to congregate, approximately adjacent to the barn, including animal-housing areas. This area is; therefore, particularly apt to become filthy with manure droppings, which may result in the soiling of the animal's udders and flanks. The grading and drainage of the lactating animal yard, as far as are practicable, are required because wet conditions are conducive to fly breeding and make it difficult to keep manure removed and the lactating animals clean. If manure and barn sweepings are allowed to accumulate in the lactating animal yard, fly breeding will be promoted, and the lactating animals, because of their habit of lying down, will be more apt to have manure-soiled udders. Lactating animals should not have access to piles of manure, in order to avoid the soiling of udders and the spread of diseases among dairy animals.~~

~~ADMINISTRATIVE PROCEDURES~~

~~This item is deemed to be satisfied when:~~

~~1. The lactating animal yard, which is the enclosed or unenclosed area adjacent to the milking barn in which the lactating animals may congregate, including animal-housing areas and feed lots, is graded and drained, depressions and soggy areas are filled, and cow lanes are reasonably dry.~~

~~2. Approaches to the barn door and the surroundings of stock watering and feed stations are solid to the footing of the animals.~~

~~3. Wastes from the barn or milk-house are not allowed to pool in the lactating animal yard. lactating animal yards which are muddy due to recent rains should not be considered as violating this item.~~

~~4. Manure, soiled bedding and waste feed are not stored or permitted to accumulate therein in such a manner as to permit the soiling of lactating animal's udders and flanks. Animal-housing areas (stables without stanchions, such as loose-housing stables, pen stables, resting barns, holding barns, loafing sheds, wandering sheds, free-stall housing) shall be considered as part of the cowyard. Manure packs shall be solid to the footing of the animals (See Appendix A).~~

~~5. Lactating animal yards are kept reasonably free of animal droppings. Animal droppings shall not be allowed to accumulate in piles that are accessible to the animals.~~

~~ITEM 5r. MILKHOUSE OR ROOM—CONSTRUCTION AND FACILITIES~~

~~A milk house or room of sufficient size shall be provided, in which the cooling, handling and storing of milk and the washing, sanitizing and storing of milk containers and utensils shall be conducted. Except as provided for in Item 12r. of this section.~~

~~The milkhouse shall be provided with a smooth floor constructed of concrete or equally impervious material, graded to drain and maintained in good repair. Liquid waste shall be disposed of in a sanitary manner. Floor drains shall be accessible and shall be trapped if connected to a sanitary sewer system.~~

~~The walls and ceilings shall be constructed of smooth material, be in good repair and be well painted, or finished in an equally suitable manner.~~

~~The milkhouse shall have adequate natural and/or artificial light and be well ventilated.~~

~~The milkhouse shall be used for no other purpose than milkhouse operations. There shall be no direct opening into any barn, stable or into a room used for domestic purposes. Provided, that a direct opening between the milkhouse and milking barn, stable or parlor is permitted when a tight-fitting, self-closing, solid door(s) hinged to be single or double acting is provided. Screened vents in the wall between the milkhouse and a breezeway, which separates the milkhouse from the milking parlor, are permitted, provided animals are not housed within the milking facility.~~

~~Water under pressure shall be piped into the milkhouse.~~

~~The milkhouse shall be equipped with a two-compartment wash vat and adequate hot water heating facilities.~~

~~A transportation tank may be used for the cooling and/or storage of milk on the dairy farm. Such tank shall be provided with a suitable shelter for the receipt of milk. Such shelter shall be adjacent to, but not a part of, the milkroom and shall comply with the requirements of the milkroom with respect to construction items, lighting, drainage, insect and rodent control and general maintenance.~~

~~**PUBLIC HEALTH REASON.** Unless a suitable, separate place is provided for the cooling, handling and storing of milk and for the washing, sanitizing and storage of milk utensils, the milk or the utensils may become contaminated. Construction which permits easy cleaning promotes cleanliness. A well drained floor of concrete or other impervious material promotes cleanliness. Ample light promotes cleanliness, and proper ventilation reduces the likelihood of odors and condensation. A well equipped milkhouse which is separated from the barn and the living quarters provides a safeguard against the exposure of milk and milk utensils to infection from persons, other than regular milk handlers, and from insects and dust.~~

~~**ADMINISTRATIVE PROCEDURES**~~

~~This item is deemed to be satisfied when:~~

~~1. A separate milkhouse of sufficient size is provided for the cooling, handling and storing of milk and the washing, sanitizing and storing of milk containers and utensils. Except as provided for in Item 12r. of this section.~~

~~2. The floors of all milkhouses are constructed of good quality concrete (float finish permissible), or equally impervious tile, or brick laid closely with impervious material, or metal surfacing with impervious joints or other material the equivalent of concrete and maintained free of breaks, depressions and surface peelings.~~

~~3. The floor slopes to drain so that there are no pools of standing water. The joints between the floor and the walls shall be watertight.~~

~~4. The liquid wastes are disposed of in a sanitary manner. All floor drains are accessible and are trapped if connected to a sanitary sewer.~~

~~5. Walls and ceilings are constructed of smooth dressed lumber or similar material; well painted with a light-colored washable paint; and are in good repair. Surfaces and joints shall be tight and smooth. Sheet metal, tile, cement block, brick, concrete, cement plaster or similar materials of light color may be used and the surfaces and joints shall be smooth.~~

~~6. A minimum of 20 foot-candles of light is provided at all working areas from natural and/or artificial light for milkhouse operations.~~

~~7. The milkhouse is adequately ventilated to minimize condensation on floors, walls, ceilings and clean utensils.~~

~~8. Vents, if installed, and lighting fixtures are installed in a manner to preclude the contamination of bulk milk tanks or clean utensil storage areas.~~

~~9. The milkhouse is used for no other purpose than milkhouse operations.~~

~~10. There is no direct opening into any barn, stable or room used for domestic purposes. Except that an opening between the milkhouse and milking barn, stable or parlor is permitted when a tight-fitting, self-closing, solid door(s) hinged to be single or double acting is provided. Except that screened vents are permitted in the wall between the milkhouse and a breezeway, which separates the milkhouse from the milking parlor, provided animals are not housed within the milking facility.~~

~~11. A vestibule, if used, complies with the applicable milkhouse construction requirements.~~

~~12. The transfer of milk from a bulk-holding cooling tank to a transport tank is through a hose port located in the milkhouse wall. The port shall be fitted with a tight door, which shall be in good repair. It shall be kept closed except when the port is in use. An easily cleanable surface shall be constructed under the hose port, adjacent to the outside wall and sufficiently large to protect the milk hose from contamination.~~

~~13. Water under pressure is piped into the milkhouse.~~

~~14. Each milkhouse is provided with facilities for heating water in sufficient quantity and to such temperatures for the effective cleaning of all equipment and utensils (See Appendix A).~~

~~15. The milkhouse is equipped with a wash-and-rinse vat having at least two compartments. Each compartment must be of sufficient size to accommodate the largest utensil or container used. The upright wash vat for milk pipelines and milk machines may be accepted as one part of the two-compartment vat. Provided, that the stationary wash rack, in or on the vat, and the milking machines inflations and appurtenances are completely removed from the vat during the washing, rinsing and/or sanitizing of other utensils and equipment. Where mechanical cleaning/recirculated systems eliminate the need for handwashing of equipment, the presence of the second wash vat compartment may be optional, if so determined by the regulatory agency, on an individual farm basis.~~

~~16. A transportation tank, with or without overhead protection may be used for cooling and storing milk on a dairy farm. If a suitable shelter is provided for a transportation truck used for cooling and storing milk, such shelter shall be adjacent to, but not a part of, the milkroom and shall comply with the prerequisites of the milkroom with respect to construction items, lighting, drainage, insect and rodent control and general maintenance. See Appendix A for suggested plans and information on size, construction, operation and maintenance of milkhouses. In addition, the following minimum criteria shall be met:~~

~~A. An accurate, accessible temperature recording device shall be installed in the milk line downstream from an effective cooling device which cools the milk to 7°C (45° F) or less.~~

~~B. The milk shall be sampled at the direction of the regulatory agency in a manner so as to preclude contaminating the tanker or sample, by a licensed milk sample collector.~~

~~C. The milk tank truck shall be effectively agitated in order to collect a representative sample.~~

~~When the regulatory agency determines conditions exist whereby the milk tanker can be adequately protected and sampled without contamination, a shelter need not be provided if the following minimum criteria are met:~~

~~(1) The milk hose connection is accessible to, and made from within, the milkroom. The milk hose connection to the milk tank truck is completely protected from the outside environment at all times.~~

~~(2) To assure continued protection of the milk, the milk tank truck manhole must be sealed after the truck has been cleaned and sanitized.~~

~~(3) The milk tank truck shall be washed and sanitized at the dairy plant receiving the milk or at a wash station acceptable to the regulatory agency.~~

~~(4) To prevent overflow from the milk tank truck which would create unsanitary conditions around the milk house, the milk tank truck shall be equipped with a liquid level sensor device of sanitary design. The sensor device shall deactivate the milk pump or sound an alarm when activated.~~

~~(5) An accurate, accessible temperature recording device shall be installed in the milk line downstream from an effective cooling device which cools the milk to 7°C (45° F) or below.~~

~~(6) The milk shall be sampled at the direction of the regulatory agency, in a manner so as to preclude contaminating the tanker or sample, by a permitted milk sample collector, or the equivalent. The milk in the milk tank truck shall be effectively agitated in order to collect a representative sample.~~

~~(7) The tanker shall be parked on a self-draining concrete or equally impervious surface during filling and storage.~~

~~ITEM 6r. MILKHOUSE OR ROOM—CLEANLINESS~~

~~The floors, walls, ceilings, windows, tables, shelves, cabinets, wash vats, non-product contact surfaces of milk containers, utensils and equipment and other milkroom equipment shall be clean. Only articles directly related to milkroom activities shall be permitted in the milkroom. The milkroom shall be free of trash, animals and fowl.~~

~~**PUBLIC HEALTH REASON.** Cleanliness in the milkroom reduces the likelihood of contamination of the milk.~~

~~ADMINISTRATIVE PROCEDURES~~

~~This item is deemed to be satisfied when:~~

~~1. The milkroom structure, equipment and other milkroom facilities used in its operation or maintenance are clean at all times.~~

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

3. Vestibules, if provided, are kept clean.

4. Animals and fowl are kept out of the milkroom.

ITEM 7r. TOILET

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

PUBLIC HEALTH REASON. The organisms of typhoid fever, dysentery and gastrointestinal disorders may be present in the body wastes of persons who have these diseases. In the case of typhoid fever, well persons (carriers) also may discharge the organisms in their body wastes. If a toilet is not fly-tight and so constructed as to prevent overflow, infection may be carried from the excreta to the milk, either by flies or through the pollution of ground water supplies or streams to which the lactating animals have access.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. There is at least one flush toilet connected to a public sewer system or to an individual sewage-disposal system or a chemical toilet, earth pit privy or other type of privy. Such sewage systems shall be constructed and operated in accordance with the standards outlined in Appendix A, or when a state or local regulatory agency has more effective standards designed specifically for that region, these standards may apply, provided, that there is no mixing of animal and human waste.

2. A toilet or privy is convenient to the milking barn and the milkroom. There shall be no evidence of human defecation or urination about the premises.

3. No privy opens directly into the milkroom.

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

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

6. Vents of earth pits are screened.

ITEM 8r. WATER SUPPLY

Water for milkhouse and milking operations shall be from a supply properly located, protected and operated and shall be easily accessible, adequate and of a safe, sanitary quality.

PUBLIC HEALTH REASON. A dairy farm water supply should be accessible in order to encourage its use in ample quantity in cleaning operations; it should be adequate so that cleaning and rinsing will be thorough; and it should be of a safe, sanitary quality in order to avoid contamination of milk utensils.

A polluted water supply, used in the rinsing of the dairy utensils and containers, may be more dangerous than a similar water supply which is used for drinking purposes only. Bacteria grow much faster in milk than in water and the severity of an attack of a given disease depends largely upon the size of the dose of

~~disease organisms taken into the system. Therefore, a small number of disease organisms consumed in a glass of water from a polluted well may possibly result in no harm; whereas, if left in a milk utensil, which has been rinsed with the water, they may after several hours growth, in the milk, increase in such numbers as to cause disease when consumed.~~

~~ADMINISTRATIVE PROCEDURES~~

~~This item is deemed to be satisfied when:~~

~~1. The water supply for milkhouse and milking operations is approved as safe by the Colorado Department of Public Health and Environment Water Quality Division and, in the case of individual water systems, complies with the specifications outlined in Appendix B, and the bacteriological standards outlined in Appendix D.~~

~~2. No cross-connection exists between a safe water supply and any unsafe or questionable water supply or any other source of pollution.~~

~~3. There are no submerged inlets through which a safe water supply may be contaminated.~~

~~4. The well or other source of water is located and constructed in such a manner that neither underground nor surface contamination from any sewerage systems, privy or other source of pollution can reach such water supply.~~

~~5. New individual water supplies and water supply systems which have been repaired or otherwise become contaminated are thoroughly disinfected before being placed in use (See Appendix B). The supply shall be made free of the disinfectant by pumping to waste before any sample for bacteriological testing shall be collected.~~

~~6. All containers and tanks used in the transportation of water are sealed and protected from possible contamination. These containers and tanks shall be subjected to a thorough cleaning and a bacteriological treatment prior to filling with potable water to be used at the dairy farm. To minimize the possibility of contamination of the water during its transfer from the potable tanks to the elevated or ground-water storage at the dairy farm, a suitable pump, hose and fittings shall be provided. When the pump, hose and fittings are not being used, the outlets shall be capped and stored in a suitable dustproof enclosure so as to prevent their contamination. The storage tank at the dairy farm shall be constructed of impervious material, provided with a dust and rainproof cover and also provided with an approved-type vent and roof hatch. All new reservoirs or reservoirs which have been cleaned shall be disinfected prior to placing them into service (See Appendix B).~~

~~7. Samples for bacteriological examination are taken upon the initial approval of the physical structure, based upon the requirements of these Regulations, when any repair or alteration of the water supply system has been made and at least every three years. Provided, that water supplies with buried well casing seals, installed prior to the adoption of this section, shall be tested at intervals no greater than six months apart. Whenever such samples indicate either the presence of bacteria of the coliform group or whenever the well casing, pump or seal need replacing or repair, the well casing and seal shall be brought above the ground surface and shall comply with all other applicable construction criteria of this section. Provided, that when water is hauled to the dairy farm, such water shall be sampled for bacteriological examination at the point of use and submitted to a laboratory at least four times in separate months during any consecutive six (6) months. Bacteriological examinations shall be conducted in a laboratory acceptable to the regulatory agency. To determine if water samples have been taken at the frequency established in this section, the interval shall include the designated period plus the remaining days of the month in which the sample is due.~~

8. Current records of water test results shall be retained on file with the regulatory agency or as the regulatory agency directs.

ITEM 9r. UTENSILS AND EQUIPMENT — CONSTRUCTION

All multi-use containers, equipment and utensils used in the handling, storage or transportation of milk shall be made of smooth, nonabsorbent, corrosion-resistant, nontoxic materials, and shall be so constructed as to be easily cleaned. All containers, utensils and equipment shall be in good repair. Multiple-use woven material shall not be used for straining milk. All single-service articles shall have been manufactured, packaged, transported and handled in a sanitary manner and shall comply with the applicable requirements of Item 11p of this section. Articles intended for single-service use shall not be reused.

Farm holding/cooling tanks, welded sanitary piping and transportation tanks shall comply with the applicable requirements of Items 10p and 11p of this section.

PUBLIC HEALTH REASON. — Milk containers and other utensils without flush joints and seams, without smooth, easily cleaned, and accessible surfaces, and not made of durable, noncorrodible material, are apt to harbor accumulations in which undesirable bacterial growth is supported. Single-service articles which have not been manufactured and handled in a sanitary manner may contaminate the milk.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. All multi-use containers, equipment and utensils, which are exposed to milk or dairy products, or from which liquids may drip, drain or be drawn into milk or dairy products, are made of smooth impervious, nonabsorbent, safe materials of the following types:

   A. Stainless steel of the AISI (American Iron and Steel Institute) 300 series; or

   B. Equally corrosion-resistant, nontoxic metal; or

   C. Heat-resistant glass; or

   D. Plastic or rubber and rubber-like materials which are inert, resistant to scratching, scoring, decomposition, crazing, chipping and distortion, under normal use conditions; are nontoxic, fat resistant, nonabsorbent, insoluble, do not release component chemicals or impart flavor or odor to the product; and which maintain their original properties under repeated use conditions.

2. Single-service articles have been manufactured, packaged, transported and handled in a sanitary manner and comply with the applicable requirements of Item 11p.

3. Articles intended for single-service use are not reused.

4. All containers, equipment and utensils are free of breaks and corrosion.

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

6. Mechanically cleaned milk pipelines and return-solution lines are self-draining. If gaskets are used, they shall be self-positioning and of material meeting specifications described in 1.d. above, and shall be of such design, finish and application as to form a smooth, flush, interior surface. If gaskets are not used, all fittings shall have self-positioning faces designed to form a smooth,

flush, interior surface. All interior surfaces of welded joints in pipelines shall be smooth and free of pits, cracks and inclusions.

7. Detailed plans for mechanically cleaned pipeline systems are submitted to the regulatory agency for written approval prior to installation. No alteration or addition shall be made to any milk pipeline system without prior written approval of the regulatory agency.

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

9. All milking machines, including heads, milk claws, milk tubing and other milk-contact surfaces can be easily cleaned and inspected. Pipelines, milking equipment and appurtenances which require a screw driver or special tool shall be considered easily accessible for inspection, providing the necessary tools are available at the milkhouse.

10. Milk cans have umbrella-type lids.

11. Farm holding/cooling tanks, welded sanitary piping and transportation tanks comply with the applicable requirements of Items 10p and 11p of this section.

12. During filling, flexible plastic/rubber hoses may be used between the fill valves of bottom fill bulk milk storage tanks, when needed for functional purposes. Such hoses shall be drainable, be as short as practical, have sanitary fittings, and be supported to maintain uniform slope and alignment. The end fittings of such hoses shall be permanently attached in such a manner that will assure a crevice-free joint between the hose and the fitting, which can be cleaned by mechanical means. The hoses shall be included as part of a mechanical cleaning system.

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

ITEM 10r. UTENSILS AND EQUIPMENT — CLEANING

The product-contact surfaces of all multi-use containers, equipment and utensils used in the handling, storage or transportation of milk shall be cleaned after each usage.

PUBLIC HEALTH REASON. — Milk cannot be kept clean or free of contamination if permitted to come into contact with unclean containers, utensils or equipment.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. There shall be a separate wash manifold for all mechanically cleaned milk pipelines in all new or extensively remodeled facilities.

2. The product-contact surface of all multi-use containers, equipment and utensils used in the handling, storage or transportation of milk are cleaned after each usage.

3. There shall be no partial removal of milk from milk storage/holding tanks by the milk hauler, except partial pickups may be permitted when the milk storage/holding tank is equipped with a seven-

day recording device complying with the specifications of Appendix E or other recording device acceptable to the state regulatory agency provided the milk storage/holding tank shall be clean and sanitized when empty and shall be emptied at least every 72 hours. In the absence of a temperature recording device, partial pickups may be permitted as long as the milk storage/holding tank is completely empty, clean and sanitized prior to the next milking. In the event of an emergency situation, such as in inclement weather, natural disaster, et cetera, a variance may be permitted at the discretion of the state regulatory agency.

ITEM 11r. UTENSILS AND EQUIPMENT — SANITIZATION

The product-contact surfaces of all multi-use containers, equipment and utensils used in the handling, storage or transportation of milk shall be sanitized before each usage.

PUBLIC HEALTH REASON. — Mere cleaning of containers, equipment and utensils does not insure the removal or destruction of all disease organisms which may have been present. Even very small numbers remaining may grow to dangerous proportions, since many kinds of disease bacteria grow rapidly in milk. For this reason, all milk containers, equipment and utensils must be treated with an effective sanitizer before each usage.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

All product-contact surfaces of multi-use containers, utensils and equipment used in the handling, storage or transportation of milk are sanitized before each usage by one of the following methods, or by any method which has been demonstrated to be equally effective:

1. Complete immersion in hot water at a temperature of at least 77°C (170°F) for at least 5 minutes; or exposure to a flow of hot water at a temperature of at least 77°C (170°F), as determined by the use of a suitable accurate thermometer (at the outlet), for at least 5 minutes.

2. Certain chemical compounds are effective for the sanitization of milk utensils, containers, and equipment. These are contained in 21 CFR 178.1010 (1999). and shall be used in accordance with label directions.

(See Appendix C, for further discussion of approved sanitizing procedures).

ITEM 12r. UTENSILS AND EQUIPMENT — STORAGE

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

PUBLIC HEALTH REASON. — Careless storage of milk utensils which previously have been properly treated is apt to result in recontamination of such utensils, thus rendering them unsafe.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. All milk containers, utensils and equipment, including milking machine vacuum hoses, are stored in the milkhouse in a sanitizing solution, or on racks, until used. Pipeline milking equipment such as milker claws, inflations, weight jars, milk hoses, milk receivers, tubular coolers, plate coolers and milk pumps which are designed for mechanical cleaning and other equipment, as accepted by CDPHE which meets these criteria, may be mechanically cleaned, sanitized and stored in the milking barn or parlor, provided this equipment is designed, installed and operated to protect the product and solution-contact surface from contamination at all times. Some of the parameters to be considered in determining protection are: proper location of equipment; proper drainage of equipment; and adequate and properly located lighting and ventilation. The milking barn or parlor must be used only for milking. Concentrates may be fed in the barn during milking but the barn shall not be used for the housing of animals. When manual cleaning of product-contact surfaces is necessary, the cleaning shall be done in the milkhouse.

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

3. Clean cans or other containers are stored in the milkhouse within a reasonable time after delivery to the dairy farm.

4. Strainer pads, parchment papers, gaskets and similar single-service articles are stored in a suitable container or cabinet and protected against contamination and in a location convenient to their use.

ITEM 13r. MILKING—FLANKS, UDDERS AND TEATS

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

PUBLIC HEALTH REASON. If milking is done elsewhere other than in a suitable place provided for this purpose, the milk may become contaminated. Cleanliness of the lactating animals is one of the most important factors affecting the bacterial count of the milk. Under usual farm conditions, lactating animals contaminate their udders by standing in polluted water or by lying down in the pasture or cowyard. Unless the udders and teats are clean and dry before milking, particles of filth or contaminated water are apt to drop or be drawn into the milk. Such contamination of the milk is particularly dangerous because manure may contain the organisms of brucellosis and tuberculosis, and polluted water may contain the organisms of typhoid fever and other intestinal diseases. Application of sanitizing solutions to the teats followed by thorough drying just prior to the time of milking has the advantage of giving an additional margin of safety with reference to such disease organisms as are not removed by ordinary cleaning and it is helpful in the control of mastitis.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. Milking is done in a milking barn, stable or parlor.

2. Brushing is completed prior to milking.

3. Flanks, bellies, tails and udders are clipped as often as necessary to facilitate cleaning of these areas and are free from dirt. The hair on the udders shall be of such length that it is not incorporated with the teat in the inflation during milking.

4. Udders and teats of all milking animals are clean and dry before milking. Teats shall be cleaned, treated with a sanitizing solution and dry just prior to milking, except that additional alternative udder preparation methods may also be used once they have been evaluated and found acceptable.

5. Wet hand milking is prohibited.

ITEM 14r. PROTECTION FROM CONTAMINATION

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

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

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

PUBLIC HEALTH REASON. Because of the nature of milk and its susceptibility to contamination by disease producing bacteria and other contaminants, every effort should be made to provide adequate protection for the milk at all times. This should include the proper placement of equipment so that work areas in the milking barn and milkhouse are not over-crowded. The quality of any air which is used for the agitation or movement of milk or is directed at a dairy product-contact surface should be such that it will not contaminate the milk.

The effect of sanitization of equipment can be nullified if the equipment is not protected after sanitizing.

To protect milk during transportation, delivery vehicles must be properly constructed and operated.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. Equipment and operations are so located within the milking barn and milkhouse as to prevent overcrowding and contamination of cleaned and sanitized containers, equipment and utensils by splash, condensation or manual contact.

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

3. All milk which has overflowed, leaked, been spilled or improperly handled is discarded.

4. All product-contact surfaces of containers, equipment and utensils are covered or otherwise protected to prevent the access of insects, dust, condensation and other contamination. All openings, including valves and piping attached to milk storage and transport tanks, pumps or vats, shall be capped or otherwise properly protected. Gravity type strainers used in the milkhouse do not have to be covered. Milk pipelines used to convey milk from pre-coolers to the farm bulk tank must be fitted with effective drip deflectors.

5. The receiving receptacle is raised above the floor (as on a dolly or cart), or placed at a distance from the lactating animals, to protect it against manure and splash when milk is poured and/or strained

in the milking. Such receptacle shall have a tight-fitting cover, which shall be closed except when milk is being poured.

6. Each pail or container of milk is transferred immediately from the milking barn, stable or parlor to the milkhouse.

7. Pails, cans and other equipment containing milk are properly covered during transfer and storage.

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

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

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

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

12. Vehicles have bodies with solid enclosures and tight, solid doors.

13. Vehicles are kept clean, inside and out.

14. No substance capable of contaminating milk is transported with the milk.

NOTE – See items 10p and 11p for information on the construction of milk tank trucks.

ITEM 15r. DRUG AND CHEMICAL CONTROL

Cleaners and sanitizers shall be stored in properly identified, dedicated end use containers.

Animal drugs and medications and animal drug and medication administration equipment shall be stored in such a way that milk, milking equipment, wash vats and hand sinks are not subject to contamination.

Animal drugs and medications shall be properly labeled and segregated (lactating from non-lactating).

Unapproved drugs shall not be used.

PUBLIC HEALTH REASON. – Accidental misuse of cleaners or sanitizers can result in adulteration of the milk.

Animal drug or medications can result in adverse reactions in people sensitive to those residues and can contribute to the development of strains of drug resistant human pathogens.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. Cleaners and sanitizers, used on dairy farms, shall be purchased in containers from the manufacturer or distributor which properly identify the contents or, if bulk cleaners and sanitizers are transferred from the manufacturer's or distributor's container, that the transfer only occur into a dedicated

end-use container which is specifically designed and maintained according to the manufacturer's specifications for that specific product. The label on the dedicated end-use container shall include the product name, chemical description, use directions, precautionary and warning statement, first aid instructions, container storage and maintenance instructions and the name and address of the manufacturer or distributor.

2. Equipment used to administer medicinals/drugs is not cleaned in the wash vats and is stored so as not to contaminate the milk or milk contact surfaces of equipment.

3. Medicinals/drugs intended for treatment of non-lactating dairy animals are segregated from those medicinals/ drugs used for lactating animals. (Separate shelves in cabinets, refrigerators or other storage facilities satisfies this item).

4. Drugs and medicinals shall be properly labeled to include the name and address of the manufacturer or distributor (for OTC medicinals/drugs), or veterinary practitioner dispensing the product (for Rx and extra label use medicinals/drugs).

5. Drugs and medicinal labels shall also include:

A. Directions for use, and prescribed withholding times;

B. Cautionary statements, if needed; and

C. Active ingredient(s) in the drug product.

6. Unapproved and/or improperly labeled medicinals/drugs are not used to treat dairy animals and are not stored in the milkhouse, milking barn, stable or parlor.

7. Drugs and medicinals are stored in such a manner that they cannot contaminate the milk or dairy product-contact surface of the equipment, containers or utensils.

NOTE – Topical antiseptics, wound dressings (unless intended for direct injection into the teat), vaccines and other biologics, and dosage form vitamins and/or mineral products are exempt from labeling and storage requirements except when it is determined that they are stored in such a manner that they may contaminate the milk or dairy product surfaces of containers or utensils.

ITEM 16r. PERSONNEL—HAND-WASHING FACILITIES

Adequate hand-washing facilities shall be provided, including a lavatory fixture with hot and cold, or warm running water, soap or detergent and individual sanitary towels, convenient to the milkhouse, milking barn, stable, parlor and flush toilet.

PUBLIC HEALTH REASON.—The hands of the milker in his preparation for milking come into contact with almost identically the same kind of material as may have contaminated the udders. During the course of their duties and natural habits outside of the milking barn, the milker's hands must be assumed to have been exposed to body discharges. Washing facilities are required in order to increase the assurance that milker's hands will be washed.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. Hand-washing facilities are located convenient to the milkhouse. milking barn, stable, parlor and flush toilet.

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

ITEM 17r. PERSONNEL—CLEANLINESS

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

PUBLIC HEALTH REASON.—The reasons for clean hands of the persons doing the milking are similar to those for the cleanliness of the animal's udder. The milker's hands must be assumed to have been exposed to contamination during the course of his normal duties on the farm and at milking time. Because the hands of all workers frequently come into contact with their clothing it is important that the clothes worn, during milking and the handling of milk, be clean.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. Hands are washed, clean and dried with an individual sanitary towel immediately before milking; before performing any milkhouse function; and immediately after the interruption of any of these activities.

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

ITEM 18r. RAW MILK COOLING

Raw milk for pasteurization shall be cooled to 10°C (50°F) or less within four hours or less of the commencement of the first milking and to 7°C (45°F) or less within two hours after the completion of milking. Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 10°C (50°F).

PUBLIC HEALTH REASON.—Milk produced by disease-free animals and under clean conditions usually contains relatively few bacteria immediately after milking. These can multiply to enormous numbers in a few hours unless the milk is cooled. However when the milk is cooled quickly to 7°C (45°F) or less, there is only a slow increase in the numbers of bacteria.

Usually, the bacteria in milk are harmless, and if this were always true there would be no reason to cool milk, except to delay souring. There is no way for the dairyman or regulating officer to be absolutely sure that no disease bacteria have entered the milk, even though observance of the other items of these Regulations will greatly reduce this likelihood. The likelihood of transmitting disease is much increased when the milk contains large numbers of disease bacteria. Therefore, it is extremely important for milk to be cooled quickly, so that small numbers of bacteria, which may have entered, will not multiply.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. Raw milk for pasteurization is cooled to 7°C (45°F) or less within two hours after milking. Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 10°C (50°F).

2. Recirculated cold water which is used in plate or tubular coolers or heat exchangers is from a safe source and protected from contamination. Such water shall be tested semiannually and shall comply with the bacteriological standards of Appendix D. All farm bulk milk tanks manufactured after January 1, 2000 shall be equipped with an approved temperature recording device.

A. The recording device shall be operated continuously and be maintained in a properly functioning manner. Circular charts shall not overlap.

B. The recording device shall be verified in a manner acceptable to the regulatory agency by a traceable standard thermometer.

C. Recording thermometer charts shall be maintained on the premises for a period of a minimum of six (6) months and available to the regulatory agency.

D. The recording thermometer should be installed in an area convenient to the milk storage tank and acceptable to the regulatory agency.

E. The recording thermometer sensor shall be located to permit the registering of the temperature of the contents when the tank contains no more than ten percent (10%) of its calibrated capacity.

F. The recording thermometer shall comply with the current technical specifications for tank recording thermometers.

G. A recording thermometer and/or any other device that meets the intent of these administrative procedures and technical specifications and is acceptable to the regulatory agency can be used to monitor/record the bulk tank temperature.

H. The recording thermometer charts shall properly identify the producer, date, and signature of the person removing the chart.

The information from recording thermometer charts on farm bulk milk tanks shall not be used for enforcement purposes except in cases where an imminent health hazard exists.

ITEM 19r. INSECT AND RODENT CONTROL

Effective measures shall be taken to prevent the contamination of milk, containers, equipment and utensils by insects and rodents and by chemicals used to control such vermin. Milk rooms shall be free of insects and rodents. Surroundings shall be kept neat, clean and free of conditions which might harbor or be conducive to the breeding of insects and rodents. Feed shall be stored in such a manner that it will not attract birds, rodents or insects.

PUBLIC HEALTH REASON.—Proper manure disposal reduces the breeding of flies, which are considered capable of transmitting infection by physical contact or through excreta to milk or milk utensils. Flies visit unsanitary places, they may carry disease organisms on their bodies, they may carry living bacteria for as long as four weeks within their bodies, and they may pass them on to succeeding generations by infecting their eggs. Effective screening tends to prevent the presence of flies, which are a public health menace. Flies may contaminate the milk with disease germs, which may multiply and become sufficiently numerous to present a public health hazard. The surroundings of a dairy should be kept neat and clean to encourage cleanliness and reduce insect and rodent harborages.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

~~1. Surroundings are kept neat, clean and free of conditions which might harbor or be conducive to the breeding of insects and rodents. During fly season, manure shall be spread directly on the fields; or stored for not more than four days in a pile on the ground surface and then spread on the fields; or stored for not more than seven days in a impervious-floored bin, or on an impervious-curbed platform and then spread; or stored in a tight-screened and trapped manure shed; or effectively treated with larvicides; or disposed of in any other manner which controls insect breeding.~~

~~2. Manure packs in loafing areas, stables without stanchions, pen stables, resting barns. wandering sheds and free-stall housing are properly bedded and managed to prevent fly breeding.~~

~~3. Milkrooms are free of insects and rodents.~~

~~4. Milkrooms are effectively screened or otherwise protected against the entrance of vermin.~~

~~5. Outer milkhouse doors are tight and self-closing. Screen doors shall open outward.~~

~~6. Effective measures are taken to prevent the contamination of milk, containers, utensils and equipment by insects and rodents and by chemicals used to control such vermin. Insecticides and rodenticides, not approved for use in the milkhouse, shall not be stored in the milkhouse.~~

~~7. Only insecticides and rodenticides approved for use by the regulatory agency and/or registered with the U.S. Environmental Protection Agency, are used for insect and rodent control.~~

~~8. Insecticides and rodenticides are used only in accordance with manufacturer's label directions and are used so as to prevent the contamination of milk, milk containers, equipment, utensils, feed and water.~~

~~9. Have covered boxes, bins or separate storage facilities for ground, chopped or concentrated feed.~~

~~10. Feed may be stored in the milking portion of the barn only in such a manner as will not attract birds, flies or rodents. Open feed dollies or carts may be used for distributing the feed, but not storing feed, in the milking barn. Feed dollies, carts, fully automated feeding systems, or other feed containers may be exempt from the use of covers provided, they do not attract birds, insects, or rodents.~~

~~**STANDARDS FOR PASTEURIZED, ULTRAPASTEURIZED, ASEPTICALLY PROCESSED MANUFACTURED MILK AND DAIRY PRODUCTS, OR PROPERLY AGED DAIRY PRODUCTS**~~

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

~~A transfer station shall comply with Items 1p, 4p, 6p, 7p, 8p, 9p, 10p, 11p, 12p, 14p, 15p, 20p and 22p and as climatic and operating conditions require, the applicable provisions of Items 2p and 3p. Provided, that in every case, overhead protection shall be provided. Facilities for the cleaning and sanitizing of milk tank trucks shall comply with Items 1p, 4p, 6p, 7p, 8p, 9p, 10p, 11p, 12p, 14p, 15p, 20p and 22p and as climatic and operating conditions require, the applicable provisions of Items 2p and 3p. Provided, that in every case, overhead protection shall be provided.~~

~~**ITEM 1p. FLOORS— CONSTRUCTION**~~

~~The floors of all rooms in which milk or dairy products are processed, handled or stored, or in which milk containers, equipment and utensils are washed, shall be constructed of concrete or other equally impervious and easily cleanable material; and shall be smooth, properly sloped, provided with trapped~~

drains and kept in good repair. Provided, that cold-storage rooms used for storing milk and dairy products need not be provided with floor drains when the floors are sloped to drain to one or more exits. Provided further, that storage rooms for storing dry ingredients and/or packaging materials need not be provided with drains and the floors may be constructed of tightly joined wood.

PUBLIC HEALTH REASON.— Floors constructed of concrete or other similarly impervious material can be kept clean more easily than floors constructed of wood or other pervious or easily disintegrating material. They will not absorb organic matter and are, therefore, more apt to be kept clean and free of odors. Properly sloped floors facilitate flushing and help to avoid undesirable conditions. Trapping of drains prevents sewer gas from entering the plant.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

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

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

3. The floors are provided with trapped drains. Cold-storage rooms used for storing milk and dairy products need not be provided with floor drains when the floors are sloped to drain to one or more exits. Storage rooms for dry ingredients and/or packaging materials need not be provided with drains.

ITEM 2p. WALLS AND CEILINGS— CONSTRUCTION

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

PUBLIC HEALTH REASON.— Painted or otherwise properly finished walls and ceilings are more easily kept clean and are, therefore, more apt to be kept clean. A light-colored paint or finish aids in the even distribution of light and the detection of unclean conditions.

ADMINISTRATIVE PROCEDURES

This item is deemed satisfied when:

1. Walls and ceilings are finished with smooth, washable, light-colored impervious materials.

2. Walls, partitions, windows and ceilings are kept in good repair.

ITEM 3p. DOORS AND WINDOWS

Effective means shall be provided to prevent the access of flies and rodents. All openings to the outside shall have solid doors or glazed windows which shall be closed during dusty weather.

PUBLIC HEALTH REASON.— Freedom from flies in the dairy plant reduces the likelihood of contamination of the milk. For information on disease transmission by flies see Item 7r, Public Health Reason.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. All openings to the outer air are effectively protected by:

A. Screening; or

B. Effective electric screen panels; or

C. Fans or air curtains which provide sufficient air velocity so as to prevent the entrance of flies; or

D. Properly constructed flaps where it is impractical to use self-closing doors or air curtains; or

E. Any effective combination of a, b, c, or d or by any other method which prevents the entrance of flies.

2. All outer doors are tight and self-closing. Screen doors shall open outward.

3. All outer openings are rodent-proofed to the extent necessary to prevent the entry of rodents.

NOTE – The evidence of insects and/or rodents in the plant shall be considered under Item 9p.

ITEM 4p. LIGHTING AND VENTILATION

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

PUBLIC HEALTH REASON. – Ample light promotes cleanliness. Proper ventilation reduces odors and prevents condensation upon interior surfaces.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

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

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

3. Pressurized ventilating systems, if used, have a filtered air intake.

ITEM 5p. SEPARATE ROOMS

There shall be separate rooms for:

1. The pasteurizing, processing, cooling and packaging of milk and dairy products.

2. The cleaning of milk cans, bottles and cases.

~~3. The fabrication of containers and closures for dairy products.~~

~~4. Cleaning and sanitizing facilities for milk tank trucks in plants receiving milk in such tanks.~~

~~5. Receiving cans of dairy products in plants receiving such cans.~~

~~Rooms in which milk or dairy products are handled, processed or stored, or in which milk containers, utensils and equipment are washed or stored, shall not open directly into any stable or any room used for domestic purposes. All rooms shall be of sufficient size for their intended purposes.~~

~~Designated areas or rooms shall be provided for the receiving, handling and storage of returned packaged milk and dairy products.~~

~~**PUBLIC HEALTH REASON.**— If the washing and sanitization of containers are conducted in the same room in which the pasteurizing, processing, cooling or packaging is done, there is opportunity for the pasteurized product to become contaminated. For this reason, separate rooms are required as indicated. The unloading of cans of raw milk directly into the pasteurizing room is apt to increase the prevalence of flies therein, as well as to render it too public.~~

~~**ADMINISTRATIVE PROCEDURES**~~

~~This item is deemed to be satisfied when:~~

~~1. Pasteurizing, processing, cooling and packaging are conducted in a single room(s), but not in the same room(s) used for the cleaning of milk cans, bottles and cases, or the unloading and/or cleaning and sanitizing of milk tank trucks. Provided, that cooling (plate or tubular) may be done in the room where milk tank trucks are unloaded and/or cleaned and sanitized. Separation/clarification of raw milk may be done in an enclosed room where tank trucks are unloaded and/or cleaned and sanitized.~~

~~2. All returned packaged milk and dairy products which have physically left the premises of the processing plant shall be received, handled and stored in separate areas or rooms isolated from the dairy operations. Such separate areas or rooms shall be clearly defined and marked for such use.~~

~~3. All bulk milk storage tanks are vented into a room used for pasteurization, processing, cooling or packaging operations, or into a storage tank gallery room. Provided, that vents located elsewhere which are adequately equipped with air filters so as to preclude the contamination of the milk, shall be considered satisfactory.~~

~~4. Solid doors installed in required partitions are self-closing.~~

~~5. Facilities for the cleaning and sanitizing of milk tank trucks are properly equipped for manual and/or mechanical operations. When such facilities are not provided on the plant premises, these operations shall be performed at a receiving station, transfer station or separate tank washing installation. (Items relating to facilities for cleaning and sanitizing milk tank trucks are listed in Appendix A.)~~

~~6. Rooms in which milk or dairy products are handled, processed or stored, or in which milk containers, utensils and equipment are washed or stored, do not open directly into any stable or any room used for domestic purposes.~~

~~7. All rooms shall be of sufficient size for their intended purposes.~~

~~**ITEM 6p. TOILET-SEWAGE DISPOSAL FACILITIES**~~

~~Every dairy plant shall be provided with toilet facilities conforming with the regulations of the 1997 Uniform Plumbing Code. Toilet rooms shall not open directly into any room in which milk and/or dairy products are processed. Toilet rooms shall be completely enclosed and shall have tight-fitting, self-closing doors. Dressing rooms, toilet rooms and fixtures shall be kept in a clean condition, in good repair and shall be well ventilated and well lighted. Sewage and other liquid wastes shall be disposed of in a sanitary manner.~~

~~**PUBLIC HEALTH REASON.**—Human excreta are potentially dangerous and must be disposed of in a sanitary manner. The organisms causing typhoid fever, para-typhoid fever and dysentery may be present in the body discharges of active cases or carriers. Sanitary toilet facilities are necessary to protect the milk, equipment and containers from fecal contamination which may be carried by flies, other insects, hands or clothing. When the toilet facilities are of a satisfactory type, are kept clean and are in good repair, the opportunities for the spread of contamination by the above means are minimized. The provision of an intervening room or vestibule between the toilet room and any room in which milk or dairy products are processed makes it less likely that contaminated flies will enter these rooms. It will also minimize the spread of odors.~~

~~The wastes resulting from the cleaning and rinsing of containers, equipment and floors, from flush toilets, and from washing facilities, should be properly disposed of so as not to contaminate the milk equipment, or to create a nuisance or a public health hazard.~~

~~**ADMINISTRATIVE PROCEDURES**~~

~~This item is deemed to be satisfied when:~~

~~1. The dairy plant is provided with toilet facilities conforming with the regulations of the 1997 Uniform Plumbing Code.~~

~~2. Toilet rooms do not open directly into any room in which milk and/or dairy products are processed.~~

~~3. Toilet rooms are completely enclosed and have tight-fitting, self-closing doors.~~

~~4. Dressing rooms, toilet rooms and fixtures are kept in a clean condition, in good repair and are well ventilated and well lighted.~~

~~5. Toilet tissue and easily cleanable covered waste receptacles are provided in toilet rooms.~~

~~6. All plumbing is installed to meet the applicable provisions of the 1997 Uniform Plumbing Code.~~

~~7. Sewage and other liquid wastes are disposed of in a sanitary manner.~~

~~8. Non-water-carried sewage disposal facilities are not used.~~

~~**ITEM 7p. WATER SUPPLY**~~

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

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

~~**ADMINISTRATIVE PROCEDURES**~~

~~This item is deemed to be satisfied when:~~

~~1. Water for dairy plant purposes is from an adequate supply, properly located, protected and operated. It shall be easily accessible and of a safe, sanitary quality.~~

~~2. The water supply is approved as safe by the State water control authority and, in the case of individual water systems, complies with at least the specification outlined in Appendix B, and the bacteriological standards in Appendix D.~~

~~3. There is no cross-connection between the safe water supply and any unsafe or questionable water supply, or any source of pollution through which the safe water supply might become contaminated. A connection between the water supply piping and a make-up tank (such as for cooling or condensing), unless protected by an air gap or effective backflow preventer, constitutes a violation of this requirement.~~

~~4. Condensing water for milk evaporators, and water used to produce vacuum and/or to condense vapors in vacuum heat processing equipment, is from a source complying with 2. above. Provided, that when approved by the regulatory agency, water from sources not complying with 2. above may be used when the evaporator or vacuum heat equipment is constructed and operated to preclude contamination of such equipment, or its contents by condensing water or by water used to produce vacuum. Means of preventing such contamination are:~~

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

~~B. Use of reliable safeguards to prevent the overflow of condensing water from the condenser into the evaporator. Such safeguards include a barometric leg extending at least 35 feet vertically from the invert of the outgoing condensing water line to the free level at which the leg discharges, or a safety shutoff valve, located on the water feed line to the condenser, automatically actuated by a control which will shut off the in-flowing water when the water level rises above a predetermined point in the condenser. This valve may be actuated by water, air or electricity, and shall be designed so that failure of the primary motivating power will automatically stop the flow of water into the condenser.~~

~~5. Condensing water for all milk evaporators, complying with 2. above, and water reclaimed from milk or dairy products may be reused when all necessary means of protection are afforded and it complies with the procedures outlined in Appendix B, Part V.~~

~~6. New individual water supplies and water supply systems, which have been repaired or otherwise become contaminated, are disinfected before being placed in use (See Appendix B). The supply shall be made free of the disinfectant by pumping to waste before any sample for bacteriological testing shall be collected.~~

~~7. Samples for bacteriological testing of individual water supplies are taken upon the initial approval of the physical structure, each 6 months thereafter and when any repair or alteration of the water supply system has been made. Samples shall be taken by the regulatory agency and examinations shall be conducted in an official laboratory. To determine if water samples have been taken at the frequency established in this section, the interval shall include the designated six month period plus the remaining days of the month in which the sample is due.~~

~~8. Current records of water test results are retained on file with the regulatory agency or as the regulatory agency directs.~~

~~ITEM 8p. HAND-WASHING FACILITIES~~

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

~~**PUBLIC HEALTH REASON.—** Proper use of hand-washing facilities is essential to personal cleanliness and reduces the likelihood of contamination of milk and dairy products.~~

~~**ADMINISTRATIVE PROCEDURES**~~

~~This item is deemed to be satisfied when:~~

~~1. Convenient hand-washing facilities are provided, including hot and cold and/or warm running water, soap and individual sanitary towels or other approved hand-drying devices.~~

~~2. Hand-washing facilities are convenient to all toilets and to all rooms in which dairy plant operations are conducted.~~

~~3. Hand-washing facilities are kept in a clean condition and in good repair.~~

~~4. Steam-water mixing valves and vats for washing bottles, cans and similar equipment are not used as hand-washing facilities.~~

~~**ITEM 9p. DAIRY PLANT CLEANLINESS**~~

~~All rooms in which milk and dairy products are handled, processed or stored, and/or in which containers, utensils or equipment are washed or stored, shall be kept clean, neat and free of evidence of insects and rodents. Only equipment directly related to processing operations or the handling of containers, utensils and equipment shall be permitted in the pasteurizing, processing, cooling, packaging and bulk milk storage rooms.~~

~~**PUBLIC HEALTH REASON.—** A clean physical facility is conducive to clean operations. Cleanliness and the absence of flies, insects and rodents reduces the likelihood of contamination of the milk or dairy product. Excess or unused equipment or equipment not directly related to the dairy plant operations can be detrimental to the cleanliness of the dairy plant.~~

~~**ADMINISTRATIVE PROCEDURES**~~

~~This item is deemed to be satisfied when:~~

~~1. Only equipment directly related to processing operations or the handling of containers, utensils and equipment is permitted in the pasteurizing, processing, cooling, packaging and bulk milk storage rooms.~~

~~2. All piping, floors, walls, ceilings, fans, shelves, tables and the non-product-contact surfaces of other facilities and equipment are clean.~~

~~3. No trash or solid waste is stored within the plant, except in covered containers. Waste containers at the packaging machine or bottle washer may be uncovered during the operation of such equipment.~~

~~4. All rooms in which milk and dairy products are handled, processed or stored, and/or in which containers, utensils, or equipment are washed or stored, are kept clean, neat and free of evidence of insects and rodents.~~

~~**ITEM 10p. SANITARY PIPING**~~

All sanitary piping, fittings and connections which are exposed to milk or dairy products, or from which liquids may drip, drain or be drawn into milk or dairy products, shall consist of smooth, impervious, corrosion-resistant, nontoxic, easily cleanable material. All piping shall be in good repair. Pasteurized milk and dairy products shall be conducted from one piece of equipment to another only through sanitary piping.

PUBLIC HEALTH REASON.—Milk piping and fittings are sometimes so designed as to be difficult to clean, or they may be constructed of metal which corrodes easily. In either case, it is unlikely that they will be kept clean. Sanitary milk piping is a term which applies to properly designed and properly constructed piping.

The purpose of sanitary milk piping and fittings is to prevent exposure of the pasteurized product to contamination.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. All sanitary piping, fittings and connections which are exposed to milk or dairy products, or from which liquids may drip, drain or be drawn into dairy products, consist of smooth, impervious, corrosion-resistant, nontoxic, easily cleanable material.

2. All sanitary piping, connections and fittings consist of:

A. Stainless steel of the AISI (American Iron and Steel Institute) 300 series; or

B. Equally corrosion-resistant metal which is nontoxic and nonabsorbent; or

C. Heat resistant glass; or

D. Plastic, or rubber and rubber-like materials which are relatively inert, resistant to scratching, scoring, decomposition, crazing, chipping and distortion under normal use conditions; are nontoxic, fat resistant, relatively nonabsorbent; which do not impart flavor or odor to the product; and which maintain their original properties under repeated use conditions, may be used for gaskets, sealing applications and for short flexible takedown jumpers or connections where flexibility is required for essential or functional reasons.

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

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

5. All mechanically cleaned milk pipelines and return-solution lines are rigid, self-draining and so supported to maintain uniform slope and alignment. Return solution lines shall be constructed of material meeting the specifications of 2. above. If gaskets are used, they shall be self-positioning, of material meeting the specifications outlined in 2. above and designed, finished and applied to form a smooth, flush interior surface. If gaskets are not used, all fittings shall have self-positioning faces designed to form a smooth, flush interior surface. All interior surfaces of welded joints in pipelines shall be smooth and free from pits, cracks or inclusions.

In the case of welded lines, all welds shall be approved by the regulatory agency. Each cleaning circuit shall have access points for inspection in addition to the entrances and exits. These may be valves, removable sections, fittings or other means of combinations that are adequate for the

~~inspection of the interior of the line. These access points shall be located at sufficient intervals to determine the general condition of the interior surfaces of the pipeline.~~

~~Detailed plans for welded pipeline systems shall be submitted to the regulatory agency for written approval prior to installation. No alteration or addition shall be made to any welded milk pipeline system without prior written approval from the regulatory agency.~~

~~6. Pasteurized milk and dairy products are conducted from one piece of equipment to another only through sanitary milk piping.~~

~~ITEM 11p. CONSTRUCTION AND REPAIR OF CONTAINERS AND EQUIPMENT~~

~~All multi-use containers and equipment with which milk or dairy products come into contact shall be of smooth, impervious, corrosion-resistant, nontoxic material; shall be constructed for ease of cleaning; and shall be kept in good repair. All single-service containers, closures, gaskets and other articles with which milk or dairy products come in contact shall be nontoxic and shall have been manufactured, packaged, transported and handled in a sanitary manner. Articles intended for single-service use shall not be reused.~~

~~PUBLIC HEALTH REASON.—~~~~When equipment is not constructed and located so that it can be easily cleaned or is not kept in good repair, it is unlikely to be properly cleaned.~~

~~Single-service articles, which have not been manufactured and handled in a sanitary manner may contaminate the milk.~~

~~ADMINISTRATIVE PROCEDURES~~

~~This item is deemed to be satisfied when:~~

~~1. All multi-use containers and equipment with which milk or dairy products come into contact are of smooth, impervious, corrosion-resistant and nontoxic material.~~

~~2. All milk-contact surfaces of multi-use containers and equipment consist of:~~

~~A. Stainless steel of the AISI (American Iron and Steel Institute) 300 series; or~~

~~B. Equally corrosion-resistant metal which is nontoxic and nonabsorbent; or~~

~~C. Heat resistant glass; or~~

~~D. Plastic or rubber and rubber-like materials which are relatively inert, resis tant to scratching, scoring, decomposition, crazing, chipping and distortion under normal use conditions; which are nontoxic, fat resistant, relatively nonabsorbent and do not impart flavor or odor to the product; and which maintain their original properties under repeated use conditions.~~

~~3. All joints in containers, equipment and utensils are flush and finished as smooth as adjoining surfaces. Where a rotating shaft is inserted through a surface with which milk or dairy products come into contact, the joint between the moving and stationary surfaces shall be close-fitting. Where a thermometer or temperature sensing element is inserted through a surface, with which milk or dairy products come into contact, a pressure-tight seal shall be provided ahead of all threads and crevices.~~

~~4. All openings in covers of tanks, vats, separators, etc. are protected by raised edges, or otherwise, to prevent the entrance of surface drainage. Condensation-diverting aprons shall be provided as~~

close to the tank or vat as possible on all pipes, thermometer, or temperature sensing elements and other equipment extending into a tank, bowl, vat or distributor, unless a watertight joint is provided.

5. All surfaces with which milk or dairy products come into contact are easily accessible or demountable for manual cleaning or are designed for mechanical cleaning. All product-contact surfaces shall be readily accessible for inspection and shall be self-draining.

6. There are no threads used in contact with milk or dairy products except where needed for functional and safety reasons, such as in clarifiers, pumps and separators. Such threads shall be of a sanitary type.

7. All multi-use containers and other equipment have rounded corners, are in good repair and free from breaks, crevices and corrosion. Milk cans shall have umbrella-type covers.

8. Strainers, if used, are of perforated metal design and so constructed as to utilize single-service strainer media. Multiple-use, woven material shall not be used for straining milk. Provided, that when required for functional reasons inherent to the production of certain dairy products, woven material may be used where it is impractical to use perforated metal. However, woven material parts shall be mechanically cleaned by such methods that thoroughly clean the woven material and do not contaminate the product.

9. All single-service containers, closures, gaskets and other articles, with which milk or dairy products come in contact, are nontoxic.

10. The manufacture, packing, transportation and handling of single-service containers, closures, caps, gaskets and similar articles shall be conducted in a manner that prevents the contamination of the milk and/or dairy products. Containers, closures, liners and wrappers shall be commercially acceptable, clean, non-toxic, and designed to protect the quality of the product.

ITEM 12p. CLEANING AND SANITIZING OF CONTAINERS AND EQUIPMENT

The product-contact surfaces of all multi-use containers, utensils and equipment used in the transportation, processing, handling and storage of milk or dairy products shall be effectively cleaned and shall be sanitized before each use. Provided, that piping, equipment and containers used to process, conduct or package aseptically processed milk and dairy products, beyond the final heat treatment process, shall be sterilized before any aseptically processed milk or dairy product is packaged and shall be resterilized whenever any unsterile product has contaminated it.

PUBLIC HEALTH REASON.—Milk and dairy products cannot be kept clean and safe if permitted to come into contact with containers, utensils and equipment which have not been properly cleaned and sanitized.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. All multi-use containers and utensils are thoroughly cleaned after each use and all equipment is thoroughly cleaned at least once each day used unless regulatory authority has reviewed and accepted information supporting the cleaning of multi-use containers and utensils at frequencies extending beyond one day. Provided, that storage tanks shall be cleaned when emptied and shall be emptied at least every 72 hours. Records must be available to verify that milk storage in these tanks does not exceed 72 hours. These records shall be available for at least the previous three months or from the time of the last regulatory inspection whichever is longer. In the case of pasteurized storage tanks which are mechanically cleaned at intervals of less than 72 hours, the

~~mechanical cleaning records required under 2.b. of this section shall be considered adequate. Storage tanks which are used to store raw milk or heat-treated dairy products longer than 24 hours and silo tanks used for the storage of raw milk or heat-treated dairy products shall be equipped with a 7-day temperature recording device complying with the specifications of Appendix E.~~

~~Whenever a milk tank truck has been cleaned and sanitized, as required by the regulatory agency, it shall bear a tag or a record shall be made showing the date, time, place and signature or initials of the employee or contract operator doing the work, unless the truck delivers to only one receiving unit where responsibility for cleaning and sanitizing can be definitely established without tagging. The tag shall be removed at the location where the tank truck is next washed and sanitized and kept on file for 15 days as directed by the regulatory agency.~~

~~2. Pipelines and/or equipment designed for mechanical cleaning meet the following requirements:~~

~~A. An effective cleaning and sanitizing regimen for each separate cleaning circuit shall be followed.~~

~~B. A temperature recording device, complying with the specifications in Appendix E, or a recording device which provides sufficient information to adequately evaluate the cleaning and sanitizing regimen and which is approved by the local regulatory agency, shall be installed in the return solution line or other appropriate area to record the temperature and time which the line or equipment is exposed to cleaning and sanitizing solutions. For purposes of this section, recording devices which produce records not meeting the specifications of Appendix E may be acceptable if;~~

~~(1) The device provides a continuous record of the monitoring of the cleaning cycle time and temperature, cleaning solution velocity or cleaning pump operation and the presence or strength of cleaning chemicals for each cleaning cycle.~~

~~(2) The record shows a pattern so typical of each circuit cleaned that changes in the cleaning regimen can be readily detected.~~

~~(3) Electronic storage of required cleaning records with or without hard copy printouts may be acceptable provided the computer and computer generated records are readily available and meet the criteria of this section and those provisions of Appendix E which are determined to be applicable by the regulatory agency.~~

~~C. Cleaning charts and electronically stored records required by this section shall be identified, dated and retained for three months or until the next regulatory inspection, whichever is longer.~~

~~D. During each official inspection, the regulatory agency shall examine charts and records to verify the cleaning regimens.~~

~~3. Plants in which containers are washed manually are equipped with a two-compartment wash-and-rinse vat for this purpose. Such plants shall also provide a steam cabinet or individual steam-jet plate with hood for sanitizing of cleaned containers, or if sanitizing is done with chemicals, a third treatment vat~~

~~4. All multi-use containers, equipment and utensils are sanitized before use, employing one or a combination of the methods prescribed under Item 11r. Assembled equipment must be sanitized prior to each day's run, unless the Colorado Department of Public Health and Environment has~~

reviewed and accepted information supporting the sanitizing of multi-use containers, equipment and utensils at frequencies extending beyond one day. Tests to determine the efficiency of sanitization should be made by the regulatory agency at intervals sufficient to satisfy the regulatory agency that the sanitization process is effective. Provided, that all piping, equipment and containers used to conduct, process or package aseptically processed milk and dairy products, beyond the final heat treatment process, shall be sterilized by heat, chemical sterilant(s) or other appropriate treatment before use and resterilized whenever it has been contaminated by unsterile product.

5.

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

B. The residual bacteria count of single-service containers, used for packaging pasteurized milk and dairy products, shall not exceed 50 per container, when the rinse test is used, except that in containers less than 100 ml, the count shall not exceed ten (10) or not over 50 colonies per eight (8) square inch (1 per square centimeter) of product contact surface, when the swab test is used, in 3-out-of-4 samples taken at random on a given day. All single-service containers shall be free of coliform organisms.

ITEM 13p. STORAGE OF CLEANED CONTAINERS AND EQUIPMENT

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

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

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. All multi-use containers, equipment and utensils, after cleaning, are transported and/or stored on approved racks or in clean cases elevated above the floor. Containers shall be stored inverted on racks or in cases constructed of relatively nonabsorbent, corrosion-resistant, nontoxic materials, or otherwise protected from contamination.

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

Single-service caps, cap stock, parchment paper, containers, gaskets and other single-service articles for use in contact with milk and dairy products shall be purchased and stored in sanitary tubes, wrappings or cartons; shall be kept therein in a clean, dry place until used; and shall be handled in a sanitary manner.

PUBLIC HEALTH REASON.—Soiled or contaminated caps, parchment paper, gaskets and single-service containers nullify the benefits of the safeguards prescribed throughout these Regulations. Packing the caps in tubes which remain unbroken until they are placed in the machine is the best method of assuring cap cleanliness.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. Single-service caps, cap stock. parchment paper, containers, gaskets and other single-service articles for use in contact with milk and dairy products are purchased and stored in sanitary tubes, wrappings or cartons; are kept in a clean, dry place until used; and are handled in a sanitary manner.

2. Paperboard shipping containers used to enclose plastic bags or unfilled containers are used only once unless other methods are employed to protect the containers from contamination.

3. Tubes or cartons are not refilled with spilled caps, gaskets or parchment papers.

4. Cartons or boxes from which contents have been partially removed are kept closed.

5. Suitable cabinets are provided for storage of tubes after removal from the large outer box, and for storage of opened cartons, unless other satisfactory means are employed to protect the caps, closures or containers.

ITEM 15p. PROTECTION FROM CONTAMINATION

Dairy plant operations, equipment and facilities shall be located and conducted to prevent any contamination of milk or dairy products, ingredients, equipment, containers and utensils. All milk or dairy products or ingredients which have been spilled, overflowed or leaked shall be discarded. The processing or handling of products other than milk or dairy products in the pasteurization plant shall be performed to preclude the contamination of such milk and dairy products. The storage, handling and use of poisonous or toxic materials shall be performed to preclude the contamination of milk and dairy products, or ingredients of such milk and dairy products or the product-contact surfaces of all equipment, containers or utensils.

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

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

ITEM 15p(A). PROTECTION FROM CONTAMINATION

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

2. Packaged milk and dairyproducts which have physically left the premises or the processing plant are not reused. The regulatory agency may, on a specific individual request, authorize reprocessing of milk and dairy products, provided all other aspects of this item, including proper storage temperature and container integrity are complied with. Provided, that the repasteurization of milk and dairy products shipped in transport tankers which have been pasteurized at another plant and have been handled in a sanitary manner and maintained at 7°C (45°F) or less is permitted. Equipment, designated areas or rooms utilized for storage, processing and handling of returned packaged milk and dairy products are maintained, operated, cleaned and sanitized so as to preclude contamination of manufactured products and equipment and the manufacturing operations.

~~3. All product-contact surfaces of containers, equipment and utensils are covered or otherwise protected to prevent the access of insects, dust, condensation and other contamination. All openings, including valves and piping attached to milk storage and milk tank trucks, pumps, vats, etc., shall be capped or otherwise properly protected. While unloading at a pasteurization plant, receiving station or transfer station, one of the following conditions shall be met:~~

~~A. If the area is completely enclosed (walls and ceiling, with doors closed) during the unloading process and the dust-cover or dome and the manhole cover is opened slightly and held in this position by the metal clamps used to close the cover, then a filter is not required. However, if the dust-cover and/or manhole cover(s) are opened in excess of that provided by the metal clamps or the covers have been removed, then a suitable filter is required for the manhole.~~

~~B. If the area is not completely enclosed or doors of the unloading area are open during unloading, a suitable filter is required for the manhole or air inlet vent and suitable protection must be provided over the filter material either by design of the filter holding apparatus or a roof or ceiling over the area. When weather and environmental conditions permit, manhole openings and covers of milk tank trucks may be opened outdoors for the short period of time necessary for the collection of samples for animal drug residue screening. Direct connections from milk tank truck to milk tank truck must be made from valve to valve or through the manhole lid. Provided, that all connections are made ferrule to ferrule and adequate protection is provided for the air vent.~~

~~Receiving and dump vats shall be completely covered, except during washing and sanitizing, and when milk is being dumped. Where strainers are used, the cover for the vat opening shall be designed to cover the opening with the strainer in place.~~

~~4. Whenever air under pressure is used for the agitation or movement of milk, or is directed at a milk-contact surface, it is free of oil, dust, rust, excessive moisture, extraneous materials and odor, and shall otherwise comply with the applicable standards of Appendix E. The use of steam containing toxic substances is expressly prohibited. Whenever steam is used in contact with milk or dairy products and shall comply with the applicable standards of Appendix E.~~

~~5. All multi-use cases used to encase packaged milk and dairy product containers are cleaned prior to their use.~~

~~6. All ingredients and non-product-contact materials used in the preparation or packaging of milk and dairy products are stored in a clean place and are so handled as to prevent their contamination.~~

~~7. Pasteurized milk is not strained or filtered except through a perforated metal strainer.~~

~~8. Only those poisonous or toxic materials, including but not limited to insecticides, rodenticides, detergents, sanitizers, caustics, acids, related cleaning compounds and medicinal agents necessary for the maintenance of the dairy plant are present in the dairy plant.~~

~~9. Those poisonous or toxic materials that are necessary are not stored in any room where milk or dairy products are received, processed, pasteurized or stored; or where equipment, containers or utensils are washed; or where single-service containers, closures or caps are stored.~~

~~10. Those poisonous or toxic materials that are necessary are stored in a separate area of the plant in prominently and distinctly labeled containers. Provided that, this does not preclude the convenient availability of detergents or sanitizers to areas where equipment, containers, and utensils are washed and sanitized.~~

11. Only insecticides and rodenticides approved by the regulatory agency and/or registered with the U.S. Environmental Protection Agency shall be used for insect and rodent control. Such insecticides and rodenticides shall be used only in accordance with the manufacturer's label directions and shall be prevented from contaminating milk, containers, equipment and utensils.

12. Raw and pasteurized milk and dairy products shall be separated by one valve from non-dairy products.

13. Except during the actual flushing of raw product lines and vessels with water, there shall be a sufficient separation between water piping and unpasteurized dairy products, or lines used to conduct unpasteurized dairy products, to prevent the accidental addition of water.

14. When steam is used for direct heating of milk and dairy products, the steam shall be clean, dry saturated, trapped, and filtered prior to addition to the product.

ITEM 15p(B) CROSS CONNECTIONS

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

A. Physically disconnecting all connection points between tanks or circuits containing cleaning and/or sanitizing solutions from pipelines and equipment used to contain or conduct milk or dairy products, or

B. Separation of all connection points between such circuits by at least two automatically controlled valves with a drainable opening to the atmosphere between the valves, or by a single bodied double seat valve, with a drainable opening to the atmosphere between the seats, if:

(1) The opening to the atmosphere (vent) is equal to the largest pipeline feeding the valve(s).

(2) Both valves (or valve seats in the case of single bodied double seat valves) are position detectable, and capable of providing an electronic signal when not properly seated in the blocked position.

(3) These valves (or valve seats in the case of single bodied double seat valves) are part of an automatic failsafe system which will prevent contamination of product with cleaning or sanitizing solutions. Automatic fail safe systems will be unique to each particular installation but are normally based on the premise that both blocking valve seats are properly seated in the blocked position before the mechanical cleaning system can be activated for the cleaning circuit containing this valve arrangement.

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

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

(6) The vent is not cleaned until milk and dairy products have been removed or isolated.

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

~~For example: In low pressure, gravity drain applications where the product line is the same size or larger than the cleaning or sanitizing solution line; the vent may be the size of the solution line and the valves or valve seats need not be position detectable (all other criteria still apply). In order to accept this variation, the valve(s) must fail to the blocked position upon loss of air or power, and there must be no pumps capable of pushing milk, dairy product, cleaning solutions, or sanitizing solutions into this valve arrangement.~~

~~**IMPORTANT NOTE—** The valve arrangement(s) described in this section shall not be used to separate raw products (dairy, non-dairy or water) from pasteurized milk or dairy products.~~

~~2. Except as permitted in 16P there shall be no physical connection between unpasteurized products (dairy, non-dairy, or water) and pasteurized milk or dairy products. Pasteurized non-dairy products or water not completely separated from pasteurized dairy products, shall be pasteurized at times and temperatures which meet at least the minimum times and temperatures provided for in Definition X or in the case of water have undergone an equivalent process found acceptable by CDPHE.~~

~~This section does not require separate raw and pasteurized mechanical cleaning systems.~~

~~3. Pasteurized re-circulation lines, divert lines, and leak detect lines connecting to the raw product constant level supply tank shall be designed so that there is an air gap between the termination of these pipelines and the raw product overflow level. This air gap must be equivalent to at least two times the diameter of the largest of these pipelines. For purposes of this section an overflow is defined as the flood rim of the constant level supply tank or any unrestricted opening below the flood rim of the constant level supply tank which is large enough that it is at least equivalent to two times the diameter of the largest of these pipelines.~~

~~4. All milk and dairy products which have overflowed, leaked, been spilled or improperly handled are discarded. Milk and dairy products drained from processing equipment at the end of a run, collected from a defoamer system and milk solids rinsed from equipment, containers or pipelines shall be repasteurized only if such milk and dairy products are handled in a sanitary manner and maintained at 7°C (45°F) or less. When the handling and/or refrigeration of such milk and dairy products are not in compliance with this requirement, they shall be discarded. Milk and dairy products from damaged, punctured or otherwise contaminated containers or product from out of code containers shall not be re-used.~~

~~5. Means are provided to prevent contamination of milk containers, utensils and equipment by drippings, spillage and splash from overhead piping, platforms or mezzanines.~~

~~6. The processing of foods and/or drinks other than dairy products are performed to preclude the contamination of milk and dairy products.~~

~~7. In no case shall pasteurized milk or dairy products be standardized with unpasteurized milk unless the standardized product is subsequently pasteurized.~~

~~8. Reconstituted or recombined milk and dairy products shall be pasteurized after reconstitution or recombining of all ingredients.~~

~~**ITEM 16p. PASTEURIZATION AND ASEPTIC PROCESSING**~~

~~Pasteurization shall be performed as defined in Section 1, Definition X of these Regulations. Aseptic processing shall be performed in accordance with 21 CFR 113 (1999) and the Administrative Procedures of Item 16p, C, D and E of this section.~~

PUBLIC HEALTH REASON.— The public health value of pasteurization is unanimously agreed upon by health officials. Long experience, conclusively shows its value in the prevention of disease which may be transmitted through milk. Pasteurization is the only practical, commercial measure which, if properly applied to all milk, will destroy all milkborne disease organisms. Examination of lactating animals and milk handlers, while desirable and of great value, can be done only at intervals and; therefore, it is possible for pathogenic bacteria to enter the milk for varying periods before the disease condition is discovered. Disease bacteria may also enter milk accidentally from other sources, such as flies, contaminated water, utensils, etc. It has been demonstrated that the time-temperature combinations specified by these Regulations, if applied to every particle of milk, will devitalize all milkborne pathogens. Compilations of outbreaks of milkborne disease by the U.S. Public Health Service, over many years, indicate that the risk of contracting disease from raw milk is approximately 50 times as great as from milk labeled "pasteurized".

NOTE— Although pasteurization devitalizes the organisms, it does not destroy the toxins that may be formed in milk when certain staphylococci are present (as from udder infections) and when the milk is not properly refrigerated before pasteurization. Such toxins may cause severe illness.

Numerous studies and observations clearly prove that the food value of milk is not significantly impaired by pasteurization.

ADMINISTRATIVE PROCEDURES

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

1. Every particle of milk or dairy product is heated in properly designed and operated equipment to one of the temperatures specified in the following table and held continuously at or above that temperature for at least the time specified:

Table 2. Pasteurization Temperature vs. Time

Temperature	**Time**
*63°C (145°F)	30 minutes
*72°C (161°F)	15 seconds
89°C (191°F)	1.0 second
90°C (194°F)	0.5 second
94°C (201°F)	0.1 second
96°C (204°F)	0.05 second
100°C (212°F)	0.01 second
*If the fat content of the dairy product is 10 percent or more, or if it contains added sweeteners, the specified temperature shall be increased by 3°C (5°F).	
Provided, that ice cream mixes shall be heated to at least the following temperature and time specifications:	
69°C (155°F)	30 minutes
80°C (175°F)	25 seconds
83°C (180°F)	15 seconds
Provided further, that nothing shall be construed as barring any other pasteurization process which has been recognized by the Food and Drug Administration to be equally efficient and which is approved by the regulatory agency.	

2. The design and the operation of pasteurization equipment and all appurtenances thereto shall comply with the applicable specifications and operational procedures of subitems (A), (B), (D) and (E) as follows:

ITEM 16p(A). BATCH PASTEURIZATION

All indicating and recording thermometers used in connection with the batch pasteurization of milk or dairy products shall comply with the applicable specifications set forth in Appendix E. Specification for test thermometer and other test equipment appear in Appendix F.

PUBLIC HEALTH REASON.— Unless the temperature-control instruments and devices used on pasteurization equipment are accurate within known limits, there can be no assurance that the proper pasteurization temperature is being applied. Pasteurization must be performed in equipment which is properly designed and operated and which insures that every particle of milk or dairy products will be held continuously at the proper temperature for the specified period of time.

Recording thermometers are the only known means for furnishing the regulatory agency with a record of the time and temperature of pasteurization. Experience has shown that recording thermometers, due to their mechanical complexity, are not entirely reliable. Therefore, mercury indicating thermometers, which are much more reliable, are needed to provide a check on the recording thermometer and assurance that proper temperatures are being applied.

The recording thermometer shows the temperature of the milk immediately surrounding its bulb, but cannot indicate the temperature of the milk in other portions of the holder. Similarly, it shows the holding time in manual-discharge vats, but not in automatic-discharge systems. The pasteurizer must; therefore, be so designed and so operated and, where necessary, provided with such automatic controls, as to assure that every portion of the milk will be subjected to the proper temperature for the required length of time.

Unless the inlet and outlet valves and connections to the vats and pockets are properly designed and operated, cold pockets of milk may be held in the outlet valve or pipeline; raw milk may leak into the vat or pocket during the holding or emptying time; and raw or incompletely pasteurized milk may leak into the outlet line during the filling, heating or holding period.

Tests have shown that when foam is present on milk in vats or pockets during pasteurization, the temperature of the foam may be well below the pasteurization temperature. In such cases, pathogenic organisms, that may be in the foam, will not be killed. Experience indicates that some foam is present at some time in all vats, particularly at certain seasons. Furthermore, in filling vats, milk frequently is splashed on the surfaces and fixtures above the milk level, as well as on the underside of the vat cover. Droplets of this splash may drop back into the body of the milk, and since they may not have been at pasteurization temperature for the required time, they may contain living pathogenic organisms. Heating the air above the milk, above pasteurization temperature, remedies these conditions.

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

Obviously, if the design and construction of pasteurization vats and pocket covers do not prevent leakage, condensation and the entrance of water and dust, the milk may become contaminated with material containing disease bacteria. Keeping the covers closed during operation will decrease the chance of dust, flies, sputum droplets, drip and splash entering the milk.

ADMINISTRATIVE PROCEDURES

1. TIME AND TEMPERATURE CONTROLS FOR BATCH PASTEURIZERS.—

A. **Temperature Difference.**— The pasteurizer shall be so designed that the simultaneous temperature difference between the milk or dairy product, at the center of the coldest milk or dairy product in the vat, will not exceed 0.5°C (1°F) at any time during the holding period.

The vat shall be provided with adequate agitation, operating throughout the holding period. No batch of milk or dairy product shall be pasteurized unless it covers a sufficient area of the agitator to insure adequate agitation.

B. **Location and Required Readings of Indicating and Recording Thermometers.**— Each batch pasteurizer shall be equipped with both an indicating and a recording thermometer.

The thermometer shall read not less than the required pasteurization temperature throughout the required holding period. The plant operator shall check daily the temperature shown by the recording thermometer against the temperature shown by the indicating thermometer. This comparison shall be noted on the recording thermometer chart. The recording thermometer shall not read higher than the indicating thermometer. No batch of milk or dairy products shall be pasteurized unless it is sufficient to cover the bulbs of both the indicating and the recording thermometer.

C. **Assurance of Minimum Holding Periods.**— Batch pasteurizers shall be so operated that every particle of milk or dairy product will be held at not less than the minimum pasteurization temperature continuously for at least 30 minutes. When milk or dairy products are raised to pasteurization temperature in the vat, and cooling is begun in the vat simultaneously with or before the opening of the outlet valve, the recorder chart shall show at least 30 minutes, at not less than minimum pasteurization temperature. When milk or dairy products are preheated to pasteurization temperature before entering the vat, the recorder chart shall show a holding period of at least 30 minutes, at not less than the minimum pasteurization temperature plus the time of filling from the level of the recorder bulb. When cooling is begun in the holder, after the opening of the outlet valve or is done entirely outside the holder, the chart shall show at least 30 minutes at not less than the minimum pasteurization temperature plus the time of emptying to the level of the recording-thermometer bulb.

When the recorder time interval on the recorder chart at the pasteurization temperature includes filling and/or emptying time, such intervals shall be indicated on the recorder chart, by the operator, by removing the recording-thermometer bulb from the milk for a sufficient time to depress the pen; or by turning cold water into the vat jacket at the end of the holding period; or by inscribing the holding time on the chart. The filling time and the emptying time for each holder, so operated, shall be determined by the regulatory agency, initially and after any change which may affect these times.

No milk shall be added to the holder after the start of the holding period.

2. AIRSPACE HEATING.—

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

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

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

3. INLET AND OUTLET VALVES AND CONNECTIONS.—

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

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

B. **"The fully open position"** shall mean that position of the valve seat which permits the maximum flow into or out of the pasteurizer.

C. **"The closed position"** shall mean any position of the valve seat which stops the flow of milk into or out of the pasteurizer.

D. **"The fully closed position"** shall mean that closed position of the valve seat which requires the maximum movement of the valve to reach the fully open position.

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

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

G. **"Leak-protector valve"** shall mean a valve provided with a leak-diverting device, which, when the valve is in any closed position, will prevent leakage of milk past the valve.

H. **"Close-coupled valve"** shall mean a valve, the seat of which is either flush with the inner wall of the pasteurizer or closely coupled that no milk in the valve inlet is more than 0.5°C (1°F) colder than the milk at the center of the pasteurizer at any time during the holding period.

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

(1) The vat outlet is flared that the smallest diameter of the large end of the flare is not less than the diameter of the outlet line, plus the depth of the flare; and

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

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

4. DESIGN AND INSTALLATION OF VALVES AND CONNECTIONS.—

All valves and connections shall comply with the following requirements:

A. Valves and pipeline connections shall meet the requirements of Item 10p.

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

C. To prevent clogging, and to promote drainage, all leak-protection grooves shall be at least 5 millimeters (0.187 inch wide) and at least 2.3 millimeters (0.094 inch) deep at the center. Mating grooves shall provide these dimensions throughout their combined length, whenever the valve is in, or approximately in, the fully closed position. All single-leak grooves, and all mating leak grooves when mated, shall extend throughout the entire depth of the seat to divert leakage occurring at all points throughout the depth of the seat and to prevent air binding. Washers or other parts shall not obstruct leak-protector grooves.

D. A stop shall be provided on all plug-type outlet valves in order to guide the operator in closing the valve so that unpasteurized milk may not inadvertently be permitted to enter the outlet line. The stop shall be so designed that the plug will be irreversible when the plug is provided with any grooves or their equivalent, unless duplicate, diametrically opposite grooves are also provided. Stops shall be so designed that the operator cannot turn the valve beyond the stop position, either by raising the plug or by any other means.

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

F. All outlets from vat pasteurizers shall be equipped with close coupled leak-protector valves or be otherwise similarly protected during filling, holding and emptying periods.

G. All inlet pipelines are disconnected or otherwise similarly protected during the holding and emptying periods.

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

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

J. Close coupled vat pasteurizer outlet valve bodies and plugs shall be made of stainless steel or of other materials that have heat transfer properties at least equal to stainless steel.

5. RECORDING CHARTS.—

All recording thermometer charts shall comply with all the applicable requirements of Item 16p(E).

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

PUBLIC-HEALTH REASON.— See Public-Health Reason under Item 16p and 16p(A).

ADMINISTRATIVE PROCEDURES

1. **INDICATING THERMOMETER AND RECORDER/CONTROLLER INSTRUMENTS.—** All indicating thermometers and recorder/controller instruments and devices used in connection with the high-temperature, short-time, continuous-flow pasteurization of milk or dairy products shall comply with the applicable specifications set forth in Appendix E.

2. **AUTOMATIC MILK CONTROLLER.—** Each high-temperature, short-time, continuous-flow pasteurization system shall be equipped with an automatic milk-flow control of the diversion type, which complies with the following definition, specifications and performance requirements:

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

B. **Flow-Diversion Devices.—**

All flow-diversion devices used in continuous pasteurizers shall comply with the following or equally satisfactory specifications:

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

(2) When a packing gland is used to prevent leakage around the actuating stem, it shall be impossible to tighten the stem packing nut to such an extent as to prevent the valve from assuming the fully-diverted position.

(3) A leak escape shall be installed on the forward-flow side of the valve seat. However, when back pressure is exerted on the forward-flow side of the valve seat, while the milk-flow is being diverted, the leak escape should lie between two valve seats or between two portions of the same seat, one upstream and the other downstream from the leak escape. The leak escape shall be designed and installed to discharge all leakage to the outside, or to the constant-level tank through a line separate from the diversion line. Provided, that when leakage is discharged to the constant-level tank, a sight glass shall be installed in the leak escape line to provide a visual means of leak detection.

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

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

(6) The flow-diversion device shall be located downstream from the holder. The flow-control sensor shall be located in the milk line not more than 46 centimeters (18 inches) upstream from the flow-control device.

(7) In the case of higher-heat, shorter-time (HHST) pasteurizing systems utilizing the temperatures of 89°C (191°F) and above and holding times of one (1) second or less, the flow-diversion device may be located downstream from the regenerator and/or cooler section. Provided, that when the flow-diversion device is located

downstream from the regenerator and/or cooler section, the flow-diversion device shall be automatically prevented from assuming the forward-flow position until all product-contact surfaces between the holding tube and flow-diversion device have been held at or above the required pasteurization temperature continuously and simultaneously for at least the required pasteurization time as defined in Definition X of these Regulations.

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

(9) When it is used, the pipeline from the leak detector port of the flow-diversion device shall be self-draining and shall be free of restrictions or valves.

(10) The flow-diversion device shall be interwired, via micro-switches to the timing pump or timing system, to insure that flow occurs only when the valve(s) are in the fully divert position at below cut-in temperature. A one second maximum "off" time delay is allowable to maintain the flow-promoting device in the "on" position through the travel time of the valve(s).

(11) If the area between the divert and detect valve seats is not self draining, a delay of at least one second and not more than five seconds is required between the movement of the divert and detect valves when the flow diversion device assumes the forward flow position. the delay may be longer than five seconds if: the timing system is magnetic flow meter based, or the holding time in diverted flow through an unrestricted divert valve line is longer than the required pasteurization time as specified in Definition X of these Regulations. Additionally, no time delay is required in pasteurization systems in which the flow diversion device is located down stream from the pasteurized regenerator and in which all forward flow product contact surfaces of the flow diversion device are sanitized (or sterilized) during the normal startup process.

C. **Milk-Flow Controller Instrumentation.** The following requirements shall be met with respect to the instrumentation of the milk-flow controller:

(1) The thermal limit controller shall be set and sealed so that forward flow of product cannot start unless the temperature at the controller sensor is above the required pasteurization temperature as defined in Definition X of these Regulations for the milk or dairy product and the process used, nor continue during descending temperatures when the temperature is below the required pasteurization temperature. The seal shall be applied by the regulatory agency after testing, and shall not be removed without immediately notifying the regulatory agency. The system shall be so designed that no milk can be bypassed around the controller sensor which shall not be removed from its proper position during the pasteurization process. The cut-in and cut-out milk temperatures, as shown by the indicating thermometer, shall be determined at the beginning of each day's operation and entered upon the recorder chart daily by the plant operator.

(2) In the case of HHST pasteurization systems, utilizing the temperatures of 89°C (191°F) and above, and holding times of 1 second or less, with the flow-diversion device located downstream from the regenerator and/or cooler section, additional temperature controllers and timers shall be inter-wired with the thermal limit controller, and the control system shall be set and sealed so that forward flow of product cannot start until all product-contact surfaces between the holding tube and flow-diversion device have been held at or above the required pasteurization temperature, continuously and simultaneously for at least the required

~~pasteurization time as defined in Definition X of these Regulations. The control system shall also be set and sealed so that forward flow cannot continue when the temperature of the product in the holding tube is below the required pasteurization temperature. The seal shall be applied by the regulatory agency after the equipment has been tested, and shall not be removed without immediately notifying the regulatory agency. The system shall be so designed that no product can be bypassed around the control sensors, which shall not be removed from their proper position during the pasteurization process. For these HHST systems, daily measurement by the operator of the cut-in and cut-out temperatures is not required.~~

~~(3) Manual switches for the control of pumps, homogenizers or other devices which produce flow through the holder, shall be wired so that the circuit is completed only when the milk is above the required pasteurization temperature as defined in Definition X of these Regulations for the milk or dairy product and the process used, or when the diversion device is in the fully-diverted position.~~

~~D.~~ **~~Holding Tube.—~~**

~~(1) Holders shall be designed to provide for the holding of every particle of milk or dairy product for at least the time required in Definition X of these Regulations for the milk or dairy product and the process used.~~

~~(2) The holder shall be so designed that the simultaneous temperature difference between the hottest and coldest milk, in any cross section of flow, at any time during the holding period, will not be greater than 0.5°C (1°F). This requirement may be assumed to have been satisfied, without testing, in tubular holders of 17.8 centimeters (7 inches) or smaller diameter which are free of any fittings through which the milk may not be thoroughly swept.~~

~~(3) No device shall be permitted for short circuiting a portion of the holder to compensate for changes in rate of milkflow. Holding tubes shall be installed so that sections of pipe cannot be left out, resulting in a shortened holding time.~~

~~(4) The holding tube shall be arranged to have a continuously upward slope in the direction of flow of not less than 2.1 centimeters per meter (0.25 inch per foot).~~

~~(5) Supports for tubes shall be provided to maintain all parts of the holding tubes in a fixed position, free from any lateral or vertical movement.~~

~~(6) The holder shall be so designed that no portion between the inlet and the flow-control temperature sensor is heated.~~

~~(7) The holding time for the HHST processes must be determined from the pumping rate rather than by the salt conductivity test, because of the short holding tube. The holding tube length must be such that the fastest flowing particle, of any product, will not traverse the holding tube in less than the required holding time. Since laminar flow (the fastest flowing particle travels twice as fast as the average flowing particle) can occur in the holding tube during pasteurization of high-viscosity products, holding tube lengths are calculated as twice the length required to hold the average flow for the time standard.~~

~~(8) With the direct steam heating processes, the holding time is reduced because the product volume increases as the steam condenses to water during heating. This surplus water is evaporated as the pasteurized product is cooled in the vacuum~~

~~chamber. For example, with a 66°C (120°F) increase by steam injection, which is probably the maximum temperature rise that will be used, a volume increase of 12 percent will occur in the holding tube. The measurement of the average flow rate, at the discharge of the pasteurizer, does not reflect this volume increase in the holding tube. However, this volume increase, i.e., holding time decrease, must be considered in the calculations.~~

~~(9) The pressure limit indicator/pressure switch must be interwired so that the flow-diversion device will move to the divert position if the product pressure falls below a prescribed value. For operating temperatures between 89°C (191°F) and 100°C (212°F) the instrument must be set at 69 kPa (10 pounds per square inch) (psi). For units which have operating temperatures above 100°C (212°F) the instrument must be set at a pressure 69 kPa (10 psi) above the boiling pressure of the product, at its maximum temperature in the holding tube. If this pressure is too low, the resultant vaporization in the holding tube will substantially reduce residence times.~~

~~(10) With the steam injection process, a differential pressure limit indicator across the injector is needed to ensure adequate isolation of the injection chamber. The instrument must have a differential pressure switch so that the flow-diversion device will move to the divert position if the pressure drop across the injector falls below 69 kPa (10 psi).~~

~~E. **Indicating and Recording Thermometers.—**~~

~~(1) An indicating thermometer shall be located as near as practicable to the temperature sensor of the recorder/controller, but may be located a short distance upstream from the latter where milk between the two thermometer does not differ significantly in temperature.~~

~~(2) The temperature shown by the recorder/controller shall be checked daily by the plant operator against the temperature shown by the indicating thermometer. Readings shall be recorded on the chart. The recorder/controller shall be adjusted to read no higher than the indicating thermometer.~~

~~(3) The recorder/controller charts shall comply with the applicable provisions of Item 16p(E).~~

~~F. **Flow-Promoting Devices.—**~~

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

~~(2) The speed of pumps or other flow-promoting devices, governing the rate of flow through the holder, shall be so controlled as to insure the holding of every particle of milk for at least the time required as defined in Definition X of these Regulations for the milk or dairy product and the process used. In all cases, the motor shall be connected to the metering pump by means of a common drive shaft, or by means of gears, pulleys, or a variable-speed drive, with the gear box,~~

the pulley box or the setting of the variable speed protected in such a manner that the holding time cannot be shortened without detection by the regulatory agency. This shall be accomplished by the application of a suitable seal(s) after being tested by the regulatory agency and such seal shall not be broken without immediately notifying the regulatory agency. This provision shall apply to all homogenizers used as timing pumps. Variable speed drives, used in connection with the metering pump, shall be so constructed that wearing or stretching of the belt results in a slowdown, rather than a speedup, of the pump.

The metering or timing pump shall be of the positive displacement type or shall comply with the specifications for magnetic flow meter systems as outlined in Appendix E. Timing pumps and homogenizers, when used as a timing pump, shall not have by-pass lines connected from their outlet pipelines to their inlet pipelines during processing if an additional flow-promoting or vacuum producing device is located within the system. When a homogenizer is used in conjunction with a timing pump it shall be either:

(a) Of larger capacity than the timing pump. In which case an unrestricted, open, recirculation line shall be used to connect the outlet pipeline from the homogenizer to its inlet line. The recirculation line must be of at least the same or larger diameter than the inlet pipeline feeding product to the homogenizer. A check valve, allowing flow from the outlet line to the inlet line, may be used in the recirculating line provided it is of the type which provides a cross-sectional area at least as large as the recirculating line.

(b) Of smaller capacity than the timing pump. In which case a relief line and valve shall be used. Such relief line shall be located after the timing pump and before the inlet to the homogenizer and shall return product to the balance tank or to the outlet of the balance tank, upstream of any booster pump or other flowpromoting device.

For those systems which do not homogenize all products and wish to utilize a by-pass line to by-pass the homogenizer while processing such product; the by-pass line must be connected with valves which are so designed that both lines cannot be open at the same time. This may be accomplished with 3-way plug valves with properly designed and operating pins or other automatic, fail-safe valves which accomplish the same objective.

(3) The holding time shall be taken to mean the flow time of the fastest particle of milk throughout the holder section, at or above the required pasteurization temperature as defined in Definition V of these Regulations. The holder section is that portion of the system that is outside of the influence of the heating medium, and slopes continuously upward in the downstream direction and is located upstream from the flow-diversion device. Tests for the holding time shall be made when all equipment and devices are operated and adjusted to provide for maximum flow. When a homogenizer is located upstream from the holder, the holding time shall be determined with the homogenizer in operation with no pressure on the homogenizer valves.

For those systems which do not homogenize all products and utilize by-pass lines as outlined in (a) above, the holding time shall be tested in both flow patterns and the fastest time used. The holding time shall be tested during both forward and diverted flow. If it is necessary to lengthen the holding time during diverted flow, an identifiable restriction may be placed in the vertical portion of the diversion pipeline. When vacuum equipment is located downstream from the

holder, the holding time shall be tested with the metering pump operating at maximum flow and the vacuum equipment adjusted to provide for the maximum vacuum.

The holding time shall be tested in both forward and diverted flow by the regulatory agency initially; semiannually thereafter; after any alteration or replacement that may affect the holding time; and whenever the seal of the speed setting has been broken.

G. **Heating by Direct Addition of Steam.** When steam is injected into a fluid, condensation of the steam may not be completed inside the injector unless the proper design criteria are used. Lack of complete condensation inside the injector would cause temperature variations in the holding tube that could lead to some product particles being processed below pasteurization temperature. When culinary steam is introduced directly into milk or dairy products, as the means of terminal heating to achieve pasteurization temperature, the steam injector shall be designed, installed and operated to comply with the following or equally satisfactory specifications:

(1) The product and steam flows must be isolated from pressure fluctuations inside the injection chamber. One method of isolation is to insert supplementary orifices on the product inlet and the heated product outlet of each injector. The two supplementary orifices must be sized for at least a 69 kPa (10 psi) product pressure drop across the injector during a simulation of normal operations. Excessive vibrations, pressure fluctuations or erratic noise levels indicate an unstable steam injection system and a need to check the isolation of the injection chamber.

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

H. **Prevention of Product Adulteration With Added Water.**

(1) When culinary steam is introduced directly into the milk or dairy product downstream from the flow-diversion device, means shall be provided to preclude the addition of steam to the product, unless the flow-diversion device is in the forward-flow position. This provision may be satisfied by the use of an automatic steam control valve with a temperature sensor located downstream from the steam inlet, or by the use of an automatic solenoid valve installed in the steam line and so wired through the flow-diversion device controls, so that steam cannot flow unless the flow-diversion device is in the forward-flow position.

(2) When culinary steam is introduced directly into the milk or dairy product, automatic means (e.g., stand-alone and/or PLC-based ration control system) shall be provided to maintain a proper temperature differential between incoming and outgoing milk to preclude dilution with water.

(3) Where a water feed line is connected to a vacuum condenser and the vacuum condenser is not separated from the vacuum chamber by a physical barrier, means shall be provided to preclude the backup and overflow of water from the

vacuum condenser to the vacuum chamber. This provision may be satisfied by the use of a safety shutoff valve, located on the water feed line to the vacuum condenser, which is automatically actuated by a control which will shut off the in-flowing water, if for example, the condensate pump stops and the water level rises above a predetermined point in the vacuum condenser. This valve may be actuated by water, air or electricity and shall be so designed that failure of the primary motivating power will automatically stop the flow of water into the vacuum condenser.

ITEM 16p(C). ASEPTIC PROCESSING SYSTEMS

PUBLIC HEALTH REASON. Aseptically processed milk and dairy products are being packaged in hermetically sealed containers and stored for long periods of time under nonrefrigerated conditions. These conditions are favorable to the growth of many types of bacteria (pathogenic, toxin producing and spoilage organisms). Because of this, every precaution must be taken to ensure that all viable organisms and their spores are destroyed by the chosen heat process, for the particular milk or dairy product, and that the subsequent handling, packaging and storage processes do not provide an opportunity for recontamination of the product. The selected process must conform to the acceptable requirements for low acid canned foods.

ADMINISTRATIVE PROCEDURES

Aseptic Processing Systems. The aseptic processing portion of this item is deemed to be satisfied when the design and operation of aseptic processing systems comply with the applicablespecifications and operational procedures ofsubitems (C), (D) and (E) as follows:

Provided, that nothing shall be construed as barring any other aseptic processing system which have been recognized by the Food and Drug Administration to be equally effective and which is approved by the regulatory agency.

1. **INDICATING THERMOMETERS AND RECORDER/CONTROLLER INSTRUMENTS.—**All indicating thermometers, recorder/controller instruments and devices, used in connection with aseptic processing systems, used for the aseptic processing of milk or dairy products shall comply with the applicable specifications set forth in Appendix E.

2. **ASEPTIC PROCESSING EQUIPMENT.—**

A. **Temperature Indicating Device—**Each aseptic processing system shall be equipped with at least one mercury-in-glass thermometer or an equivalent temperature-indicating device.

B. **Temperature Recorder-Controller—**An accurate temperature recorder/controller shall be installed in the product at the holding-tube outlet and before the inlet to the cooler or regenerator. The following requirements shall be met with respect to the instrumentation of the temperature recorder/controller.

(1) The temperature recorder/controller shall be set and sealed so that during product processing the forward flow of product cannot start unless the temperature at the controller sensor is above the required temperature for the product and the process used, nor continue during descending temperatures when the temperature is below the required temperature.

The seal shall be applied by the regulatory agency after testing and shall not be removed without immediately notifying the regulatory agency. The system shall be so designed that no product can be bypassed around the controller sensor

~~which shall not be removed from its proper position during the processing of aseptic milk and dairy products.~~

~~(2) Additional temperature controllers and timers shall be interwired with the thermal limit controller, and the control system shall be set and sealed so that forward flow of product cannot start until all product-contact surfaces between the holding tube and flow-diversion device have been held at or above the required sterilization temperature, continuously and simultaneously for at least the required sterilization time. The control system shall also be set and sealed so that forward flow cannot continue when the temperature of the product in the holding tube is below the required temperature. The seal shall be applied by the regulatory agency after being tested and shall not be removed without immediately notifying the regulatory agency. The system shall be so designed that no product can be bypassed around the control sensors, which shall not be removed from their proper position during the processing of aseptic milk and dairy products.~~

~~(3) Manual switches for the control of pumps, homogenizers or other devices which produce flow through the holder, shall be wired so that the circuit is completed only when the milk is above the required temperature for the product and the process used, or when the diversion device is in the fully-diverted position.~~

~~C.~~ ~~**Metering Pump.—**~~

~~(1) A metering pump shall be located upstream from the holding tube and shall be operated to maintain the required rate of product flow. The motor shall be connected to the metering pump by means of a common drive shaft, or by means of gears, pulleys or a variable-speed drive, with the gear box, the pulley box or the setting of the variable speed protected in such a manner that the hold time cannot be shortened without detection by the regulatory agency. This shall be accomplished by the application of a suitable seal(s) after being tested by the regulatory agency and such seal shall not be broken without immediately notifying the regulatory agency. This provision shall apply to all homogenizers used as timing pumps. Variable speed drives, used in connection with the metering pump, shall be so constructed that wearing or stretching of the belt results in a slowdown, rather than a speedup, of the pump. The metering or timing pump shall be of the positive displacement type or shall comply with the specifications for magnetic flow meter systems.~~

~~(2) The holding time shall be taken to mean the flow time of the fastest particle of product throughout the holder section; i.e., that portion of the system that is outside of the influence of the heating medium; and slopes continuously upward in the down-stream direction; and is located upstream from the flow-diversion device. Tests for holding time shall be made when all equipment and devices are operated and adjusted to provide for maximum flow. When a homogenizer is located upstream from the holder, the holding time shall be determined with the homogenizer in operation with no pressure on the homogenizer valves. Where bypass lines are provided, either upstream or downstream from the metering pump, the holding time shall be tested with both the regular and bypass line open, unless the bypass valve is so designed that both lines cannot be open at the same time. When vacuum equipment is located downstream from the holder, the holding time shall be tested with the metering pump operating at maximum flow and the vacuum equipment adjusted to provide for maximum vacuum. The holding time shall be tested by the regulatory agency initially; semiannually thereafter; after any alteration or replacement that may affect the holding time; and whenever the seal of the speed setting has been broken.~~

D. **Product Holding Tube.—**

(1) The product holding tube shall be designed to give continuous holding of every particle of product for at least the minimum holding time specified in the scheduled process. The holding tube shall be designed, so that no portion of the tube between the product inlet and the product outlet can be heated and it must be sloped upward at least 2.1 centimeters per meter (0.25 inch per foot). Supports for tubes shall be provided to maintain all parts of the holding tubes in a fixed position, free from any lateral or vertical movement.

(2) No device shall be permitted for short circuiting a portion of the holder to compensate for changes in rate of production flow. Holding tubes shall be installed so that sections of pipe cannot be left out, resulting in a shortened holding time. The holding time for the processes must be determined from the pumping rate, rather than by the salt conductivity test.

(3) The holding tube length must be such that the fastest flowing particle of any product will not traverse the holding tube in less than the required holding time.

NOTE – Since laminar flow (the fastest flowing particle travels twice as fast as the average flowing particle) can occur in the holding tube during aseptic processing of high-viscosity products, holding tube lengths are calculated as twice the length required to hold the average flow for the time standard. With the steam injection process, the holding time is reduced because the product volume increases as the steam condenses to water during heating in the injector. This surplus water is evaporated as the aseptically processed product is cooled in the vacuum chamber. For example, with a 66°C (120°F) increase by steam injection, which is probably the maximum temperature rise that will be used, a volume increase of 12 percent will occur in the holding tube. The measurement of the average flow rate at the discharge of the aseptic processor does not reflect this volume increase in the holding tube. However, this volume increase, i.e., holding time decrease, must be considered in the calculations.

(4) An aseptic processing system which can operate with product in forward flow mode, with less than 518 kPA (75psig) pressure in the holding tube shall be equipped with a pressure limit indicator/pressure switch in the holding tube to assure that the heated product remains in the liquid phase. In systems which do not have a vacuum chamber between the holding tube and the aseptic product side of the regenerator, this can be established by verifying that the aeptic processing equipment cannot operate in forward flow with less than 518 kPa (75psig) pressure on the aseptically processed side of the regenerator. The pressure limit indicator/pressure switch must be interwired so that the flow-diversion device, product divert system, product divert valve or other acceptable control system will move to the divert position, if the product pressure falls below a prescribed value. The instrument must be set at a pressure 69 kPa (10 psi) above the boiling pressure of the product at its maximum temperature in the holding tube. If this pressure is too low, the resultant vaporization in the holding tube will substantially reduce residence times.

(5) With the steam injection process, a differential pressure limit indicator, across the injector, is needed to ensure adequate isolation of the injection chamber. The instrument must have a differential pressure switch so that the flow-diversion device will move to the divert position if the pressure drop across the injector falls below 69 kPa (10 psi).

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

(1) The product and steam flows must be isolated from pressure fluctuations inside the injection chamber. One method of isolation is to insert supplementary orifices on the product inlet and the heated product outlet of each injector. The two supplementary orifices must be sized for at least a 69 kPa (10 psi) product pressure drop across the injector during a simulation of normal operations. Excessive vibrations, pressure fluctuations or erratic noise levels indicate an unstable steam injection system and a need to check the isolation of the injection chamber.

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

F. **Prevention of Product Adulteration With Added Water.**

(1) When culinary steam is introduced directly into the milk or dairy product, automatic means (e.g., stand-alone and/or PLC-based ratio control system) shall be provided to maintain a proper temperature differential between incoming and outgoing milk to preclude dilution with water.

(2) Where a water feed line is connected to a vacuum condenser and the vacuum condenser is not separated from the vacuum chamber by a physical barrier, means shall be provided to preclude the back-up and overflow of water from the vacuum condenser to the vacuum chamber. This provision may be satisfied by the use of a safety shutoff valve, located on the water feed line to the vacuum condenser, which is automatically actuated by a control, which will shut off the in-flowing water, if for example, the condensate pump stops and the water level rises above a predetermined point in the vacuum condenser. This valve may be actuated by water, air or electricity and shall be so designed that failure of the primary motivating power will automatically stop the flow of water into the vacuum condenser.

G. **Flow-Diversion Device.**—All flow-diversion devices used in continuous aseptic process systems shall comply with 16-B-2-b or equally satisfactory specifications.

ITEM 16p(D). PASTEURIZERS AND ASEPTIC PROCESSING SYSTEMS EMPLOYING REGENERATIVE HEATING

PUBLIC HEALTH REASON. To prevent contamination of the pasteurized milk in regenerators, the raw milk must always be under less pressure than the pasteurized milk or the heat-transfer medium. In the case of milk-to-milk regenerators, this requirement is necessary to prevent contamination of the pasteurized product by the raw milk if flaws should develop in the metal or in the joints separating the two kinds of milk.

ADMINISTRATIVE PROCEDURES

Milk-to-Milk Regenerative

Heating.—

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

1. Regenerators shall be constructed, installed and operated so that pasteurized or aseptic product in the regenerator will automatically be under greater pressure than raw milk in the regenerator at all times.

2. The pasteurized or aseptic product, between its outlet from the regenerator and the nearest point downstream open to the atmosphere, shall rise to a vertical elevation of 30.48 centimeter (12 inches) above the highest raw milk level, downstream from the constant-level tank, and shall be open to the atmosphere at this or a higher elevation.

3. The overflow of the top rim of the constant level raw milk tank shall always be lower than the lowest milk level in the regenerator.

4. No pump or flow-promoting device which can affect the proper pressure relationships within the regenerator shall be located between the pasteurized or aseptic product outlet from the regenerator and the nearest downstream point open to the atmosphere.

5. No pump shall be located between the raw milk inlet to the regenerator and the raw milk supply tank, unless it is designed and installed to operate only when milk is flowing through the pasteurized or aseptic product side of the regenerator and when the pressure of the pasteurized or aseptic product is higher than the maximum pressure produced by the pump. This may be accomplished by wiring the booster pump so that it cannot operate unless:

   A. The metering pump is in operation;

   B. The flow-diversion device is in forward-flow position; and

   C. The pasteurized or aseptic product pressure exceeds, by at least 6.9 kPa (1 psi). the maximum pressure developed by the booster pump. Pressure gauges shall be installed at the raw milk inlet to the regenerator and the pasteurized or aseptic product outlet of the regenerator or the outlet of the cooler. The accuracy of these required pressure gauges shall be checked, by the regulatory agency, on installation; quarterly thereafter; and following repair or adjustment.

6. The motor, casing and impeller of the booster pump shall be identified, and such records maintained as directed by the regulatory agency. All electric wiring interconnections should be in permanent conduit (except that rubber covered cable may be used for final connections), with no electrical connections to defeat the purpose of any provisions of these Regulations.

7. All raw milk in the regenerator will drain freely back into the constant-level raw milk tank when the raw milk pump(s) are shut down and the raw milk outlet from the regenerator is disconnected.

8. When vacuum equipment is located downstream from the flow-diversion device, means shall be provided to prevent the lowering of the pasteurized or aseptic product level in the regenerator during periods of diverted flow or shutdown. An effective vacuum breaker, plus an automatic means of preventing a negative pressure, shall be installed in the line between the vacuum chamber and the pasteurized or aseptic product inlet to the regenerator.

9. In the case of HHST pasteurization systems utilizing the temperatures of 89°C (191°F) and above and holding times of one (1) second or less, with the flow-diversion device located downstream from the regenerator and/or cooler section, the requirement that the pasteurized product from the outlet of the regenerator or cooler shall rise to a vertical elevation of 30.5 centimeters (12 inches) above the highest raw product level down-stream from the constant-level tank and shall be open to the atmosphere at this or a higher elevation, may be eliminated. Provided, that a differential pressure controller is used to monitor the highest pressure in the raw product side of the regenerator and the lowest pressure in the pasteurized side of the regenerator, and the controller is interlocked with the flow-diversion device and is set and sealed so that whenever improper pressures occur in the regenerator, forward flow of product is automatically prevented and will not start again until all product-contact surfaces between the holding tube and flow-diversion device have been held at or above the required pasteurization temperature, continuously and simultaneously for at least the required pasteurization time as defined in Definition X of these Regulations.

In the case of aseptic processing systems used for producing aseptic milk and dairy products, there shall be an accurate differential pressure recorder-controller installed on the regenerator. The scale divisions shall not exceed 13.8 kPa (2 pounds per square inch) on the working scale of not more than 138 kPa (20 pounds per square inch) per 25.4 millimeter (1 inch). The controller shall be tested for accuracy against a known accurate standard pressure indicator upon installation; at least once every three months of operation thereafter; or more frequently if necessary, to ensure its accuracy. One pressure sensor shall be installed at the aseptic product regenerator outlet and the other pressure sensor shall be installed at the raw product regenerator inlet.

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

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

MILK-TO-WATER-TO MILK

REGENERATIVE HEATING.—

Milk-to-water-to-milk regenerators shall comply with the following or equally satisfactory specifications:

Milk-to-water-to-milk regenerators shall be constructed, installed and operated such that the pasteurized or aseptic product in the regenerator will be under greater pressure than the heat-transfer-medium in the pasteurized or aseptic product side of the regenerator.

1. A differential pressure controller shall be used to monitor pressures of the pasteurized product and the heat-transfer medium.

2. In the case of aseptic processing systems, a differential pressure-recorder shall be used to monitor pressures of the aseptic product and the heat transfer medium.

3. In either case, one pressure sensor shall be installed at the pasteurized or aseptic product outlet of the regenerator and the other pressure sensor shall be installed at the heat-transfer-medium inlet of the pasteurized or aseptic product side of the regenerator. This controller or recorder-controller

shall divert the flow diversion device whenever the lowest pressure of pasteurized or aseptic product in the regenerator fails to exceed the highest pressure of heat-transfer-medium in the pasteurized or aseptic product side of the regenerator by at least 6.9 kPa (1 psi). Forward flow of product shall be automatically prevented until all product-contact surfaces between the holding tube and the flow diversion device have been held at or above the required pasteurization or sterilization temperature continuously and simultaneously for at least the pasteurization or sterilization time.

4. The heat-transfer-medium pump shall be wired so that it cannot operate unless the metering pump is in operation.

NOTE – See Appendix E for further discussion concerning methods of achieving the required pressure relationships within the regenerator.

ITEM 16p(E). PASTEURIZATION AND ASEPTIC PROCESSING RECORDS, EQUIPMENT TESTS AND EXAMINATIONS

1. **PASTEURIZATION AND ASEPTIC PROCESSING RECORDS.—**

All temperature and flow rate pasteurization recording charts or alternative records acceptable to the regulatory agency in place of charts shall be preserved for a period of six months. Provided, that all records and recording charts for aseptic milk and dairy product systems shall be retained for a period of six years. The use of such charts shall not exceed the time limit for which they are designed. Overlapping of recorded data shall be a violation of this item. The following information shall be entered on the charts as applicable or other records acceptable to the regulatory agency in place of charts as applicable:

A. Batch Pasteurizers.—

(1) Date.

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

(3) A continuous record of the product temperature.

(4) Extent of holding period, including filling and emptying times when required.

(5) Reading of airspace thermometer, within the holding period, at a given time or reference point as indicated on the chart.

(6) Reading of indicating thermometer, within the holding period, at a given time or reference point as indicated on the chart.

(7) Semi-annually, the initials of the regulatory agency opposite the required readings of the indicating thermometer and airspace thermometer.

(8) Semi-annually, the time accuracy of the recorder, as determined by the regulatory agency.

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

(10) Record of unusual occurrences.

(11) Signature or initials of operator.

(12) Name of dairy plant.

B. High-Temperature, Short-Time Pasteurizers. Recording thermometer charts shall contain all the information specified in a. above, except 4, 5 and reference to the airspace thermometer in item 7, and in addition, shall include the following:

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

(2) The cut-in and cut-out milk temperatures, recorded daily by the operator, at the beginning of the run, and initialed semi-annually by the regulatory agency.

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

C. Continuous Flow Pasteurizers or aseptic processing equipment with Meter Based Timing Systems. Flow rate recording charts shall be capable of continuously recording flow at the flow alarm set point and at least 19 liters (5 gallons) per minute higher than the high flow alarm setting. Flow rate recording charts shall contain all the information specified in a. above, except 3, 4, 5, 6, and 7 and in addition shall include the following:

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

(2) A continuous record of the flow rate.

D. Aseptic Processing Systems. Recording charts shall contain all the information specified in a. above, except 4, 5 and references to the airspace thermometers in item 6 and 7. In addition these records shall include c. above if applicable and the following:

(1) A continuous record of the time during which the flow diversion device, valve or system is in the forward flow position.

(2) A continuous record of applicable regenerator pressures.

(3) Not later than one working day after the actual process, and before shipment or release for distribution, a representative of plant management, who is qualified by suitable training or experience, shall review all processing and production records for completeness and to ensure that the product received the schedule process. The records, including the recording thermometer chart(s), shall be signed or initialed and dated by the reviewer.

(4) Number six from above shall also be recorded immediately after a chart has been changed.

2. EQUIPMENT TESTS AND EXAMINATIONS. The regulatory agency shall perform the indicated tests on the following instruments and devices initially on installation; and at least once each six months and the remaining days of the month in which the equipment tests are due and whenever any alteration or replacement is made which may affect the proper operation of the instrument or device. Provided, that the holding time test shall be conducted at least every six months and the remaining days of the month in which the equipment check is due.

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

A. The individual applying the seal(s) is employed in a supervisory capacity by the plant in which the seal was removed; and

B. The individual has satisfactorily completed a course of instruction, acceptable to the regulatory agency, on test controls for pasteurization equipment that includes a minimum of 8 hours classroom instruction; and

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

D. The individual is in possession of authorization from the regulatory agency to perform these tests; and

E. The individual will immediately notify the regulatory agency of the time of the shutdown that would necessitate the removal of the regulatory seals. Permission to test (and seal) the equipment must be obtained for each specific incident. The individual will also notify the regulatory agency of the identity of the controls affected, the cause (if known) of the equipment failure, the repairs made and the result of testing (when completed). The individual will provide the identity and volume of products processed during the period that temporary seals were applied to the regulatory agency; and

F. If regulatory tests reveal that equipment or controls are not in compliance with the provisions of this document, all products that were processed during that period will be recalled; and

G. The regulatory agency will remove the temporary seals, retest the equipment and apply regulatory seals following notification by industry.

ITEM 16P(F). MANUFACTURE OF DAIRY PRODUCTS FROM RAW MILK

Only products that are allowed by 21 CFR 133.102 – 133.127 and 133.133 – 133.196 (1999) and/or deemed to be safe by CDPHE may be manufactured from raw milk. This will involve the proper aging of the product, for which the following conditions shall be met:

- The manufacturing process shall be approved by CDPHE prior to implementation.
- Proper aging may include culturing, coagulating and salting during the process.
- The temperature during the aging process shall be maintained at no less than the minimum temperature specified by 21 CFR 133.102 – 133.127 and 133.133 – 133.196 (1999) for the product being manufactured.
- The product shall be aged for no less than the mimimum number of days as required by 21 CFR 133.102 – 133.127 and 133.133 – 133.196 (1999).
- Process records shall include documentation that each lot/batch has met the time and temperature requirements as specified in 16p(F)2. and 16p(F)3.
- A coding system shall be used to identify each lot/batch during the aging process.
- Processing records shall be maintained for a minimum of two years and shall be available for review during inspection.

ITEM 17p. COOLING OF MILK

All raw milk and dairy products shall be maintained at 7°C (45°F) or less until processed. All pasteurized milk and dairy products, except those to be cultured, shall be cooled immediately prior to filling or packaging, in approved equipment, to a temperature of 7°C (45°F) or less. All pasteurized milk and dairy products shall be stored at a temperature of 7°C (45°F) or less. On delivery vehicles, the temperature of milk and dairy products shall not exceed 7°C (45°F). Every room or tank in which milk or dairy products are stored shall be equipped with an accurate thermometer. Provided, that products undergoing a proper aging process, and aseptically processed milk and dairy products to be packaged in hermetically sealed containers shall be exempt from the cooling requirements of this item.

PUBLIC HEALTH REASON. When milk is not cooled within a reasonable time, after it is received at the pasteurization plant, its bacterial content will be materially increased. The same reasoning applies to cooling the milk and dairy products after pasteurization.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

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

2. All pasteurized milk and dairy products, except those to be cultured, are cooled immediately in approved equipment prior to filling and packaging to a temperature of 7°C (45°F) or less. All pasteurized milk and dairy products shall be stored at a temperature of 7°C (45°F) or less. On delivery vehicles, the temperature of milk and dairy products shall not exceed (7°C) 45°F.

3. Each refrigerator room in which milk or dairy products are stored, except aseptically processed milk and dairy products, is equipped with an indicating thermometer which complies with the applicable specifications of Appendix E. Such thermometer shall be located in the warmest zone of the refrigerator room.

Each storage tank shall be equipped with an indicating thermometer, the sensor of which shall be located to permit the registering of the temperature of the contents when the tank contains no more than 20 percent of its calibrated capacity. Such thermometer shall comply with the applicable specifications of Appendix E.

4. All surface coolers comply with the following specifications:

A. The sections of open-surface coolers shall be so installed as to leave a gap of at least 6.4 millimeters (0.25 inch) between the header sections to permit easy cleaning.

B. Where header ends are not completely enclosed within the cooler covers, products by so shaping the exposed header faces, above and below all gaps, that condensation is directed away from the tubes, and by using deflectors at the bottom of the headers; or by shortening the bottom of the headers; or by shortening the bottom trough; or by some other approved method.

C. The location of supports of cooler sections shall prevent drip from entering the milk or dairy products.

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

5. Recirculated cold water which is used in coolers and exchangers, including those systems in which a freezing point depressant is used, is from a safe source and protected from contamination. Such water shall be tested semiannually and shall comply with the bacteriological standards of Appendix D. Samples shall be taken by the regulatory agency and examination shall be

~~conducted in an official laboratory. Recirculated water systems, which become contaminated through repair work or otherwise, shall be properly treated and tested before being returned to use. Freezing point depressants, when used in recirculating systems, shall be nontoxic.~~

~~**ITEM 18p. PACKAGING**~~

~~Packaging of milk and dairy products shall be done in a sanitary manner.~~

~~**PUBLIC HEALTH REASON.** Unsanitary packaging of dairy products is apt to result in the exposure of the milk and dairy products to contamination, which would nullify the effect of pasteurization or proper aging.~~

~~**ADMINISTRATIVE PROCEDURES**~~

~~This item is deemed to be satisfied when:~~

~~1. All milk and dairy products, are packaged at the plant where final pasteurization or proper aging is performed. Such packaging shall be done without undue delay following final pasteurization.~~

~~2. All packaging is performed with approved equipment or in a sanitary manner.~~

~~3. All pipes, connections, defoaming devices and similar appurtenances shall comply with items 10p and 11p of this section. Milk and dairy products from continuous defoamers are not returned directly to the filler bowl.~~

~~4. Packaging machine supply tanks and bowls have covers which are constructed to prevent any contamination from reaching the inside of the filler tank or bowl. All covers shall be in place during operation.~~

~~5. Container in-feed conveyors to automatic packaging machines have overhead shields to protect the packages from contamination.~~

~~6. Container coding/dating devices are designed, installed and operated such that the coding/dating operations are performed in such a manner that open containers are not subjected to contamination. Shielding shall be properly designed and installed to preclude contamination of open containers.~~

~~7. Container fabricating materials, such as paper stock, foil, wax, plastic, etc., are handled in a sanitary manner and protected against undue exposure during the package assembly operation.~~

~~8. The filler pipe of packaging machines have an apron or other approved device, as close to the filler bowl as possible, to prevent condensation or drippage from reaching the inside of the filler bowl.~~

~~9. Filling cylinders on packaging machines are protected from contamination by the use of overhead shields. When any lubricant is applied to the filler pistons, cylinders or other milk-contact surfaces, the lubricant shall be nontoxic, sterile and shall be sparingly applied in a sanitary manner.~~

~~10. In the case of aseptic processing systems used for producing aseptic milk and dairy products, the aseptic product shall be aseptically filled into sterilized containers and hermetically sealed in conformance with the applicable requirements of 21 CFR 113 (1999).~~

~~**ITEM 19p. PACKAGING CLOSURES**~~

~~Closing of milk and dairy product containers shall be done in a sanitary manner.~~

~~**ADMINISTRATIVE PROCEDURES**~~

~~This item is deemed to be satisfied when:~~

~~1. Closing of dairy product containers is done in a sanitary manner. Other methods which eliminate all possibility of contamination may be approved by the regulatory agency.~~

~~2. Packages which have been imperfectly closed are discarded or repackaged immediately into approved sanitary containers. Dairy products shall be protected from contamination and maintained at 7°C (45°F) or less.~~

~~**ITEM 20p. PERSONNEL—CLEANLINESS**~~

~~Hands shall be thoroughly washed before commencing plant functions and as often as may be required to prevent contamination. Employees shall not resume work after visiting the toilet room without thoroughly washing their hands. All persons, while engaged in the processing, pasteurization, handling, storage or transportation of milk, dairy products, containers, equipment and utensils shall wear clean outer garments. All persons, while engaged in the processing of milk or dairy products shall wear adequate hair coverings and shall not use tobacco.~~

~~**PUBLIC HEALTH REASON.** Clean clothing and clean hands (including clean fingernails) reduce the possibility of milk, dairy products, containers and equipment from becoming contaminated.~~

~~**ADMINISTRATIVE PROCEDURES**~~

~~This item is deemed to be satisfied when:~~

~~1. Hands are thoroughly washed before commencing plant functions and as often as may be required to prevent contamination.~~

~~2. Each employee washes his or her hands following a visit to the toilet room and prior to resuming work.~~

~~3. All persons while engaged in the processing, pasteurization, handling, storage or transportation of milk, dairy products, containers, equipment and utensils wear clean outer garments.~~

~~4. The use of tobacco products is prohibited in all rooms in which milk or dairy products are processed, handled or stored, or in which milk containers, equipment and utensils are washed. These rooms shall include, but are not limited, to the receiving, processing, packaging, product storage (cooling and dry storage ingredients), single-service article storage and container/utensil washing areas. Adequate head coverings are worn by any person engaged in the processing of milk or dairy products.~~

~~**ITEM 21p. VEHICLES**~~

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

~~**PUBLIC HEALTH REASON.** The exposure of milk to the sun will alter the flavor of milk, will tend to increase the temperature, thus increasing the possibility of bacterial growth. Freezing alters the physical and chemical properties of milk. Dairy products, as well as empty containers, should be protected against contamination at all times.~~

~~**ADMINISTRATIVE PROCEDURES**~~

This item is deemed to be satisfied when:

1. All vehicles are kept clean.

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

3. Vehicles are fully enclosed with well-fitted, solid doors.

ITEM 22p. SURROUNDINGS

Dairy plant surroundings shall be kept neat, clean and free from conditions which might attract or harbor flies, other insects and rodents or which otherwise constitute a nuisance.

PUBLIC HEALTH REASON. The surroundings of a dairy plant should be kept neat and clean to prevent the attraction of rodents, flies and other insects, which may contaminate the milk or dairy products. Insecticides and rodenticides, not approved for use in dairy plants, or approved insecticides and rodenticides, not used in accordance with label recommendations, may contaminate the milk or dairy product processed by the dairy plant.

ADMINISTRATIVE PROCEDURES

This item is deemed to be satisfied when:

1. There is no accumulation of trash, garbage or similar waste in areas adjacent to the dairy plant. Waste material stored in suitable covered containers shall be considered in compliance.

2. Driveways, lanes and areas serving dairy plant vehicular traffic are graded, drained and free from pools of standing water.

3. Outdoor areas for milk tank truck unloading are constructed of smooth concrete or equally impervious material, properly sloped to drain and equipped with trapped drains of sufficient size.

4. Only insecticides and rodenticides approved for use by the regulatory agency and/or registered with the U.S. Environmental Protection Agency shall be used for insect and rodent control.

SECTION 8. ANIMAL HEALTH

1. All milk for pasteurization, ultrapasteurization, aseptic procesing or proper aging, shall be from herds which are located in a Modified Accredited Tuberculosis Area as determined by the U.S. Department of Agriculture. Provided, that herds located in an area that fails to maintain such accredited status shall have been accredited by said Department as tuberculosis free or shall have passed an annual tuberculosis test.

2. All milk for pasteurization, ultrapasteurization, aseptic processing or proper aging, shall be from herds under a brucellosis eradication program which meets one of the following conditions:

A. Located in a Certified Brucellosis-Free Area as defined by the U.S. Department of Agriculture and enrolled in the testing program for such areas; or

B. Meet U.S. Department of Agriculture requirements for an individually certified herd; or

C. Participating in a milk ring testing program at least two times per year at approximately 180 day intervals and all herds with positive milk ring results shall have the entire herd blood tested within 30 days from the date of the laboratory ring tests; or

D. Have an individual blood agglutination test annually with an allowable maximum grace period not exceeding two months.

3. Goat milk, sheep milk, and milk from other lactating animals used for pasteurization, ultrapasteurization aseptic processing or proper aging, shall be from a herd or flock which has passed an annual whole herd or flock tuberculosis and brucellosis test as recommended by the State veterinarian or regional USDA veterinarian in charge (VIC) or from a herd or flock which has passed an initial whole herd Burcellosis test, followed only by testing replacement animals or any animals entering the milking group or sold as dairy animals.

For diseases other than brucellosis and tuberculosis, the regulatory agency shall require such physical, chemical or bacteriological tests as it deems necessary. The diagnosis of other diseases in dairy animals shall be based upon the findings of a licensed veterinarian or a veterinarian in the employ of an official agency. Any diseased animal disclosed by such test(s) shall be disposed of as the regulatory agency directs.

PUBLIC HEALTH REASON. The health of the animal is a very important consideration, because a number of diseases of cattle, including tuberculosis, brucellosis, Q-fever, salmonellosis, staphylococcal infection and streptococci infection, may be transmitted to man through the medium of milk. The organisms of most of these diseases may get into the milk either directly from the udder, or indirectly through infected body discharges which may drop, splash or be blown into the milk.

ADMINISTRATIVE PROCEDURES

TUBERCULOSIS. All tuberculin tests and retests shall be made, and any reactors disposed of, in accordance with the *Bovine Tuberculosis Eradication, Uniform Methods and Rules January 22, 1999*, as approved by the U. S. Department of Agriculture at the time of the adoption of these Regulations. For tuberculosis test purposes, the herd is defined as all adult cattle 24 months of age and over, including any commingled beef animals. Dairy cattle less than 2 years of age and already milking, shall be included in the herd test. A letter or other official correspondence attesting to the accreditation status of the locality in which the herd is located, including the date of accreditation, or a certificate identifying the animals tested, the date of injection, the date of reading of the test and the results of the test signed by a U.S. Department of Agriculture accredited veterinarian, shall be evidence of compliance with the above requirements and shall be filed with the regulatory agency.

BRUCELLOSIS. All brucellosis tests, retests, disposal of reactors, vaccination of calves and certification of herds and areas shall be in accordance with *Brucellosis Eradication Uniform Methods and Rules, February 1, 1998,* as approved by the U.S. Department of Agriculture. All reactors disclosed on blood agglutination tests shall be separated immediately from the milking herd and the milk of these reactors shall not be used for human consumption.

A certificate identifying each animal, signed by the veterinarian and the director of the laboratory making the test, shall be filed as directed by the regulatory agency. Provided, that in the event the herd is subject to the milk ring test, the record shall be required to show only the date and results of such test. Within 30 days following the expiration of an official milk ring testing program, or in the case of a herd subject to annual blood tests, 13 months following the last annual blood tests, the regulatory agency shall notify the herd owner or operator of the necessity to comply with the brucellosis requirements. The failure of the herd owner or operator to comply with the brucellosis requirements within 30 days of written notice shall result in immediate suspension of the permit.

SECTION 9. MILK AND DAIRY PRODUCTS FROM SOURCES OUTSIDE OF COLORADO

Milk and dairy products from points beyond the limits of routine inspection of the State of Colorado, or its jurisdiction, are permitted to be sold in Colorado, or its jurisdiction, provided they are produced under regulations which are substantially equivalent to these Regulations.

ADMINISTRATIVE PROCEDURE

The regulatory agency should accept, without their actual physical inspection, supplies of milk and dairy products from an area or an individual shipper not under their routine inspection. Provided, that:

1. Milk and dairy products upon arrival shall comply with bacteriological, chemical and temperature standards of Section 7. Provided, that direct shipped producer milk that is under the supervision of more than one regulatory agency may be exempt from the bacteriological requirement for commingled samples. However, the receiving regulatory agency shall have the right to use the individual producer samples to determine compliance with the bacteriological standards;

2. After receipt, pasteurized and ultra-pasteurized milk and dairy products, including aged raw dairy products, shall comply with Sections 2, 4 and 8;

3. The milk or dairy products are produced and processed under regulations substantially equivalent to these Regulations;

4. The supplies are under routine official supervision by the regulatory agency.

SECTION 10. PLANS FOR CONSTRUCTION

Properly prepared plans for all milkhouses, milking barns and parlors, dairy plants, receiving stations and transfer stations regulated under these Regulations which are hereafter constructed, reconstructed or extensively altered shall be submitted to the regulatory agency for written approval before work is begun.

SECTION 11. PERSONNEL HEALTH

No persons affected with any disease capable of being transmitted to others through the contamination of food shall work at a dairy plant in any capacity which brings them into direct contact with products, such as pasteurized or aseptically processed milk or dairy products, or which brings them into direct contact with product contact surfaces.

ADMINISTRATIVE PROCEDURES

Dairy plant operators who have received reports, under this section, from employees who have handled dairy products or associated product contact surfaces shall immediately report these facts to the regulatory agency.

Dairy plant employees (or applicants to whom a conditional offer of employment has been made) shall be instructed by the dairy plant that the employee or applicant is responsible to report to the dairy plant management, if he or she:

1. Is diagnosed with an illness due to Hepatitis A virus, Salmonella typhi, Shigella species, Norwalk and Norwalk-like Viruses, Staphylococcus aureus, Streptococcus pyogenes, Escherichia coli 0157:H7, enterohemorrhagic Escherichia coli, entero-toxigenic Escherichia coli, Campylobacter jejuni, Entamoeba histolytica, Giardia lamblia, Non-typhoidal Salmonella, Rotovirus, Taenia solium, Yersinia enterocolitica, Vibrio cholerae 0l or other infectious or communicable disease that is known to be transmissible to others through the handling of food; or

2. Is exposed to, or suspected of causing, a confirmed foodborne disease outbreak of one of the diseases specified in number one above; or

3. Lives in the same household as a person who attends or works in an institution such as a day care center or school, experiencing a confirmed outbreak of one of the diseases specified in number one above; or

4. Has a symptom associated with acute gastrointestinal illness such as: abdominal cramps or discomfort, diarrhea, fever, loss of appetite for three or more days, vomiting, jaundice; or

5. Has a pustular lesion such as a boil or infected wound.

SECTION 12. PROCEDURE WHEN INFECTION OR HIGH RISK OF INFECTION IS DISCOVERED

When a person who may have handled pasteurized or aseptically processed milk or dairy products or pasteurized or aseptically processed dairy product contact surfaces meets one or more of the conditions specified in the administrative procedures of Section 11, the regulatory agency is authorized to require any or all of the following measures:

1. The immediate restricting of that person from duties which require handling finished product, such as pasteurized milk or adiry products, or the handling of related product contact surfaces. This restriction may be lifted after an appropriate medical clearance or cessation of symptoms or both, according to the following criteria:

Table 3. Removal of Restrictions When Infection or High Risk of Infection is Discovered

Health Status		**Removing Restrictions**
a.	Is diagnosed with an illness due to Hepatitis A virus, Salmonella typhi, Shigella species, Norwalk and Norwalk-like Viruses, Staphylococcus aureus, Streptococcus pyogenes, Escherichia coli 0157:H7, enterohemorrhagic Escherichia coli, enterotoxigenic Escherichia coli, Campylobactor jejuni, Entamoeba histolytica, Giardia lamblia, Non-typhoidal Salmonella, Rotovirus, Taenia solium, Arsine enterocolitica, Vibrio cholerae O1 or other infectious or communicable disease that is known to be transmissible to others through the handling of food.	Restrictions lifted by medical clearance.
b.	Meeting a high risk scenario as specified in Section 11 (2 or 3) and/or experiencing symptoms in Section 11 (4, 5 or 6).	Restrictions lifted when symptoms cease or medical documentation is provided that infection does not exist.
c.	Asymptomatic, but stools positive for Salmonella typhi, Shigella or Escherichia coli 0157:H7.	Restrictions lifted by medical clearance.
d.	Past illness from Salmonella typhi, Shigella, Escherichia coli 0157:H7 or other human pathogens for which humans have been determined to be carriers.	Restrictions lifted by medical clearance.
e.	In the case of diagnosed or suspected Hepatitis A, onset of jaundice within the last seven (7) days.	Restrictions lifted by medical clearance.
f.	In the case of diagnosed or suspected Hepatitis A, onset of jaundice occurred more than seven (7) days ago.	Restrictions lifted by medical clearance or jaundice ceases.
g.	In case of a pustular lesion such as a boil or infected wound.	Restriction lifted provided lesion is covered by a tight-fitting barrier.

2. The immediate exclusion of the affected dairy products from distribution and use when medically appropriate (i.e., a medical evaluation of the sequence of events indicates that contamination of product may have occurred).

3. The immediate requesting of medical and bacteriological examination of the person at risk.

NOTE: Persons at risk who decline to be examined may be reassigned to duties where they will not be required to handle products, or associated product contact surfaces.

SECTION 13. ENFORCEMENT

These Regulations shall be enforced by the regulatory agency in accordance with §§25-1-107(1)(o)(I and IV) C.R.S., and Article 5.5 of Title 25, C.R.S.

SECTION 14. PENALTY

Any person who violates any of the provisions of these Regulations shall be guilty of a misdemeanor and upon conviction thereof may be punished by a fine and/or imprisonment as set forth in §§25-5.5-116, 25-5.5-209 or 25-5.5-312, C.R.S.

SECTION 15. JUDICIAL REVIEW

A license or certificate holder adversely affected or aggrieved by a regulatory agency action may appeal the final action of the Department as provided in section §24-4-106, C.R.S. Suspension or revocation of a license may be reviewed, upon application for an order in the nature of mandamus or otherwise, by any court of general jurisdiction as provided in section §25-4-1609, C.R.S.

SECTION 16. INJUNCTIVE RELIEF

When serious or repeated violations of these rules and regulation have been found, the regulatory agency or its authorized agents may abate the nuisance by seeking injunctive relief through judicial means, as provided under section §§16-13-308 and 309, C.R.S.

SECTION 17. REPEAL AND DATE OF EFFECT

All ordinances and parts of ordinances in conflict with these Regulations shall be repealed 12 months after the adoption of these Regulations, at which time these Regulations shall be in full force and effect, as provided by law.

SECTION 18. SEPARABILITY CLAUSE

Should any section, paragraph, sentence, clause or phrase of these Regulations be declared unconstitutional or invalid for any reason, the remainder of these Regulations shall not be affected thereby.

SECTION 19. MATERIALS INCORPORATED BY REFERENCE

Any materials incorporated by reference in these rules can be obtained or inspected by contacting:

Division DirectorConsumer Protection DivisionColorado Department of Public Health and Environment4300 Cherry Creek Drive SouthDenver, CO 08246-1530

Materials incorporated do not include later amendments to or editions of the referenced material.

The incorporated material may be examined at any state publications depository library.

SECTION 20. EXEMPTIONS

A provisional exemption from complying with the pasteurization requirements of Section 7 Item 16p of these regulations is granted to the following goat dairy operations:

- Le-Platt Hi-Country Goat Dairy, 21604 County Rd. 41.6, Trinidad, Co. 81082
- Philpott Goat Dairy, P.O. Box 113, Hoehne, Co. 81046
- Provost Goat Dairy, 2227 41-1/2 Lane Olsen, Avondale, Co. 81022
- Zubal Goat Dairy, P.O. Box 71, Hoehne, Co. 81046

~~Any new cheese or other dairy product manufacturers would not be exempt from the requirements of Section 7 Item 16p. In addition, if an exempted goat diary operation changes ownership as defined in Definition C, moves, or performs a major remodel on an existing operation, this exemption shall no longer apply. Exempted goat dairies shall be required to label their products in a minimum of 1/16th inch type size (as measured by the height of the smallest letter used in the statement) with the following statement: "This product is manufactured without using a recognized pasteurization process. Although there are no known reports of health problems related to this product, there are possible health risks associated with the consumption of unpasteurized milk." Any of the exempted goat dairies that process the raw milk with a recognized and an approved pasteurization process or properly age the cheese are not required to comply with this labeling.~~

~~SECTION 21. MILK AND DAIRY PRODUCTS WHICH MAY BE SOLD~~

~~Twelve months after the effective date of these regulations, only the sale of manufactured milk and dairy products processed according to these regulations is permitted.~~

~~APPENDIX A. DAIRY FARM AND DAIRY PLANT CONSTRUCTION STANDARDS~~

~~Plans for dairy farm and dairy plant new construction or major remodeling shall be submitted to the Colorado Department of Public Health and Environment, Consumer Protection Division, prior to commencement of construction.~~

~~Private sewage systems shall be constructed in accordance with the standards of the local regulatory agency. The local regulatory agency shall be contacted to determine if plans for the private sewage system are required to be submitted prior to commencement of construction.~~

~~The plans submitted to Colorado Department of Public Health and Environment, Consumer Protection Division shall include, but are not limited to, building construction, water supply, placement and specifications of equipment. Final approval of equipment is subject to field evaluation.~~

~~APPENDIX B. STANDARDS FOR WATER SOURCES~~

~~I. LOCATION OF WATER SOURCES~~

~~DISTANCE FROM SOURCES OF CONTAMINATION~~

~~All ground water sources should be located a safe distance from sources of contamination. In cases where sources are severely limited; however, a ground water aquifer that might become contaminated may be considered for a water supply, if treatment is provided. After a decision has been made to locate a water source in an area, it is necessary to determine the distance the source should be placed from the origin of contamination and the direction of water movement. A determination of a safe distance is based on specific local factors described in the section on "Sanitary Survey."~~

~~Because many factors affect the determination of "safe" distances between ground water supplies and sources of pollution, it is impractical to set fixed distances. Where insufficient information is available to determine the "safe" distance, the distance should be the maximum that economics, land ownership, geology and topography will permit. It should be noted that the direction of ground water flow does not always follow the slope of the land surface. Each installation should be inspected by a person with sufficient training and experience to evaluate all of the factors involved.~~

~~Since safety of a ground water source depends primarily on considerations of good well construction and geology, these factors should be the guides in determining safe distances for different situations. The following criteria apply only to properly constructed wells, as described in this appendix. There is no safe distance for a poorly constructed well.~~

~~When a properly constructed well penetrates an unconsolidated formation, with good filtering properties, and when the aquifer itself is separated from sources of contamination by similar materials, research and experience have demonstrated that 15 meters (50 feet) is an adequate distance separating the two.~~

Lesser distances should be accepted, only after a comprehensive sanitary survey, conducted by qualified State or local health agency officials, has satisfied the officials that such lesser distances are both necessary and safe.

If it is proposed to install a properly constructed well in formations of unknown character, the State or U.S. Geological Survey and the State or local health agency should be consulted.

When wells must be constructed in consolidated formations, extra care should always be taken in the location of the well and in setting "safe" distances, since pollutants have been known to travel great distances in such formations. The owner should request assistance from the State or local health agency.

The following table is offered as a guide in determining distance:

Table 4. Distance of Well from Sources of Contamination

Formation	**Minimum Acceptable Distance of Well from Sources of Contamination**
Favorable (Unconsolidated)	15 meters (50 feet) - lesser distances only on health department approval following comprehensive sanitary survey of proposed site and immediate surroundings.
Unknown	15 meters (50 feet) - Only after comprehensive geological survey of the site and its surroundings has established, to the satisfaction of the health agency, that favorable formations do exist.
Poor (Consolidated)	Safe distances can be established only following both the comprehensive geological and comprehensive sanitary surveys. These surveys also permit determining the direction in which a well may be located with respect to sources of contamination. In no case should the acceptable distance be less than 15 meters (50 feet).

EVALUATING CONTAMINATION THREATS TO WELLS

Conditions unfavorable to the control of contamination and that may require specifying greater distances between a well and sources of contamination are:

1. **Nature of the Contaminant.**—Human and animal excreta and toxic chemical wastes are serious health hazards. Salts, detergents and other substances that dissolve in water can mix with ground water and travel with it. They are not ordinarily removed by natural filtration.

2. **Deeper Disposal.**—Cesspools, dry wells, disposal and waste injection wells and deep leaching pits that reach aquifers or reduce the amount of filtering earth materials between the wastes and the aquifer increase the danger of contamination.

3. **Limited Filtration.**—When earth materials surrounding the well and overlying the aquifer are too coarse to provide effective filtration, as in limestone, coarse gravel, etc., or when they form a layer too thin, the risk of contamination is increased.

4. **The Aquifer.**—When the materials of the aquifer itself are too coarse to provide good filtration, as in limestone, fractured rock, etc., contaminants entering the aquifer through outcrops or excavations may travel great distances. It is especially important in such cases to know the direction of ground water flow and whether there are outcrops of the formation (or excavations reaching it) "upstream" and close enough to be a threat.

5. **Volume of Waste Discharged.**—Since greater volumes of wastes discharged and reaching an aquifer can significantly change the slope of the water table and the direction of ground water flow, it is obvious that heavier discharges can increase the threat of contamination.

6. **Contact Surface.—** When pits and channels are designed and constructed to increase the rate of absorption, as in septic tank leaching systems, cesspools and leaching pits, more separation from the water source will be needed than when tight sewer lines or waste pipes are used.

7. **Concentration of Contamination Sources.—** The existence of more than one source of contamination, contributing to the general area, increases the total pollution load and, consequently, the danger of contamination.

SANITARY SURVEY

The importance of a sanitary survey of water sources cannot be overemphasized. With a new supply, the sanitary survey should be made in conjunction with the collection of initial engineering data, covering the development of a given source and its capacity to meet existing and future needs. The sanitary survey should include the detection of all health hazards and the assessment of their present and future importance. Persons trained and competent in public health engineering and the epidemiology of waterborne diseases should conduct the sanitary survey. In the case of an existing supply, the sanitary survey should be made at a frequency compatible with the control of the health hazards and the maintenance of a good sanitary quality.

The information furnished by the sanitary survey is essential to complete the interpretation of bacteriological and frequently the chemical data. This information should always accompany the laboratory findings. The following outline covers the essential factors which should be investigated or considered in a sanitary survey. Not all of the items are pertinent to any one supply and, in some cases, items not in the list would be important additions to the survey list.

1. **Ground Water Supplies.—**

A. Character of local geology and slope of ground surface.

B. Nature of soil and underlying porous strata; whether clay, sand, gravel, rock (especially porous limestone); coarseness of sand or gravel; thickness of water-bearing stratum; depth to water table and location, log and construction details of local wells in use and abandoned.

C. Slope of water table, preferably determined from observational wells or as indicated, presumptively, but not certainly, by the slope of ground surface.

D. Extent of drainage area likely to contribute water to the supply.

E. Nature, distance and direction of local sources of pollution.

F. Possibility of surface-drainage water entering the supply and of wells becoming flooded and methods of protection.

G. Methods used for protecting the supply against pollution by means of sewage treatment, waste disposal and the like.

H. Well construction:

(1) Total depth of well.

(2) Casing: diameter, wall thickness, material and lengths from surface.

(3) Screen or perf-orations: diameter, material, construction, locations and lengths.

(4) Formation seal: material (cement, sand, bentonite, etc.), depth intervals, annular thickness and method of placement.

I. Protection of well at top: presence of sanitary well seal, casing height above ground floor or flood level, protection of well vent and protection of well from erosion and animals.

J. Pumphouse construction (floors, drains, etc.), capacity of pumps and draw down when pumps are in operation.

K. Availability of an unsafe supply, usable in place of normal supply, hence involving danger to the public health.

L. Disinfection: equipment, supervision, test kits or other types of laboratory control.

2. **Surface Water Supplies.—**

A. Nature of surface geology: character of soils and rocks.

B. Character of vegetation, forests, cultivated and irrigated land, including salinity, effect on irrigation water, etc.

C. Population and sewered population per square mile of catchment area.

D. Methods of sewage disposal, whether by diversion from watershed or by treatment.

E. Character and efficiency of sewage-treatment works on watershed.

F. Proximity of sources of fecal pollution to intake of water supply.

G. Proximity, sources and character of industrial wastes, oil field brines, acid mine waters, etc.

H. Adequacy of supply as to quantity.

I. For lake or reservoir supplies: wind direction and velocity data, drift of pollution and sunshine data (algae).

J. Character and quality of raw water: coliform organisms (MPN), algae, turbidity, color and objectionable mineral constituents.

K. Nominal period of detention in reservoirs or storage basin.

L. Probable minimum time required for water to flow from sources of pollution to reservoir and through reservoir intake.

M. Shape of reservoir, with reference to possible currents of water, induced by wind or reservoir discharge, from inlet to water-supply intake.

N. Protective measures in connection with the use of watershed to control fishing, boating, landing of airplanes, swimming, wading, ice cutting and permitting animals on marginal shore areas and in or upon the water, etc.

O. Efficiency and con-stancy of policing.

P. Treatment of water: kind and adequacy of equipment; duplication of parts; effectiveness of treatment; adequacy of supervision and testing; contact period after disinfection and free chlorine residuals carried.

Q. Pumping facilities: pumphouse, pump capacity and standby units and storage facilities.

II. CONSTRUCTION

SANITARY CONSTRUCTION OF WELLS

The penetration of a water-bearing formation by a well provides a direct route for possible contamination of the ground water. Although there are different types of wells and well construction, there are basic sanitary aspects that must be considered and followed.

1. The annular space outside the casing shall be filled with a watertight cement grout or puddled clay from a point just below the frost line or deepest level of excavation near the well to as deep as necessary to prevent entry of contaminated water.

2. For artesian aquifers, the casing shall be sealed into the overlying impermeable formations so as to retain the artesian pressure.

3. When a water-bearing formation containing water of poor quality is penetrated, the formation shall be sealed off to prevent the infiltration of water into the well and aquifer.

4. A sanitary well seal, with an approved vent, shall be installed at the top of the well casing to prevent the entrance of contaminated water or other objectionable material.

Well Casing or Lining.—All that part of the suction pipe or drop pipe of any well within 3 meters (10 feet) of and below the ground surface shall be surrounded by a watertight casing pipe extending above the ground, platform or floor surface, as the case maybe, and covered at the top as herein provided. The casing of every well shall terminate above the ground level; the annular space outside the casing shall be filled with a watertight cement grout or clay, with similar sealing properties, from the surface to a minimum of 3 meters (10 feet) below the ground surface. A dug well, in lieu of a casing pipe, may be provided with a substantial watertight lining of concrete, vitrified tile with outer concrete lining, or other suitable material. Such lining shall extend at least 3 meters (10 feet) below the surface and shall extend up to the well platform or pump room floor with a watertight connection. In such case, the platform or floor shall have a suitable sleeve pipe, surrounding the suction pipe or drop pipe, and projecting above as herein provided for a casing pipe.

Well Covers and Seals.—Every well shall be provided with an overlapping, tight-fitting cover at the top of the casing or pipe sleeve to prevent contaminated water or other material from entering the well.

The sanitary well seal, in a well exposed to possible flooding, shall be either watertight or elevated at least .6 meters (2 feet) above the highest known flood level. When it is expected that a well seal may become flooded, it shall be watertight and equipped with a vent line, whose opening to the atmosphere, is at least .06 meters (2 feet) above the highest known flood level.

The seal in a well not exposed to possible flooding shall be either watertight (with an approved vent line) or self-draining, with an overlapping and downward flange. If the seal is of the self-draining (non-watertight) type, all openings in the cover should be either watertight or flanged upward and provided with overlapping, downward flanged covers.

Some pump and power units have closed bases that effectively seal the upper terminal of the well casing. When the unit is the open type, or when it is located at the side (some jet- and suction-pump-type installations), it is especially important that a sanitary well seal be used. There are several acceptable

designs consisting of an expandable neoprene gasket, compressed between two steel plates. They are easily installed and removed for well servicing. Pump and water well suppliers normally stock sanitary well seals.

If the pump is not installed immediately after well drilling and placement of the casing, the top of the casing should be closed with a metal cap screwed or tack welded into place, or covered with a sanitary well seal.

For large-diameter wells such as dug wells, it would be difficult to provide a sanitary well seal, consequently, a reinforced concrete slab, overlapping the casing and sealed to it with a flexible seal and/or rubber gasket, should be installed. The annular space outside the casing should first be filed with suitable grouting or sealing materials, i.e., cement, clay, or fine sand.

A well slab alone is not an effective sanitary defense, since it can be undermined by burrowing animals and insects, cracked from settlement or frost heave or broken by vehicles and vibrating machinery. The cement grout formation seal is far more effective. It is recognized; however, that there are situations that call for a concrete slab or floor around the well casing to facilitate cleaning and improve appearance. When such a floor is necessary, it shall be placed only after the formation seal and the pitless installation have been inspected.

Well covers and pump platforms shall be elevated above the adjacent finished ground level. Pump room floors shall be constructed of reinforced, watertight concrete and carefully leveled or sloped away from the well, so that surface and waste water cannot stand near the well. The minimum thickness of such a slab or floor shall be 10 centimeters (four inches). Concrete slabs or floors shall be poured separately from the cement formation seal and when the threat of freezing exists, insulated from it and the well casing by a plastic or mastic coating or sleeve to prevent bonding of the concrete to either.

All water wells shall be readily accessible at the top for inspection, servicing and testing. This requires that any structure over the well be easily removable to provide full, unobstructed access for well servicing equipment. The so-called “buried seal,” with the well cover buried under several meters (yards) of earth, is unacceptable because:

1. It discourages periodic inspection and preventive maintenance;

2. It makes severe contamination during pump servicing and well repair more likely;

3. Any well servicing is more expensive; and

4. Excavation to expose the top of the well increases the risk of damage to the well, the cover, the vent and the electrical connections.

Well Pits and Drainage.—Because of the pollution hazards involved, the well head, well casing, pump, pumping machinery, valve connected with the suction pump or exposed suction pipe shall not be permitted in any pit, room or space extending below ground level, or in any room or space above the ground, which is walled-in or otherwise enclosed, so that it does not have free drainage by gravity to the surface of the ground. Provided, that a dug well properly constructed, lined and covered, as herein prescribed, shall not be construed to be a pit. Provided further, that pumping equipment and appurtenances may be located in a residential basement, which is not subject to flooding. Provided further, that in the case of existing water supplies which otherwise comply with the applicable requirements of this appendix, pit installations may be accepted, under the following conditions, when permitted by the State water-control authority:

1. Pits shall be of watertight construction, with walls extending at least 15 centimeters (6 inches) above the established ground surface at all points.

2. Pits shall be provided with a watertight, concrete floor, sloping to a drain which discharges to the ground surface at a lower elevation than the pit, and preferably at least 9 meters (30 feet) from it; or if this should be impossible, to a watertight, concrete sump, in the pit, equipped with a sump-pump discharging to the ground surface, preferably at least 9 meters (30 feet) from the pit.

3. Pits shall be provided with a concrete base for pumps or pumping machinery, so that such units shall be located at least 30 centimeters (12 inches) above the floor of the pit.

4. Pits shall be provided with a watertight housing or cover in all cases.

5. If inspection should reveal that these conditions are not being properly maintained, the supply shall be disapproved.

Manholes.—Manholes may be provided on dug wells, reservoirs, tanks and other similar features of water supplies. A manhole, if installed, shall be provided with a curb, the top of which extends at least 10 centimeters (4 inches) above the slab and shall be equipped, where necessary for physical protection, with a locked or bolted overlapping watertight cover. The sides of which extend downward at least 5 centimeters (2 inches). The covers shall be kept closed at all times, except when it may be necessary to open the manhole.

Vent Opening.—Any reservoir, well, tank or other structure containing water for the dairy water supply may be provided with vents, overflows, or water-level control gauges, which shall be so constructed as to prevent the entrance of birds, insects, dust, rodents or contaminating material of any kind. Openings on vents shall be not less than 46 centimeters (18 inches) above the floor of a pump room, or above the roof or cover of a reservoir. Vent openings on other structures shall be at least 46 cm (18 inches) above the surface on which the vents are located. Vent openings shall be turned down and screened with corrosion-resistant screen of not less than 16 x 20 mesh. Overflow outlets shall discharge above and not less than 6 inches from a roof, roof drain, floor, floor drain or over an open water-supplied fixture. The overflow outlet shall be covered by a corrosion-resistant screen of not less than 16 x 20 mesh and by .6 centimeters (1/4-inch) hardware cloth, or shall terminate in a horizontal angle seat check valve.

DEVELOPMENT OF SPRINGS

There are two general requirements necessary in the development of a spring, used as a source of domestic water.

1. Selection of a spring with adequate capacity to provide the required quantity and quality of water for its intended use throughout the year.

2. Protection of the sanitary quality of the spring. The measures taken to develop a spring must be tailored to its geological conditions and sources.

The features of a spring encasement are the following:

1. An open-bottom, watertight basin intercepting the source which extends to bedrock or a system of collection pipes and a storage tank;

2. A cover that prevents the entrance of surface drainage or debris into the storage tank;

3. Provisions for the cleanout and emptying of the tank contents;

4. Provision for overflow; and

5. A connection to the distribution system or auxiliary supply.

~~A tank is usually constructed in place with reinforced concrete, of such dimensions, as to enclose or intercept as much of the spring as possible. When a spring is located on a hillside, the downhill wall and sides are extended to bedrock or to a depth that will insure maintenance of an adequate water level in the tank. Supplementary cutoff walls, of concrete or impermeable clay, extending laterally from the tank may be used to assist in controlling the water table in the locality of the tank. The lower portion of the uphill wall of the tank can be constructed of stone, brick or other material, so placed that water may move freely into the tank from the formation. Backfill of graded gravel and sand will aid in restricting movement of fine material from the formation toward the tank.~~

~~The tank cover shall be cast in place to insure a good fit. Forms should be designed to allow for shrinkage of concrete and expansion of form lumber. The cover shall extend down over the top edge of the tank at least 5 centimeters (2 inches). The tank cover shall be heavy enough so that it cannot be dislodged by children and shall be equipped for locking.~~

~~A drain pipe with an exterior valve shall be placed close to the wall of the tank near the bottom. The pipe shall extend horizontally so as to clear the normal ground level at the point of discharge by at least 15 centimeters (6 inches). The discharge end of the pipe shall be screened to prevent the entrance of rodents and insects.~~

~~The overflow is usually placed slightly below the maximum water-level elevation and screened. A drain apron of rock shall be provided to prevent soil erosion at the point of overflow discharge.~~

~~The supply outlet, from the developed spring, shall be located at least 15 cm (6 inches) above the drain outlet and properly screened. Care shall be taken in casting pipes into the walls of the tank to insure good bond with the concrete and freedom from honeycomb around the pipes.~~

~~SANITARY PROTECTION OF SPRINGS~~

~~Springs usually become contaminated when barnyards, sewers, septic tanks, cesspools or other sources of pollution are located on higher adjacent land. In limestone formations; however, contaminated material frequently enters the water-bearing channels through sink holes or other large openings and may be carried along with ground water for long distances. Similarly, if material from such sources of contamination finds access to the tubular channels in glacial drift, this water may retain its contamination for long periods of time and for long distances.~~

~~The following precautionary measures will help to insure developed spring water of consistently high quality:~~

~~1. Provide for the removal of surface drainage from the site. A surface drainage ditch shall be located uphill from the source so as to intercept surface-water runoff and carry it away from the source. Location of the ditch and the points at which the water should be discharged are a matter of judgement. Criteria used should include the topography, the subsurface geology, land ownership and land use.~~

~~2. Construct a fence to prevent entry of livestock. Its location should be guided by the considerations mentioned in item 1. The fence shall exclude livestock from the surface-water drainage system at all points uphill from the source.~~

~~3. Provide for access to the tank for maintenance, but prevent removal of the cover by a suitable locking device.~~

~~4. Monitor the quality of the spring water with periodic checks for contamination. A marked increase in turbidity or flow after a rainstorm is a good indication that surface runoff is reaching the spring.~~

~~SURFACE WATER~~

~~The selection and use of surface water sources, for individual water supply systems, require consideration of additional factors not usually associated with ground water sources. When small streams, open ponds, lakes or open reservoirs must be used as sources of water supply, the danger of contamination and the consequent spread of enteric diseases, such as typhoid fever and dysentery is increased. As a rule, surface water shall be used only when ground water sources are not available or are inadequate. Clear water is not always safe, and the old saying that running water "purifies itself", to drinking water quality, within a stated distance is false.~~

~~The physical and bacteriological contamination of surface water makes it necessary to regard such sources of supply as unsafe for domestic use, unless reliable treatment, including filtration and disinfection, is provided.~~

~~The treatment of surface water to insure a constant, safe supply requires diligent attention to operation and maintenance by the owner of the system.~~

~~When ground water sources are limited, consideration shall be given to their development for domestic purposes only. Surface water sources can then provide water needed for stock and poultry watering, gardening, firefighting and similar purposes. Treatment of surface water used for livestock is not generally considered essential. There is; however, a trend to provide stock and poultry drinking water which is free from bacterial contamination and certain chemical elements.~~

~~Where resort must be made to surface water for all uses, a wide variety of sources, including farm ponds, lakes, streams and the roof runoff of buildings may be considered. These sources are regarded, without exception, to be contaminated, and their use cannot be condoned unless an individually tailored treatment process can be used, which will make them safe and satisfactory. Such treatment may include aeration and the use of suitable filtration or precipitation devices to remove suspended matter, in addition to routine full-time disinfection.~~

~~The milk producer or dairy plant operator, who is considering surface sources of water for milking, milkhouse and dairy plant operations shall receive the advance approval of the regulatory agency and shall comply with all applicable requirements of the State water control authority on the construction, protection and treatment of the chosen supply.~~

~~III. DISINFECTION OF WATER SOURCES~~

~~All newly constructed or newly repaired wells shall be disinfected to counteract contamination introduced during construction or repair. Every well shall be disinfected immediately after construction or repair and flushed prior to bacteriological testing.~~

~~An effective and economical method of disinfecting wells and appurtenances is the use of calcium hypochlorite, containing approximately 70 percent available chlorine. This chemical can be purchased in granular form at hardware stores, swimming pool equipment supply outlets or chemical supply houses.~~

~~When used in the disinfection of wells, calcium hypochlorite should be added in sufficient amounts to provide a dosage of approximately 50 mg. available chlorine per liter in the well water. This concentration is roughly equivalent to a mixture of one gram (.03 ounce) of dry chemical per 13.5 liter (3.56 gallons) of water to be disinfected. A stock solution of disinfectant may be prepared by mixing 30 grams (one ounce) of high-test hypochlorite with two liters (two quarts) of water. Mixing is facilitated if a small amount of the water is first added to the granular calcium hypochlorite and stirred to a smooth watery paste free of lumps. The stock solution should be stirred thoroughly for 10 to 15 minutes. The inert ingredients should then be allowed to settle. The liquid containing the chlorine should be used and the inert material discarded. Each 1.9 liter (two quarts) of stock solution will provide a concentration of approximately 50 mg/l when added to 378 liters (100 gallons) of water. The solution should be prepared in a clean utensil. The use of metal containers should be avoided, as they are corroded by strong chlorine solutions. Crockery, glass or rubberlined containers are recommended.~~

~~Where small quantities of disinfectant are required and a scale is not available, the material can be measured with a spoon. A heaping tablespoonful of granular calcium hypochlorite weighs approximately 14 grams (1/2 ounce).~~

~~When calcium hypochlorite is not available, other sources of available chlorine such as sodium hypochlorite (12–15 percent of volume) can be used. Sodium hypochlorite, which is also commonly available as liquid household bleach with 5.25 percent available chlorine, can be diluted with two parts of water to produce the stock solution. 1.9 liter (two quarts) of this solution can be used for disinfecting 378 liters (100 gallons) of water.~~

~~Stock solutions of chlorine in any form will deteriorate rapidly unless properly stored. Dark glass or plastic bottles with airtight caps are recommended. Bottles containing solution should be kept in a cool place and protected from direct sunlight. If proper storage facilities are not available, the solution should always be prepared fresh, immediately before use.~~

~~Complete information concerning the test for residual chlorine is included in the 18th Edition of the *Standard Methods for the Examination of Water and Wastewater*, published by the American Public Health Association.~~

~~DRILLED, DRIVEN, AND BORED WELLS~~

~~After the casing or lining has been completed, follow the procedure outlined below:~~

~~1. Remove all equipment and materials which will not form a permanent part of the completed structure.~~

~~2. When the well is being tested for yield, the test pump should be operated until the well water is clear and as free from turbidity as possible.~~

~~3. After the testing equipment has been removed, slowly pour the required amount of chlorine solution into the well just before installing the permanent pumping equipment. Diffusion of the chemical with the well water may be facilitated as previously described.~~

~~4. Wash the exterior surface of the pump cylinder and drop pipe with chlorine solution as the assembly is being lowered into the well.~~

~~5. After the pump has been set in position, operate the pump until water discharge through the entire distribution system to waste has a distinct odor of chlorine. Repeat this procedure a few times, at one-hour intervals, to insure complete circulation of the chlorine solution through the column of water in the well and the pumping equipment.~~

~~6. Allow the chlorine solution to remain in the well for at least 24 hours.~~

~~7. After 24 hours or more have elapsed, flush the well to remove all traces of chlorine. The pump should be operated until water discharged to waste is free from the chlorine odor.~~

~~In the case of deep wells having a high water level, it may be necessary to resort to special methods of introducing the disinfecting agent into the well so as to insure proper diffusion of chlorine throughout the well. The following method is suggested.~~

~~Place the granulated calcium hypochlorite in a short section of pipe capped at both ends. A number of small holes should be drilled through each cap or into the sides of the pipe. One of the caps should be fitted with an eye to facilitate attachment of a suitable cable. The disinfecting agent is distributed when the pipe section is lowered and raised throughout the depth of the water.~~

~~WATER-BEARING STRATA~~

~~Sometimes a well is encountered that does not respond to the usual methods of disinfection. A well like this has usually been contaminated by water that entered under sufficient head to displace water into the water-bearing formation. The displaced water carries contamination with it. The contamination that has been carried into the water-bearing formation can be eliminated or reduced by forcing chlorine into the formation. Chlorine may be introduced in a number of ways, depending on the construction of the well. In some wells, it is advisable to chlorinate the water and then add a considerable volume of a chlorine solution in order to force the treated water into the formation. When this procedure is followed, all chlorinated water should have a chlorine strength of approximately 50 mg/l. In other wells, such as the drilled well cased with standard weight casing pipe, it is entirely practicable to chlorinate the water, cap the well and apply a head of air. When air is alternately applied and released, a vigorous surging effect is obtained and chlorinated water is forced into the water bearing formation. In this procedure, the chlorine strength of the treated water, in the well, will be reduced by dilution as it mixes with the water in the water-bearing formation. It is; therefore, advisable to double or triple the quantity of chlorine compound to be used so as to have a chlorine strength of 100 to 150 mg/l in the well as the surging process is started. After treating a well in this manner, it is necessary to flush it to remove the excess chlorine.~~

~~DISINFECTION OF SPRINGS~~

~~Springs and encasements should be disinfected by a procedure similar to that used for dug well. If the water pressure is not sufficient to raise the water to the top of the encasement, it may be possible to shut off the flow and thus keep the disinfectant in the encasement for 24 hours. If the flow cannot be shut off entirely, arrangements should be made to supply disinfectant continuously for as long a period as practicable.~~

~~DISINFECTION OF WATER DISTRIBUTION SYSTEMS~~

~~These instructions cover the disinfection of water distribution systems and attendant standpipes or tanks. It is always necessary to disinfect a water system before placing it in use under the following conditions:~~

~~1. Disinfection of a system which has been in service with raw or polluted water, preparatory to transferring the service to treated water.~~

~~2. Disinfection of a new system upon completion and preparatory to placing in operation with treated water or water of satisfactory quality.~~

~~3. Disinfection of a system after completion of maintenance and repair operations.~~

~~The entire system, including tank or standpipe, should be thoroughly flushed with water to remove any sediment which may have collected during operation with raw water. Following flushing, the system should be filled with a disinfecting solution of calcium hypochlorite and treated water. This solution is prepared by adding 550 grams (1.2 pounds) of high-test 70 percent calcium hypochlorite to each 3,785 liters (1,000 gallons) of water. A mixture of this kind provides a solution having not less than 100 mg/l of available chlorine.~~

~~The disinfectant should be retained in the system, tank or standpipe, if included, for not less than 24 hours, then examined for residual chlorine and drained out. If no residual chlorine is found present, the process should be repeated. The system is next flushed with treated water and put into operation.~~

~~IV. CONTINUOUS WATER DISINFECTION~~

~~Water supplies which are otherwise deemed satisfactory, but which prove unable to meet the bacteriological standards prescribed herein, shall be subjected to continuous disinfection. The individual character of the supply shall be investigated and a treatment program developed which shall produce a safe supply as determined by bacteriological testing.~~

~~For numerous reasons, including economy, effectiveness, stability, ease of use and availability, chlorine is by far the most popular chemical agent employed for the disinfection of water supplies. This does not preclude the use of other chemicals or procedures demonstrated to be safe and effective. The amount necessary to provide adequate protection varies with the supply and the amount of organic and other oxidizable material which it contains. Proper disinfection can only be assured when a residual concentration of chlorine remains, for bactericidal activity, after the demands of these other substances are met. In general, these factors exert the most important influences on the bactericidal efficiency of chlorine:~~

~~1. Free chlorine residual; the higher the residual, the more effective the disinfection and the faster the disinfection rate.~~

~~2. Contact time between the organism and the disinfectant; the longer the time, the more effective the disinfection.~~

~~3. Temperature of the water in which contact is made; the lower the temperature, the less effective the disinfection.~~

~~4. The pH of the water in which contact is made; the higher the pH. the less effective disinfection.~~

~~For example, when a high pH and low temperature combination is encountered in a water, either the concentration of chlorine or the contact time must be increased. Likewise, chlorine residual will need to be increased if sufficient contact time is not available in the distribution system before the water reaches the first user.~~

~~SUPERCHLORINATION—DECHLORINATION~~

~~**Superchlorination.**—The technique of superchlorination involves the use of an excessive amount of chlorine to destroy quickly the harmful organisms which may be present in the water. If an excessive amount of chlorine is used, a free chlorine residual will be present. When the quantity of chlorine is increased, disinfection is faster and the amount of contact time required to insure safe water is decreased.~~

~~**Dechlorination.**—The dechlorination process may be described as the partial or complete reduction of any chlorine present in the water. When dechlorination is provided in conjunction with proper superchlorination, the water will be both properly disinfected and acceptable to the consumer for domestic or culinary uses.~~

~~Dechlorination can be accomplished in individual water systems by the use of activated carbon (dechlorinating) filters. Chemical dechlorination by reducing agents such as sulphur dioxide or sodium thiosulfate can be used for batch dechlorination. Sodium thiosulfate is also used to dechlorinate water samples prior to submission for bacteriological examination.~~

~~DISINFECTION EQUIPMENT~~

~~Hypochlorinators are the most commonly employed equipment for the chemical elimination of bacteriological contamination. They operate by pumping or injecting a chlorine solution into the water. When properly maintained, hypochlorinators provide a reliable method for applying chlorine to disinfect water.~~

~~Types of hypochlorinators include positive displacement feeders, aspirator feeders, suction feeders and tablet hypochlorinators.~~

This equipment can be readily adapted to meet the needs of other systems of treatment, which require the regulated discharge of a solution into the supply.

Positive Displacement Feeders. A common type of positive displacement hypochlorinator is one which uses a piston or diaphragm pump to inject the solution. This type of equipment, which is adjustable during operation, can be designed to give reliable and accurate feed rates. When electricity is available, the stopping and starting of the hypochlorinator can be synchronized with the pumping unit. A hypochlorinator of this kind can be used with any water system. However, it is especially desirable in systems where water pressure is low and fluctuating.

Aspirator Feeders. The aspirator feeder operates on a simple hydraulic principle that employs the use of the vacuum created when water flows either through a venturi tube or perpendicular to a nozzle. The vacuum created, draws the chlorine solution from a container into the chlorinator unit where it is mixed with water passing through the unit and the solution is then injected into the water system. In most cases, the water inlet line to the chlorinator is connected to receive water from the discharge side of the water pump, with the chlorine solution being injected back into the suction side of the same pump. The chlorinator operates only when the pump is operating. Solution flow rate is regulated by means of a control valve; pressure variations are known to cause changes in the feed rate.

Suction Feeders. One type of suction feeder consists of a single line that runs from the chlorine solution container, through the chlorinator unit and connects to the suction side of the pump. The chlorine solution is pulled from the container by suction created by the operating water pump.

Another type of suction feeder operates on the siphon principle, with the chlorine solution being introduced directly into the well. This type also consists of a single line, but the line terminates in the well below the water surface instead of the influent side of the water pump. When the pump is operating, the chlorinator is activated so that a valve is opened and the chlorine solution is passed into the well.

Tablet Chlorinator. These hypochlorinators inject water into a bed of concentrated calcium hypochlorite tablets. The result is metered into the pump suction line.

V. WATER RECLAIMED FROM THE CONDENSING OF MILK AND DAIRY PRODUCTS

Condensing water from milk evaporators and water reclaimed from milk and dairy products may be reused in a milk processing plant. Acceptable uses of this water fall into three general categories:

1. Reclaimed water which may be used for all potable water purposes including the production of culinary steam.

2. Reclaimed water which may be used for limited purposes including the production of culinary steam.

3. Use of reclaimed water not meeting the requirements of this section.

Requirements: Reclaimed water to be used for potable water purposes, including the production of culinary steam, shall meet the following requirements:

1. Water shall comply with the bacteriological standards of Appendix D, and, in addition, shall not exceed a total plate count of 500 per milliliter.

2. Samples shall be collected daily for two weeks following initial approval of the installation and semi-annually thereafter. Provided, that daily tests shall be conducted for one week following any repairs or alteration to the system.

3. The organic content shall be less than 12 mg/l as measured by the chemical oxygen demand or permanganate-consumed test; or a standard turbidity of less than five (5) units.

4. Automatic fail safe monitoring devices shall be used to monitor and automatically divert (to the sewer) any water which exceeds the standard.

5. The water shall be of satisfactory organoleptic quality and shall have no off-flavors, odors or slime formations.

6. The water shall be sampled and tested organoleptically at weekly intervals.

7. Approved chemicals, such as chlorine, with a suitable detention period, may be used to suppress the development of bacterial growth and prevent the development of tastes and odors.

8. The addition of chemicals shall be by an automatic proportioning device, prior to the water entering the storage tank, to assure satisfactory quality water in the storage tank at all times.

9. When chemicals are added, a daily testing program for such added chemicals shall be in effect and such chemicals shall not add substances that will prove deleterious to the use of the water or contribute to product contamination.

10. The storage vessel shall be properly constructed of such material that it will not contaminate the water and can be satisfactorily cleaned.

11. The distribution system, within a plant, for such reclaimed water shall be a separate system with no cross-connections to a municipal or private water system.

12. All physical, chemical and microbiological tests shall be conducted in accordance with the 18th Edition of the *Standard Methods for the Examination of Water and Wastewater*.

Reclaimed water may be used for limited purposes including:

1. Production of culinary steam.

2. Pre-rinsing of the product surfaces where pre-rinses will not be used in food products.

3. Cleaning solution make-up water. Provided that for these uses requirements #3-11 of this section are satisfied and:

A. There is no carry-over of water from one day to the next, and any water collected is used promptly; or

The temperature of all water in the storage and distribution system is maintained at 63°C (145°F) or higher by automatic means; or

The water is treated with a suitable, approved chemical to suppress bacterial propagation by means of an automatic proportioning device, prior to the water entering the storage tank; and that,

B. Distribution lines and hose stations are clearly identified as “limited use reclaimed water;” and

C. Water handling practices and guidelines are clearly described and prominently displayed at appropriate locations within the plant; and

D. These water lines are not permanently connected to product vessels, without a break to the atmosphere and sufficient automatic controls, to prevent the inadvertent addition of this water to product streams.

~~Recovered water not meeting the requirements of this section may be used as boiler feedwater for boilers, not used for generating culinary steam, or in a thick, double walled, enclosed heat exchanger.~~

~~**VI. WATER RECLAIMED FROM HEAT EXCHANGER PROCESSES**~~

~~Potable water utilized for heat exchange purposes in plate or other type heat exchangers or compressors on dairy farms may be salvaged for the milking operation if the following criteria are met:~~

~~1. The water shall be stored in a storage vessel properly constructed of such material that it will not contaminate the water and be designed to protect the water supply from possible contamination.~~

~~2. The storage vessel shall be equipped with a drain and access point to allow for cleaning.~~

~~3. No cross-connection shall exist between this supply and any unsafe or questionable water supply or any other source of pollution.~~

~~4. There are no submerged inlets through which this supply may be contaminated.~~

~~5. The water shall be of satisfactory organoleptic quality and shall have no off flavors or odors.~~

~~6. The water shall comply with the bacteriological standards of Appendix D.~~

~~7. Samples shall be collected and analyzed prior to initial approval and semi-annually thereafter.~~

~~8. Approved chemicals, such as chlorine, with a suitable retention period, may be used to suppress the development of bacterial growth and prevent the development of tastes and odors.~~

~~9. When chemicals are added, a monitoring program for such added chemicals shall be in effect and such chemicals shall not add substances that will prove deleterious to the use of the water or contribute to product contamination.~~

~~10. If the water is to be used for the sanitizing of teats or equipment (backflush systems), approved sanitizers, such as iodine may be added by an automatic proportioning device located downstream from the storage vessel but prior to its end-use application.~~

~~**APPENDIX C. SANITIZATION**~~

~~**I. METHODS OF SANITIZATION**~~

~~**CHEMICAL**~~

~~Certain chemical compounds are effective for the sanitization of milk utensils, containers and equipment. These are contained in 21 CFR 178.1010 (1999) and shall be used in accordance with label directions.~~

~~**STEAM**~~

~~When steam is used, each group of assembled piping shall be treated separately by inserting the steam hose into the inlet and maintaining steam flow from the outlet for at least 5 minutes after the temperature of the drainage at the outlet has reached 94°C (200°F). (The period of exposure required here is longer than that required for individual cans, because of the heat lost through the large surface exposed to the air.) Covers must be in place during treatment.~~

~~**HOT WATER**~~

~~Hot water may be used by pumping it through the inlet, if the temperature at outlet end of the assembly is maintained to at least 77°C (170°F) for at least 5 minutes~~

APPENDIX D. CHEMICAL AND BACTERIOLOGICAL TESTS

I. PRIVATE WATER SUPPLIES AND RECIRCULATED WATER—BACTERIOLOGICAL

Reference.—Items 8r, 19r, 7p and 17p.

Application.—To private water supplies, used by dairy farms, dairy plants, receiving stations and transfer stations, and to recirculated cooling water, used in dairy plants and dairy farms.

Frequency.—Initially, and after repair, modification or disinfection of the private water supplies of dairy farms and dairy plants and thereafter; semiannually for all dairy plant water supplies and at least every 3 years on dairy farms. Recirculated cooling water in dairy plants and dairy farms shall be tested semiannually.

Criteria.—An MPN (Most Probable Number of coliform organisms) of less than 1.1 per 100 ml, when ten replicate tubes containing 10 ml are tested, using the multiple tube fermentation technique, or less than 1 per 100 ml by the membrane filter technique, or less than 1.1 per 100 ml when using an mmo-mug technique. The MMO-MUG technique is not acceptable for recirculated cooling water. 100 ± 2.5 ml water will be used for this analysis. Any sample producing a bacteriological result of TNTC—Too Numerous To Count—(greater than 200 total bacteriological colonies per 100 ml by the membrane filter technique) or confluent growth by the multiple tube fermentation Most Probable Number - MPN technique, without coliform present, shall have a subsequent heterotrophic plate count of less that 500 colonies per ml in order to be deemed satisfactory. Findings shall be reported as present or less than 1 per 100 ml (absent) for coliform organisms.

Apparatus, Method, and Procedure.—Tests performed shall conform with the 18th Edition of the *Standard Methods for Examination of Water and Wastewater* or with FDA approved, EPA promulgated methods for the examination of water and waste water.

Corrective Action.—When the laboratory report on the sample is unsatisfactory, the water supply in question shall again be physically inspected and necessary corrections made until subsequent samples are bacteriologically satisfactory.

II. PASTEURIZATION EFFICIENCY-FIELD PHOSPHATASE TEST

Reference.—Section 6.

Frequency.—When any laboratory phosphatase test is positive, or any doubt arises as to the adequacy of pasteurization due to noncompliance with equipment, or standards of Item 16p.

Criteria.—Less than 1 microgram per milliliter by Scharer Rapid Method (or equivalent by other means). See the 16th Edition of *Standard Methods for the Examination of Dairy Products*.

Apparatus.—Field phosphatase test kit (obtainable from Applied Research Institute, 40 Brighton Ave., Perth Amboy, NJ 08861), standards, extra test tubes, stoppers or other approved phosphatase equipment.

Methods.—The test is based on the detection of the phosphatase enzyme, a constituent that is inactivated by pasteurization at 63° C (145° F) for 30 minutes or 72° C (161° F) for 15 seconds. When pasteurization is faulty, some phosphatase remains and is detected through its action on phosphoricphenyl esters, releasing phenol, which is measured quantitatively by the addition of dibromo- or dichlo-roquinonechlorimide to form an indophenol blue color.

Procedure.—See the 16th Edition of *Standard Methods for Examination of Dairy Products* for details on phosphatase tests.

Corrective Action. Whenever a phosphatase test is positive, the cause shall be determined. Where the cause is improper pasteurization, it shall be corrected and any milk or dairy products involved shall not be offered for sale.

III. PHOSPHATASE REACTIVATION IN HTST PASTEURIZED PRODUCTS

The presence of an appreciable quantity of phosphatase in milk and cream after heat treatment has been traditionally regarded as evidence of inadequate pasteurization. However, with the advent of modern high-temperature, short-time (HTST) methods, evidence has been accumulating that under certain conditions, the relationship between inadequate pasteurization and the presence of phosphatase does not hold.

A number of investigators who have studied HTST pasteurizing methods have concluded that while a negative test can be obtained immediately after pasteurization, the same sample may yield a positive test after a short period of storage, particularly if the product is not continuously or adequately refrigerated.

This phenomenon has come to be known as reactivation.

Reactivation may occur in HTST pasteurized products, after storage, at temperatures as low as 10° C (50° F), although 34° C (93° F) is optimum. Products of high fat content generally produce relatively more reactivable phosphatase.

Reactivation is greatest in products pasteurized at about 110° C (230° F) but may occur in products pasteurized at much higher temperatures and as low as 73° C (163° F).

It has been noted that an increase in holding time during pasteurization will reduce reactivation.

The addition of magnesium chloride to HTST processed milk or cream, after pasteurization but before storage, accelerates reactivation. The difference in activity between an adequately pasteurized sample, stored with and without magnesium, and an inadequately pasteurized sample, stored with and without magnesium, forms the basis of a test for differentiating reactivated from residual (inadequately pasteurized) phosphatase.

IV. DETECTION OF DRUG RESIDUES IN MILK

The problem of drug residues in milk is associated with their use in the treatment of mastitis and other diseases. Failure to withhold milk from the market for a sufficient length of time after treatment may result in the presence of drug residues in milk. Such milk is undesirable for two reasons; first, it comes from an unhealthy lactating animal, and second, it is adulterated.

The allergenic properties of certain drugs in common use make their presence in milk potentially hazardous to consumers. Also, substantial losses of byproducts may be sustained by the milk industry each year because of the inhibitory effects of drug residues on the culturing process. Drug residues should be tested for using tests provided in Section 6. These tests are specified in informational memoranda from the FDA.

APPENDIX E. PASTEURIZATION EQUIPMENT AND PROCEDURES

I. HTST PASTEURIZATION

OPERATION OF HTST SYSTEMS

HTST pasteurization has become important to the dairy industry because of the operating efficiencies which it affords. Properly operated, these units allow a high volume of production in a minimum of processing space.

~~The ability of HTST pasteurizers to assure a safe, finished product hinges on the reliability of the time-temperature-pressure relationships which must prevail whenever the system is in operation. It is important that the plant operator understand the HTST process in order to maintain proper surveillance over the equipment. The basic flow pattern is described below:~~

~~1. Cold raw milk, in a constant level supply tank, is drawn into the regenerator section of the HTST pasteurizer.~~

~~**NOTE** – Some operators prefer to bypass the regenerator when starting. Under this system, cold milk is drawn directly through the timing pump (step 3) and into the heater section. The remaining steps are performed without exception. This bypass arrangement facilitates and speeds up the starting operation. After forward flow is established at the flow-diversion device, the bypass, which may be manually or automatically controlled, is not used and the raw milk flows through the regenerator. A second start-up technique involves the use of sanitizing solution at 77° C (170° F). This is passed through the complete unit and followed immediately by milk. Dilution of the first milk does occur; however, care must be taken to prevent this from being packaged.~~

~~2. In the regenerator section, the cold raw milk is warmed by hot pasteurized milk flowing in a counter current direction on the opposite sides of thin stainless steel surfaces.~~

~~3. The raw milk, still under suction, passes through a positive displacement timing pump which delivers it under pressure through the rest of the HTST pasteurization system.~~

~~4. The raw milk is pumped through the heater section, where hot water or steam on opposite sides of thin stainless steel surfaces heats the milk to a temperature of at least 72°C (161°F).~~

~~5. The milk, at pasteurization temperature, and under pressure, flows through the holding tube where it is held for at least 15 seconds. (The maximum velocity of the milk through the holding tube is governed by the speed of the timing pump, the diameter and length of the holding tube and surface friction.)~~

~~6. After passing the sensing bulbs of an indicating thermometer and a recorder/controller, the milk passes into the flow-diversion device which automatically assumes a forward-flow position, if the milk passes the recorder/controller bulb at the preset cut-in temperature (i.e., 72°C or 161°F).~~

~~7. Improperly heated milk flows through the diverted-flow line back to the raw milk constant level supply tank.~~

~~8. Properly heated milk flows through the forward-flow line to the pasteurized milk regenerator section where it serves to warm the cold raw milk and, in turn, is cooled.~~

~~9. The warm milk passes through the cooling section, where coolant, on the sides of thin stainless steel surfaces opposite the pasteurized milk, reduces its temperature to 4°C (40°F) and below.~~

~~10. The cold pasteurized milk then passes to a storage tank or vat to await packaging.~~

~~**HTST PASTEURIZERS EMPLOYING MILK-TO-MILK REGENERATORS WITH BOTH SIDES CLOSED TO THE ATMOSPHERE**~~

~~Item 16. 2p(C) of Section 7 establishes standards for regenerators. These standards insure that the raw milk will always be under less pressure than pasteurized milk in order to prevent contamination of the pasteurized milk in the event flaws should develop in the metal or joints separating it from the raw milk. An explanation of regenerator specifications is given below.~~

~~During normal operation (i.e., while the timing pump is operating), raw milk will be drawn through the regenerator at sub-atmospheric pressure. The pasteurized milk in the milk-to-milk regenerator will be above atmospheric pressure. The required pressure differential will be assured when there is no flow-promoting device downstream from the pasteurized milk side of the regenerator to draw the pasteurized milk through the regenerator, and the pasteurized milk downstream from the regenerator rises to at least 30 centimeters (1-foot elevation) above the highest raw milk level downstream from the constant-level tank, and is open to the atmosphere at this or a higher elevation, as required in Item 16. 2p(D)2.~~

~~During a shutdown (i.e., when the timing pump stops), the raw milk in the regenerator will be retained under suction, except as this suction may be gradually relieved by possible entrance of air drawn through the regenerator plate gaskets from the higher outside atmospheric pressure. With a free draining regenerator, as required under Item 16p(D)7, the raw milk level in the regenerator may drop slowly, depending on the tightness of the gaskets, ultimately falling below the level of the plates to the product level in the raw milk supply tank. However, under these conditions, as long as any raw milk remains in the regenerator, it will be at sub-atmospheric pressure.~~

~~During shutdown, the pasteurized milk in the regenerator is maintained at atmospheric pressure or above by meeting the elevation requirement of Item 16p(D)2. Pressure greater than atmospheric is maintained when the level of pasteurized milk is at or above the required elevation and loss of pressure, due to suction, is prevented by prohibiting a downstream pump.~~

~~Any backflow of milk through the flow-diversion device would lower the pasteurized milk level, during pump shutdowns, thus tending to reduce the pressure on the pasteurized milk side of the regenerator. A flow-diversion valve cannot be relied upon to prevent backflow in such instances, because during the first few minutes following a pump shutdown, the milk is still at a sufficiently high temperature to keep the diversion valve in the forward-flow position. Compliance with the provisions of Item 16p(D)2 and 3; however, will insure a proper pressure differential in the regenerator.~~

~~At the beginning of a run, from the time raw milk or water is drawn through the regenerator, until the pasteurized milk or water has risen to the elevation specified in Item 16p(D)2, the pasteurized milk side of the regenerator is at atmospheric pressure or higher. Even if the metering pump should stop during this period, the pressure on the pasteurized milk side of the regenerator will be greater than the sub-atmospheric pressure on the raw milk side. This will be assured by compliance with Item 16p(D)2 and 3, as long as any raw milk remains in the generator.~~

~~When a raw milk booster pump is incorporated into the HTST system, Item 16p(D)5 requires, in part, that automatic means shall be provided to assure, at all times, the required pressure differential between raw and pasteurized milk in the regenerator, before the booster pump can operate. The most common control employed to accomplish this is a sanitary pressure switch, installed at or downstream from the pasteurized milk outlet of the regenerator. The pressure switch is adjusted to energize the booster pump only after the pasteurized milk pressure in the regenerator exceeds, by at least .07 KPA (1 pound per square inch), the maximum operating pressure developed by the booster pump.~~

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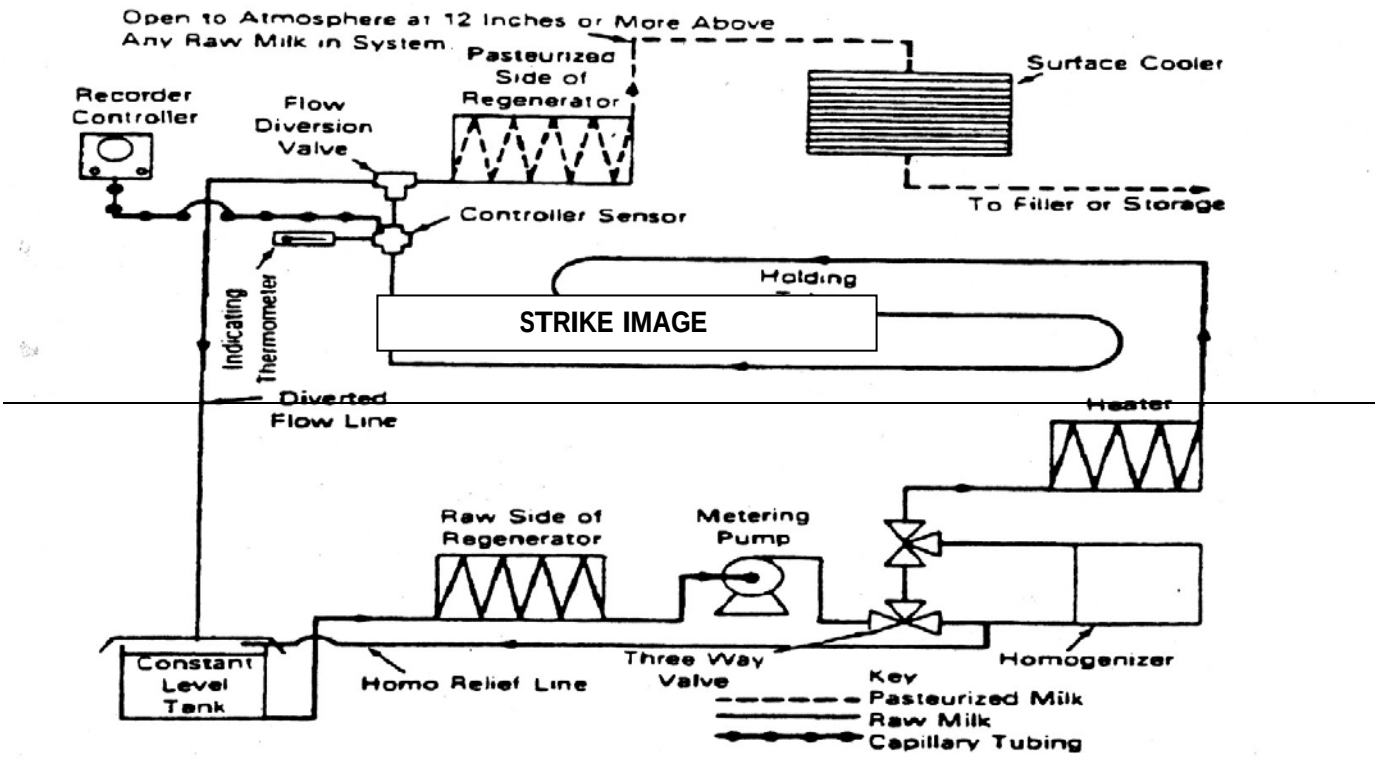

Figure 2. Milk-to-Milk Regeneration--Surface Cooler

~~The setting and checking of the pressure switch that is used to control the proper operation of the raw milk booster pump is described in Appendix F, Test 9,1.~~

~~As an alternative control to the use of the pressure switch, the adjustable time delay relay in conjunction with a hydrostatic head, has been effectively used in HTST systems equipped with raw milk booster pumps of relatively low capacity. Such time delay provides a predetermined time lapse between the moment the flow diversion device assumes the forward flow position and the moment the booster pump is energized. The time lapse required is that necessary for the forward flow of milk through the regenerator and cooler to rise to a height sufficiently above the booster pump outlet to provide a pressure at least .07 KPA (one pound) greater than the maximum pressure developed by the booster pump. The pasteurized milk pipeline is vented to the atmosphere at or above the necessary vertical rise.~~

~~The setting and checking of the time delay relay and hydrostatic head used to control the proper operation of the raw milk booster pump is described in Appendix F, Test 9, 2.~~

~~**MAGNETIC FLOW METER BASED TIMING SYSTEMS FOR HTST PASTEURIZERS**~~

~~Recent developments in the design of HTST pasteurizing systems have introduced the use of magnetic flow meter based timing systems to be used as replacements for positive displacement timing pumps with a fixed or sealed speed below the required holding time.~~

~~These systems are of two basic types:~~

~~1. Those employing a constant speed centrifugal pump and a control valve, or~~

2. Those employing an A-C variable frequency motor speed control for the centrifugal pump. In this case the timing pump may be centrifugal or positive displacement type.

Item 16p(B)2(f) of Section 7 provides for their use provided, they meet the following specifications for design, installation and use.

COMPONENTS. Magnetic flow meter based timing systems shall consist of the following components:

1. A sanitary magnetic flow meter which has been reviewed by USPHS/FDA or one which is equally accurate, reliable and will produce six (6) consecutive measurements of holding time within one-half (0.5) second of each other.

2. Suitable converters for conversion of electric and/or air signals to the proper mode for the operation of the system.

3. A suitable flow recorder capable of recording flow at the flow alarm set point and also at least 19 liters (5 gallons) per minute higher than the flow alarm setting. The flow recorder shall have an event pen which shall indicate the position of the flow alarm with respect to flow rate.

4. A flow alarm, with an adjustable set point, shall be installed within the system which will automatically cause the flow diversion device to be moved to the divert position whenever excessive flow rate causes the product holding time to be less than the legal holding time for the pasteurization process being used. The flow alarm shall be tested by the regulatory agency in accordance with the procedures of Appendix F, Test 11.2.A and B at the frequency specified. The flow alarm adjustment shall be sealed.

5. A loss of signal alarm shall be installed with the system which will automatically cause the flow diversion device to be moved to the divert position whenever there is a loss of signal from the meter. The loss of signal provision shall be tested by the regulatory agency in accordance with Appendix F, Test 11.2.C at the frequency specified. The loss of signal provision shall be sealed.

6. When the legal flow rate has been re-established, following an excessive flow rate, a time delay must be instituted which will prevent the flow diversion device from assuming the forward flow position until at least a 15 seconds (milk) or 25 seconds (frozen dessert mix) continuous legal flow has been re-established. The time delay must be tested by the regulatory agency and if it is of the adjustable type shall be sealed.

7. When a constant speed centrifugal pump is used, a sanitary, spring-loaded-to- close; air-to-open, control valve shall be used to control the rate of flow of product through the HTST system.

8. When an A-C variable frequency motor speed control is used on the timing pump, the control valve is not needed as the flow rate of product through the system is controlled by feeding the signal from the magnetic flow meter to a controller which in turn varies the A-C frequency to the pump motor, thus controlling the flow rate of product through the system. With these A-C variable frequency systems, a sanitary product check valve is needed, in the sanitary milk pipe line to prevent a positive pressure in the raw milk side of the regenerator whenever a power failure, shutdown or flow diversion occurs.

9. When a regenerator is used with large systems, it will be necessary to bypass the regenerator during start-up and when the flow diversion device is in the diverted flow position. Care should be taken in the design of such bypass systems to assure that a dead-end does not exist. A dead-end could allow product to remain at ambient temperature for long periods of time and allow bacterial growth in the product. Caution should also be observed with such bypass systems and any valves used in them so that raw dairy product will not be trapped, under pressure in the raw

~~regenerator plates, and not have free drainage back to the constant level tank when shutdown occurs.~~

~~10. Most systems will utilize a dual stem flow diversion device and will be using the timing pump during the mechanical cleaning cycle. All public health controls, required of such systems, must be applicable. When switching to the CIP position, the flow diversion device must move to the divert position and must remain in the diverted flow position for at least 10 minutes, regardless of temperature, and the booster pump cannot run during this 10 minute time delay.~~

~~11. All systems shall be designed, installed and operated so that all applicable tests required by Section 18, Item 162p(E) (See Appendix F) can be performed by the regulatory agency, at the frequency specified. Where adjustment or changes can be made to these devices or controls, appropriate seals shall be applied after testing so that changes cannot be made without detection.~~

~~12. Except for those requirements directly related to the physical presence of the metering pump, all other requirements of the most recent edition of the these Regulations are applicable.~~

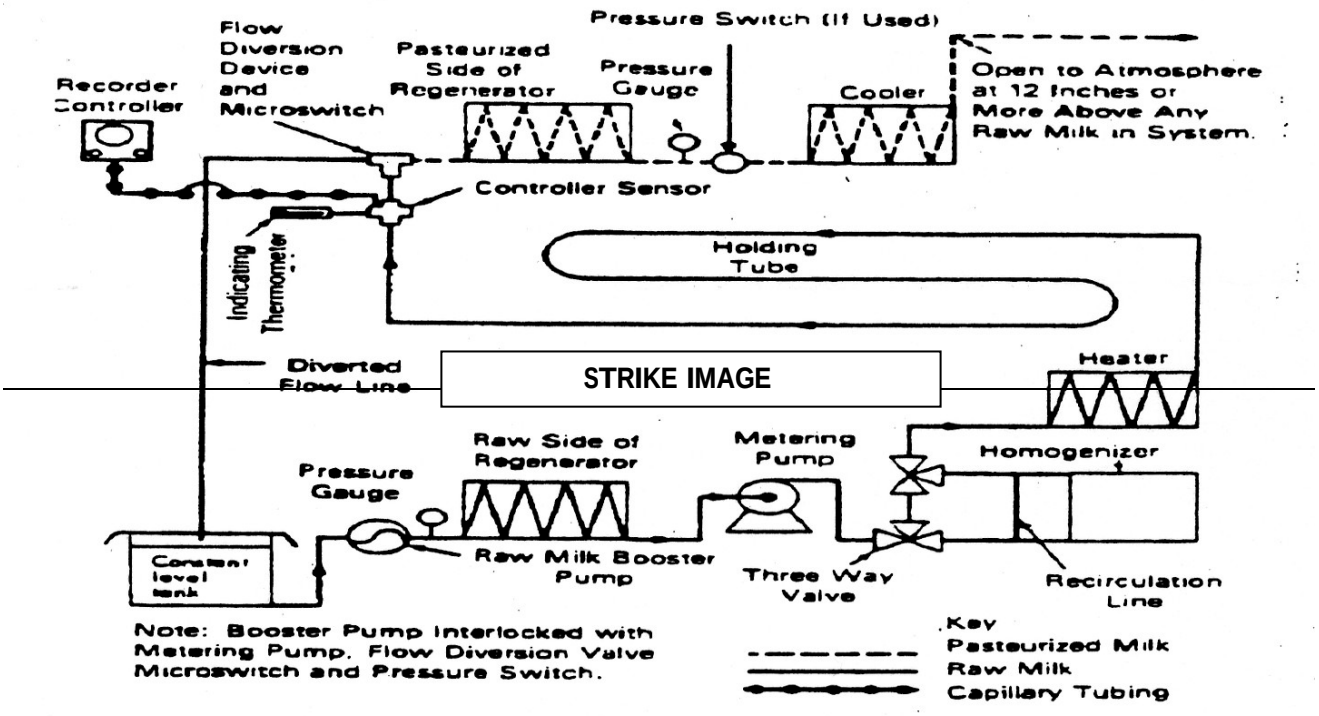

Figure 3. Milk-to-Milk Regeneration--Booster Pump

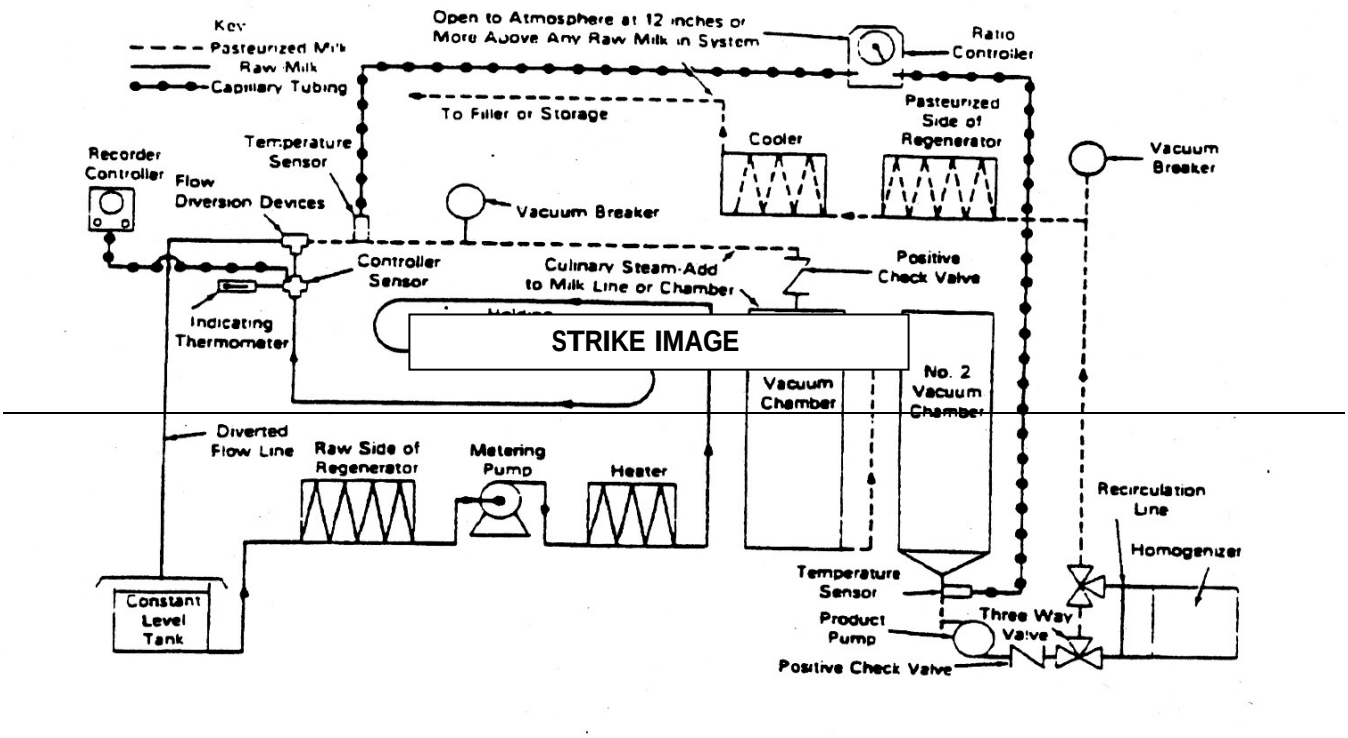

Figure 4. Milk-to-Milk Regeneration--Homogenizer and Vacuum Chambers Downstrean from Flow-Diversion Device

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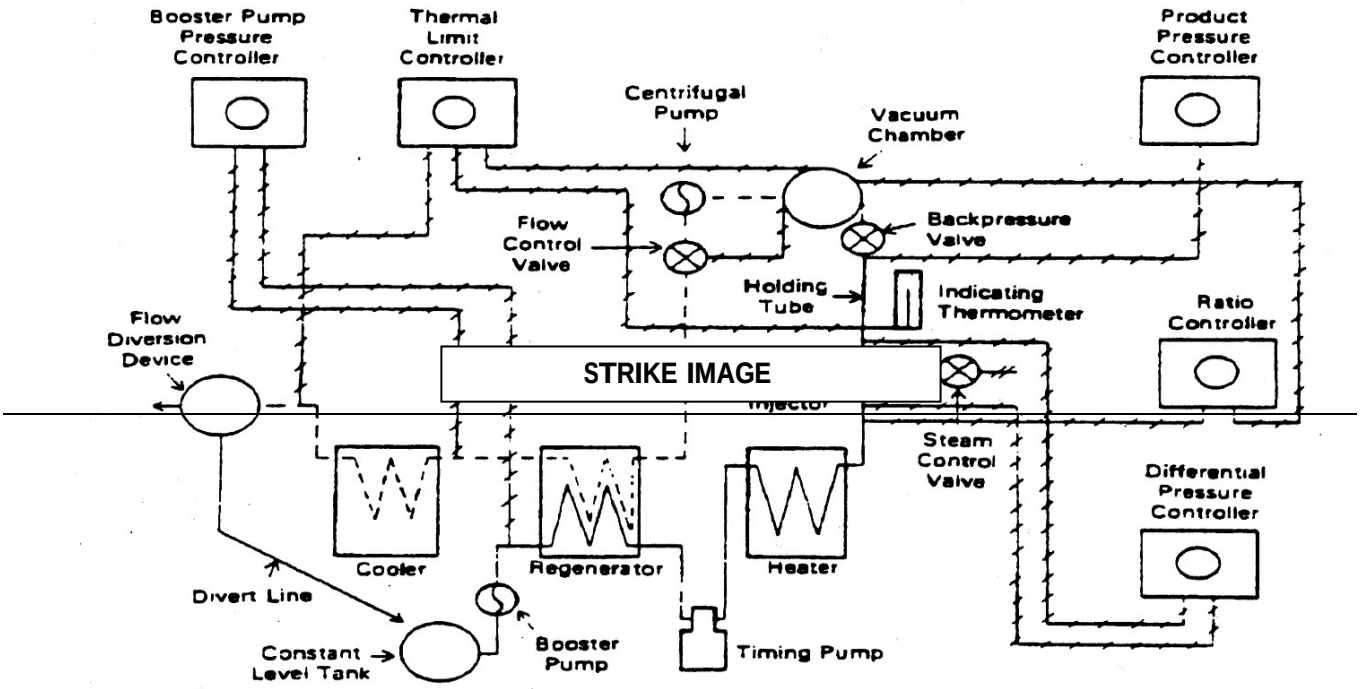

Figure 5. HTST System with a Magnetic Flow Meter Using a Constant Speed centrifugal Pump and a Control Valve

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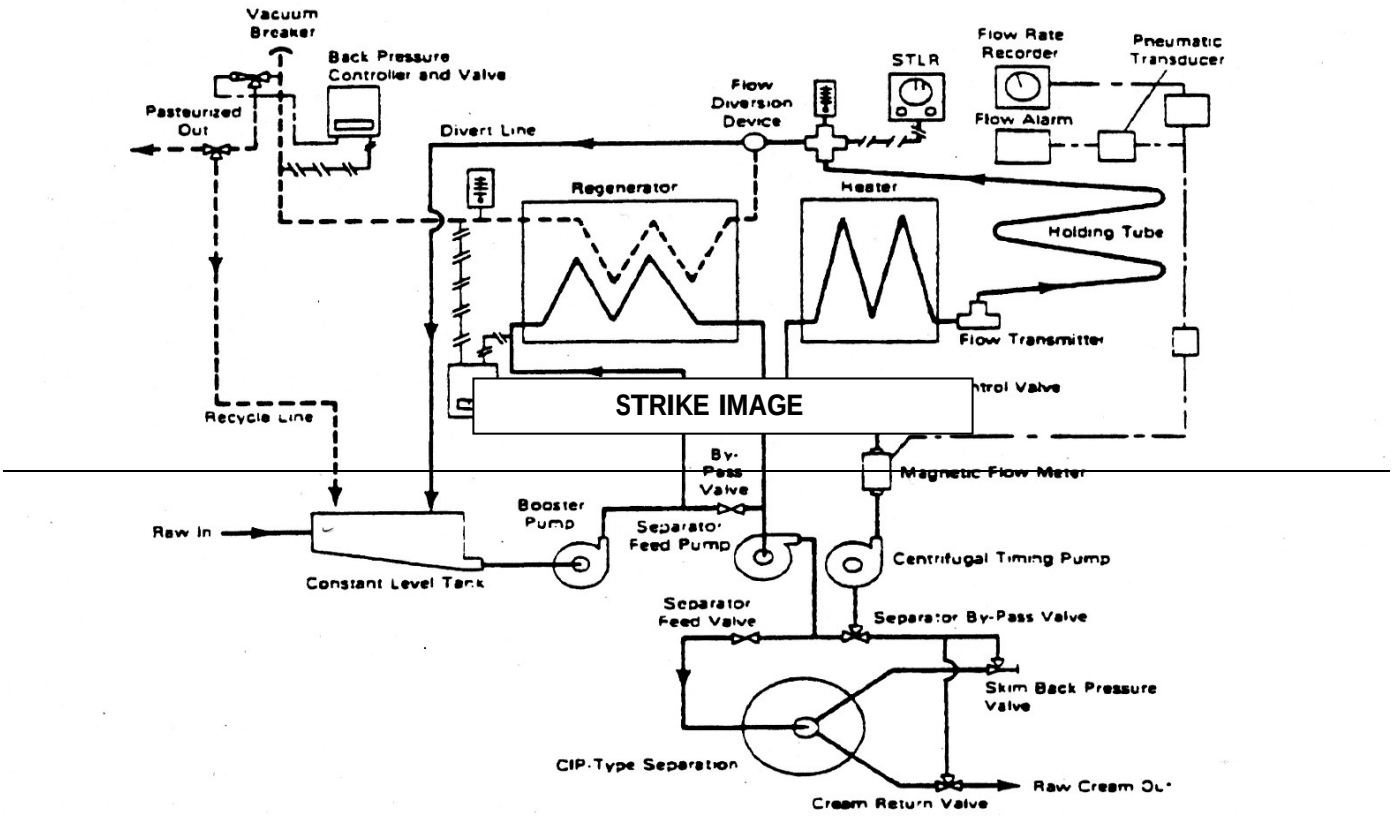

Figure 6. HTST System with a Magnetic Flow Meter Using a Constant Speed Centrifugal Pump and a Control Valve

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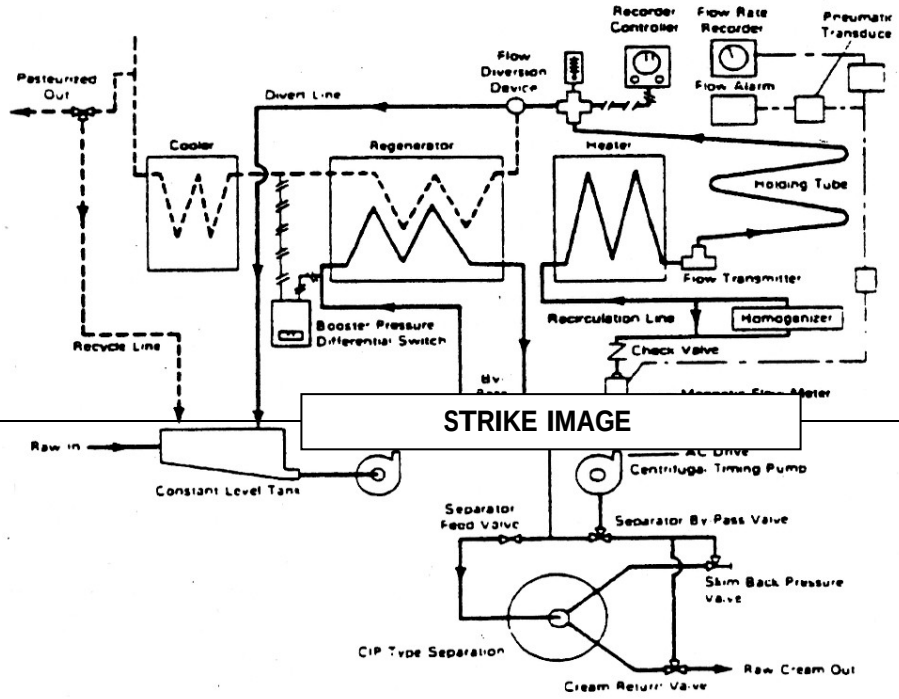


Figure 7. HTST System with a Magnetic Flow Meter Using an A-C Variable Speed Centrifugal Pump

4029

4030 ~~**PLACEMENT OF COMPONENTS.** Individual components in the magnetic flow meter based timing~~
4031 ~~systems shall comply with the following placement condition:~~

4032 ~~1. The timing pump shall be located downstream from the raw milk regenerator section, if a regenerator~~
4033 ~~is used.~~

4034 ~~2. The magnetic flow meter shall be placed downstream from the timing pump. There shall be no~~
4035 ~~intervening flow promoting components between the timing pump and the meter.~~

4036 ~~3. The control valve, used with the constant speed timing pump, shall be located downstream of the~~
4037 ~~magnetic flow meter.~~

4038 ~~4. The timing pump, the magnetic flow meter, the control valve, when used with the constant speed~~
4039 ~~timing pump system, and the sanitary product check valve, when used with the A-C variable~~
4040 ~~frequency motor speed control system, shall all be located upstream from the start of the holding~~
4041 ~~tube.~~

4042 ~~5. All flow promoting devices, which are upstream of the flow diversion device, such as timing pumps~~
4043 ~~(constant speed or A-C variable frequency motor control types), booster pumps, stuffer pumps,~~
4044 ~~separators and clarifiers shall be properly interwired with the flow diversion device so that they~~
4045 ~~may run and produce flow through the system at sublegal temperatures, only when the flow~~
4046 ~~diversion device is in the fully diverted position, when in product run mode. Separators or~~
4047 ~~clarifiers which continue to run, after power is shut off to them, must be automatically valved out~~
4048 ~~of the system, with fail-safe valves, so that they are incapable of producing flow.~~

6. There shall be no product entering or leaving the system (i.e., cream or skim from a separator or other product components) between the timing pump and the flow diversion device.

7. The magnetic flow meter shall be so installed that the product has contact with both electrodes at all times when there is flow through the system. This is most easily accomplished by mounting the flow tube of the magnetic flow meter in a vertical position with the direction of flow from the bottom to the top. However, horizontal mounting is acceptable when other precautions are taken to assure that both electrodes are in contact with product. They should not be mounted on a high horizontal line which may be only partially full and thereby trap air.

8. The magnetic flow meter shall be piped in such a manner that at least 10 pipe diameters of straight pipe exists, upstream and downstream from the center of the meter, before any elbow or change of direction takes place. Figure 6 and 7 are schematic drawings of two typical magnetic flow meter based timing systems which illustrate proper placement of components.

II. AIR UNDER PRESSURE.— MILK AND DAIRY PRODUCT CONTACT SURFACES

MATERIAL

Filter Media.— Air intake and pipeline filters shall consist of fiberglass, cotton flannel, wool flannel, spun metal, electrostatic material or other equally acceptable filtering media, which are non-shedding and which do not release to the air, toxic volatiles, or volatiles which may impart any flavor or odor to the product.

Disposable media filters shall consist of cotton flannel, wool flannel, spun metal, non-woven fabric, U.S.P. absorbent cotton fiber or suitable inorganic materials which, under conditions of use, are non-toxic and non-shedding. Chemical bonding material, contained in the media, shall be nontoxic, nonvolatile and insoluble under all conditions of use. Disposable media shall not be cleaned and reused.

Piping.— Air distribution piping, fittings and gaskets between the terminal filter and any product-contact surface, shall be sanitary milk piping, except, where the compressing equipment is of the fan or blower type. When the air is used for such operations, as removing containers from mandrels, other non-toxic materials may be used.

FABRICATION AND INSTALLATION

Air Supply Equipment.— The compressing equipment shall be designed to preclude contamination of the air with lubricant vapors and fumes. Oil-free air may be produced by one of the following methods or their equivalent:

1. Use of a carbon ring piston compressor.

2. Use of oil-lubricated compressor with effective provision for removal of any oil vapor by cooling the compressed air.

3. Water-lubricated or nonlubricated blowers.

The air supply shall be taken from a clean space or from relatively clean outer air and shall pass through a filter upstream from the compressing equipment. This filter shall be located and constructed so that it is easily accessible for examination, and the filter media are easily removable for cleaning or replacing. The filter shall be protected from weather, drainage, water, product spillage and physical damage.

Moisture Removal Equipment.— If it is necessary to cool the compressed air, an aftercooler shall be installed between the compressor and the air storage tank for the purpose of removing moisture from the compressed air.

Filters and Moisture Traps. Filters shall be constructed so as to assure effective passage of air through the filter media only.

The air under pressure shall pass through an oil-free filter and moisture trap for removal of solids and liquids. The filter and trap shall be located in the air pipeline, downstream from the compressing equipment, and from the air tank, if one is used. Air pipeline filters and moisture traps, downstream from compressing equipment, shall not be required where the compressing equipment is of the fan or blower type.

A disposable media filter shall be located in the sanitary air pipelines upstream from and as close as possible to each point of application or ultimate use of the air.

Air Piping. The air piping from the compressing equipment to the filter and moisture trap shall be readily drainable.

A product-check valve of sanitary design shall be installed in the air piping, downstream from the disposable media filter, to prevent backflow of product into the air pipeline, except that a check valve shall not be required if the air piping enters the product zone from a point higher than the product overflow level which is open to the atmosphere.

The requirements of this section do not apply when the compressing equipment is of the fan or blower type. See illustrations depicting various air supply systems.

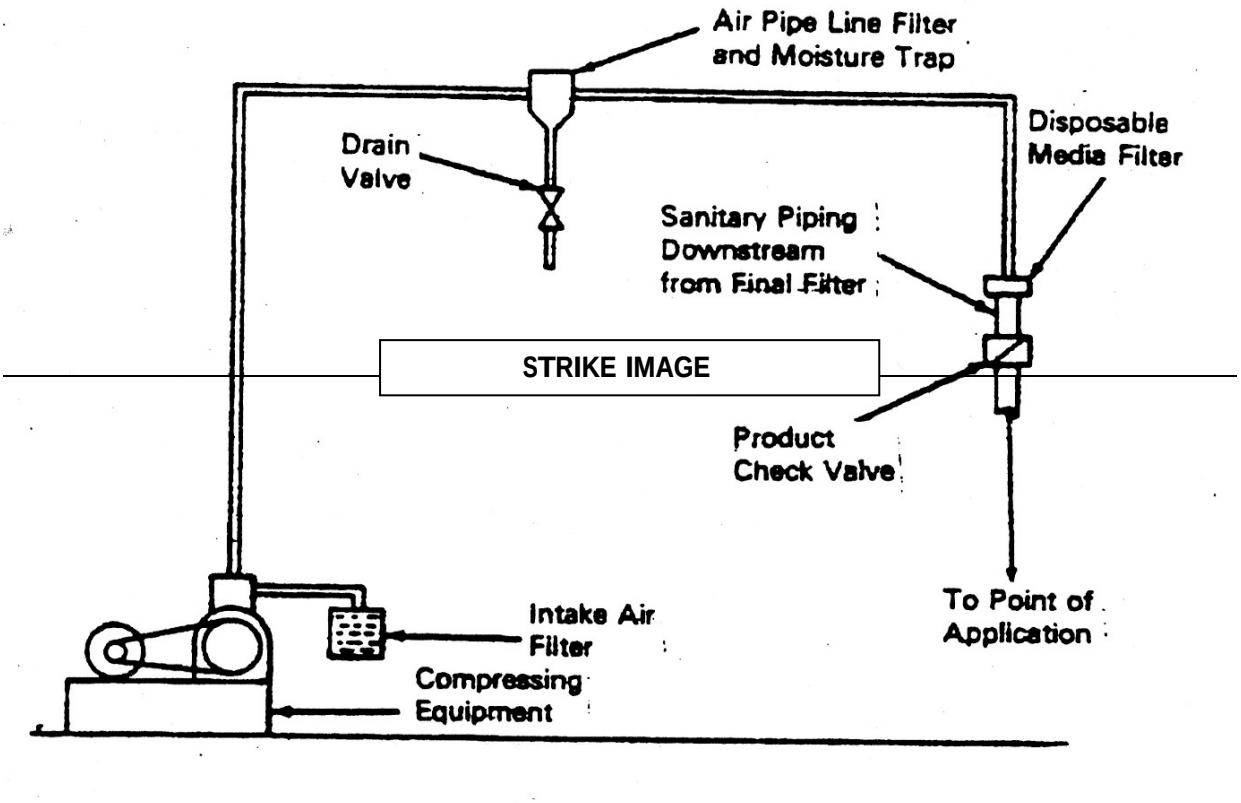


Figure 8. Individual compression-Type Air Supply

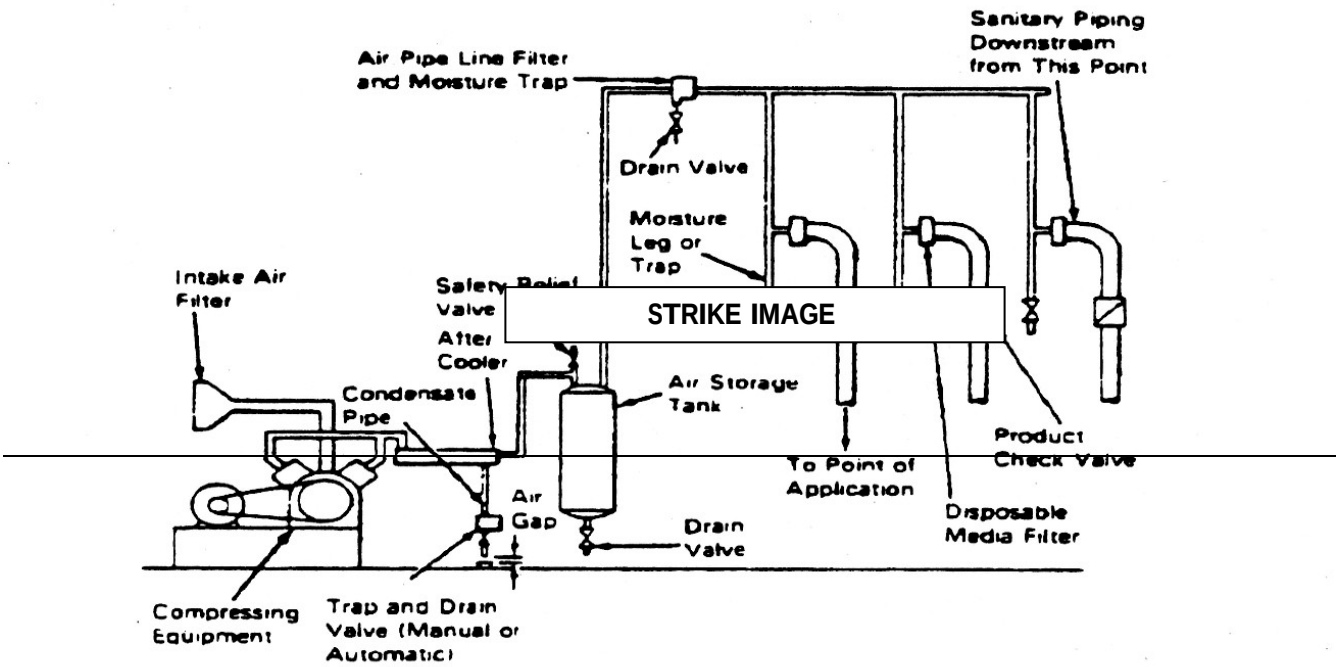


Figure 9. Central Compression-Type Air Supply.

4108

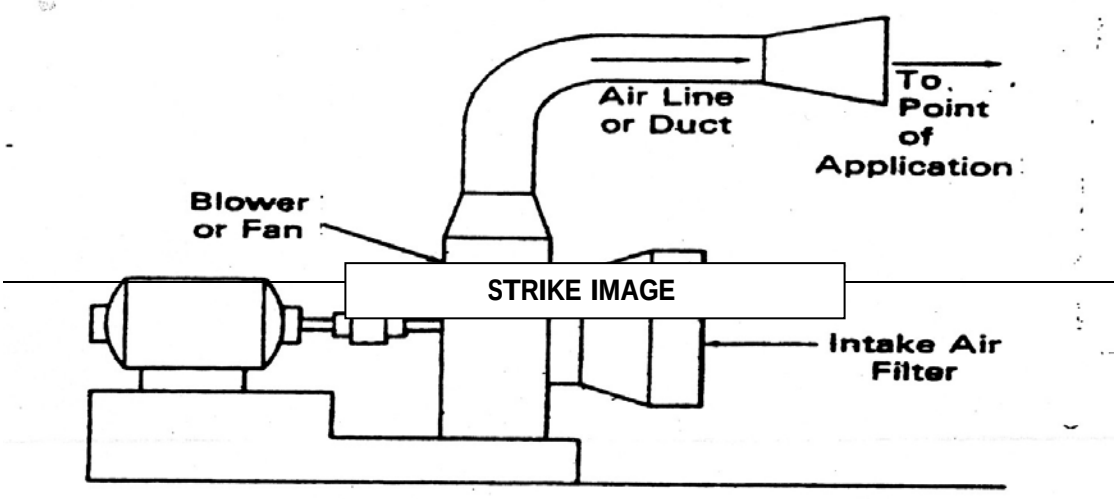


Figure 10. Individual Blower Type Air Supply

4109

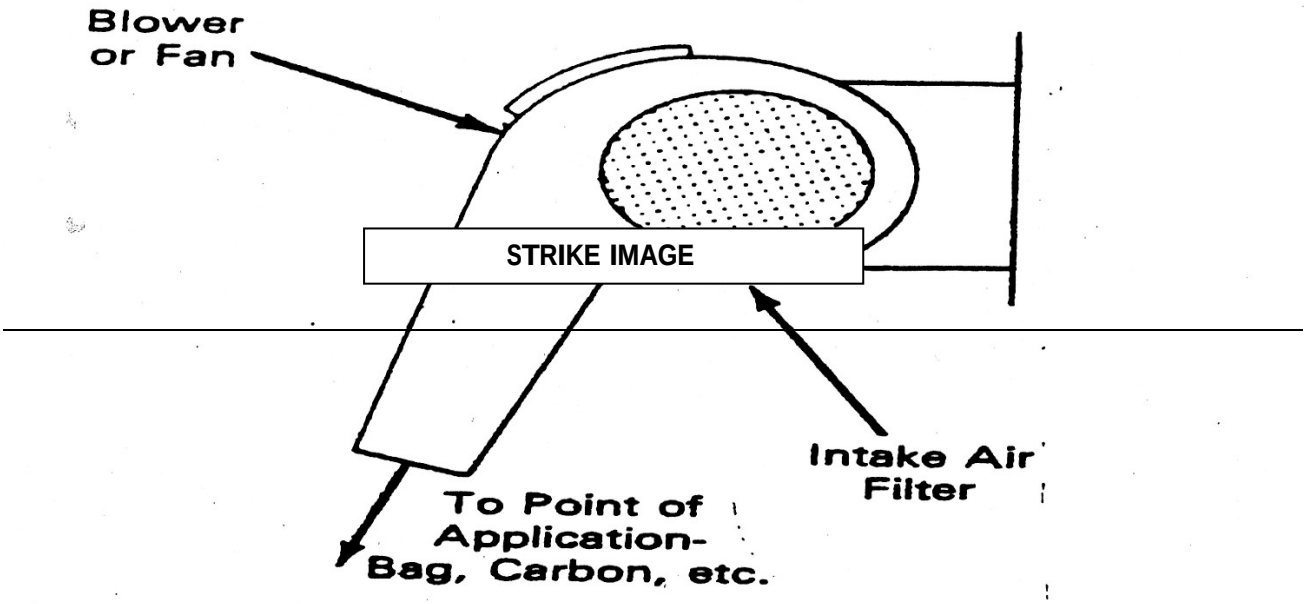


Figure 11. Individual Fan Type Air Supply

4110

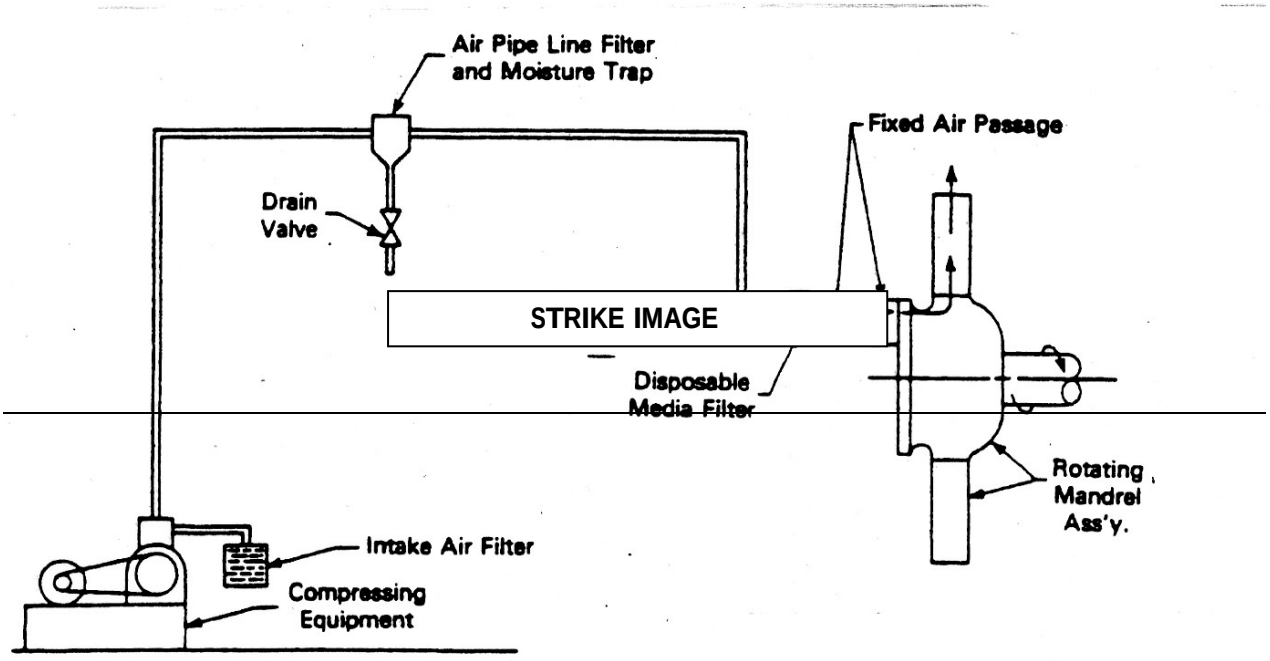


Figure 12. Rotating Mandrel Assembly

4111

III. CULINARY STEAM—MILK AND DAIRY PRODUCTS

The following methods and procedures will provide steam of culinary quality for use in the processing of milk and dairy products.

SOURCE OF BOILER FEED WATER

Potable water or water supplies, acceptable to the regulatory agency, will be used.

FEED WATER TREATMENT

Feed waters may be treated, if necessary, for proper boiler care and operation. Boiler feed water treatment and control shall be under the supervision of trained personnel or a firm specializing in industrial water conditioning. Such personnel shall be informed that the steam is to be used for culinary purposes. Pretreatment of feed waters for boilers or steam generating systems to reduce water hardness, before entering the boiler or steam generator by ion exchange or other acceptable procedures, is preferable to the addition of conditioning compounds to boiler waters. Only compounds complying with 21 CFR 173.310 (1999) may be used to prevent corrosion and scale in boilers, or to facilitate sludge removal.

Greater amounts shall not be used of the boiler water treatment compounds than the minimum necessary for controlling boiler scale or other boiler water treatment purposes. No greater amount of steam shall be used for the treatment and/or pasteurization of milk and dairy products than necessary.

It should be noted that tannin, which is also frequently added to boiler water to facilitate sludge removal during boiler blow-down, has been reported to give rise to odor problems, and should be used with caution.

Boiler compounds containing cyclohexylmine, morpholine, octadecylamine, diethylaminoethanol, trisodium nitrilotriacetae, and hydrazine shall not be permitted for use in steam in contact with milk and dairy products.

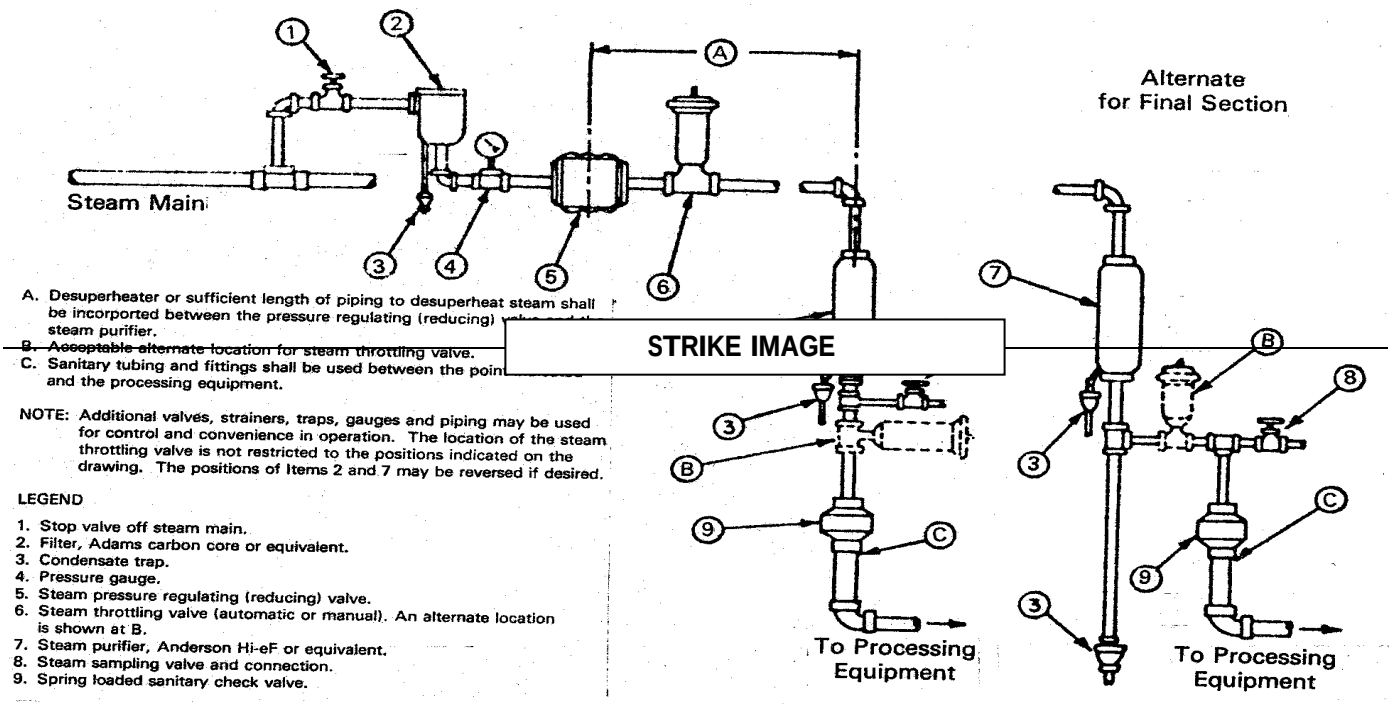
BOILER OPERATION

A supply of clean, dry saturated steam is necessary for proper equipment operation. Boilers and steam generation equipment shall be operated in such a manner as to prevent foaming, priming, carryover and excessive entrainment of boiler water into the steam. Carryover of boiler water additives can result in the production of milk off-flavors. Manufacturers' instructions regarding recommended water level and blow-down should be consulted and rigorously followed. The blow-down of the boiler should be carefully watched, so that an over-concentration of the boiler water solids and foaming is avoided. It is recommended that periodic analyses be made of condensate samples. Such samples should be taken from the line between the final steam separating equipment and the point of the introduction of steam into the product.

PIPING ASSEMBLIES

Suggested piping assemblies for steam infusion or injection were shown previously.

Other assemblies which will assure a clean, dry saturated steam are acceptable.



4148

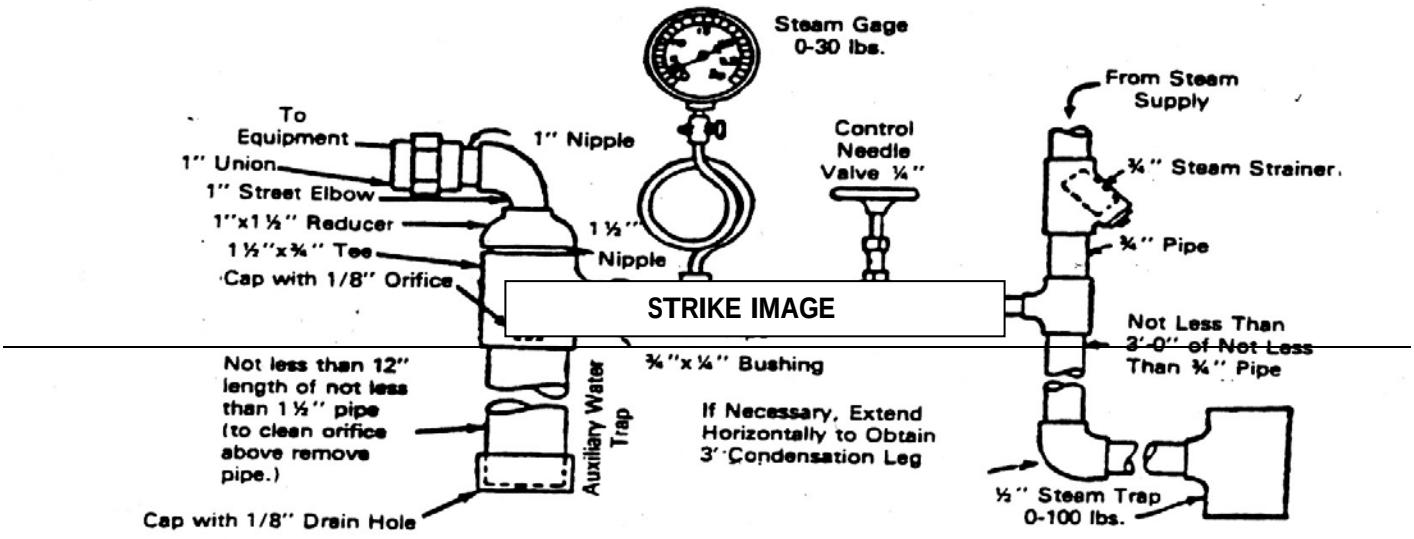


Figure 14. Examples of Steam Piping Assembly for Airspace Heating or Defoaming

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4153 ~~**IV. THERMOMETER SPECIFICATIONS**~~

4154 ~~**INDICATING THERMOMETERS FOR BATCH PASTEURIZERS**~~

~~Mercury-actuated, direct-reading; contained in a corrosion-resistant case, which protects against breakage and permits easy observation of column and scale; filling above mercury, nitrogen or other suitable gas.~~

~~**Magnification of Mercury Column.** To apparent width of not less than 1.6 millimeters (0.0625 of an inch).~~

~~**Scale.** Shall have a span of not less than 14° C (25° F), including the past-eurization temperature, plus and minus 3°C (5 F); graduated in 0.5° C (1° F) divisions, with not more than 9° C (16° F) per inch of span; protected against damage at 105° C (220° F). Provided, that on batch pasteurizers used solely for 30-minute pasteurization of dairy products at temperatures above 71° C (160° F), indicating thermometers with 1° C (2° F) scale graduations, with not more than 6° C per centimeters (28° F per inch) of span, may be used.~~

~~**Accuracy.** Within 0.2° C (0.5° F), plus or minus, through the specified scale span. Provided, that on batch pasteurizers used solely for 30-minute pasteurization of dairy products at temperatures above 71° C (160° F), indicating thermometers shall be accurate to within .5° C (1° F) plus or minus. (Appendix F, Test 1).~~

~~**Submerged Stem Fitting.** Pressure-tight seat against inside wall of holder; no threads exposed to milk; location of seat to conform to that of the 3A Sanitary Standard for a wall-type fitting or other equivalent sanitary fitting.~~

~~**Bulb.** Corning normal or equally suitable thermometric glass.~~

~~**INDICATING THERMOMETERS LOCATED ON PASTEURIZATION PIPELINES**~~

~~**Type.**~~

~~1. Mercury-actuated; direct-reading; contained in corrosion-resistant case, which protects against breakage and permits easy observation of column and scale; filling above mercury, nitrogen or equally suitable gas.~~

~~2. Digital;~~

~~A. No more than 0.2° C (0.5° F) drift over 3 months use on an HTST system compared to a certified temperature source.~~

~~B. Self-diagnostic circuitry which provides constant monitoring of all sensing, input and conditioning circuits. The diagnostic circuitry should be capable of detecting "open" circuits, "short" circuits, poor connections and faulty components. Upon detection of failure of any component the device shall blank or become unreadable.~~

~~C. The electromagnetic compatibility of this device for this use shall be documented and available to public health authorities. The device must be tested to determine the effects of electrostatic discharge, power fluctuation, conductive emission and susceptibility, and radiative emission and susceptibility. The device must comply to the requirements for performance level characteristics of industrial devices.~~

~~D. The effect of exposure to specific environmental conditions shall be documented. The device must be tested to determine the effects of low and high temperatures, thermal shock, humidity, physical shock and salt fog.~~

~~E. Both probe and display case shall be constructed so that they may be sealed by a regulatory agency.~~

F. Calibration of the device shall be protected against unauthorized changes.

G. The device shall be protected against unauthorized component or sensing element replacement. Replacement of any component or sensing element shall be regarded as a replacement of the indicating thermometer and subject to regulatory agency inspection and all applicable tests under Appendix F.

H. The sensing element shall be encased in appropriate material constructed in such way that the final assembly meets the conditions of item 11p in these Regulations.

I. The device must be tested from the sensing probe through the final output.

Scale. Shall have a span of not less than 14° C (25° F), including the pasteurization temperature, plus and minus 02.5° C (5° F) division, protected against damage at 105° C (220° F). Mercury actuated thermometers shall be graduated in 0.2° C (0.5° F) divisions with not more than 4° C (8° F) per 25 millimeters (approx. 1 inch) of scale. Digital thermometer readout shall be display in units with a least count of 0.05° C (0.1°F).

Accuracy. Within 0.2° C (0.5° F), plus or minus, throughout the specified scale span. (Appendix F, Test 1).

Stem Fittings. Pressure-tight seat against inside wall of fittings; no threads exposed to milk. Probe to be designed such that sensitive area is discernible from the remainder of the stem. Overall probe length to be such that the sensitive area is positioned in the product flow path when properly installed.

Thermometric Response. When the thermometer is at room temperature and then is immersed in a well-stirred water bath 11° C (19° F) or less above the pasteurization temperature; the time required for the reading to increase from water bath temperature, minus 11° C (19° F), to water bath temperature, minus 4° C (7° F), shall not exceed 4 seconds. (Appendix F, Test 7). Digital thermometer displays shall change at a rate that can be noted by the operator or regulatory agency during the thermometric lag test (Appendix F, Test 7).

Bulb. Corning normal, or equally suitable thermometric glass.

AIRSPACE INDICATING THERMOMETER FOR BATCH PASTEURIZERS

Type. Mercury-actuated, direct-reading; contained in corrosion-resistant case, which protects against breakage and permits easy observation of column and scale; bottom of bulb chamber, not less than 51 millimeters (2 inches) and not more than 89 millimeters (3.5 inches), below underside of cover; filling above mercury, nitrogen or equally suitable gas.

Magnification of Mercury Column. To apparent width of not less than 159 millimeters (0.0625 of an inch).

Scale. Shall have a span of not less than 14° C (25° F), including the 66° C (150° F), plus and minus 3° C (5° F); graduated in not more than 1° C (2° F) divisions, with not more than 9° C (16° F) per 25 millimeters (inch) of scale; protected against damage at (105° C) 220° F.

Accuracy. Within 0.5°C (1°F), plus or minus, throughout the specified scale span. (Appendix F, Test 1).

Stem Fittings. Pressure-tight seat or other suitable sanitary fittings. No threads exposed.

RECORDING THERMOMETERS FOR BATCH PASTEURIZERS UTILIZING TEMPERATURES LESS THAN 71°C (160°F)

Case. Moisture proof under normal operating conditions in pasteurization plants.

Scale. Shall have a span of not less than 11° C (20° F), including pasteurization temperature, plus and minus 3° C (5.0° F), graduated in temperature-scale divisions of 0.5° C (1° F), spaced not less than 1.6 millimeter (0.0625 of an inch) apart between 60° C and 69° C (140 F° and 155° F). Provided, that temperature-scale divisions of 0.5° C (1° F), spaced not less than 1 millimeter (0.040 of an inch) apart, are permitted when the ink line is thin enough to be easily distinguished from the printed line; graduated in time-scale divisions of not more than 10 minutes; and having a chord of straight-line length of not less than 6.3 millimeters (0.25 inch), between 63° C and 66° C (145° F and 150° F).

Temperature Accuracy. Within 0.5° C (1° F), plus or minus, between 60° C and 69° C (140° F and 155° F) (Appendix F, Test 2).

Time Accuracy. The recorded elapsed time, as indicated by the chart rotation, shall not exceed the true elapsed time, as compared to an accurate watch, over a period of at least 30 minutes at pasteurization temperature. Recorders for batch pasteurizers may be equipped with spring operated or electrically operated clocks (Appendix F, Test 3).

Pen-Arm Setting Device. Easily accessible; simple to adjust.

Temperature Sensing Device. Protected against damage at a temperature of 105° C (220° F).

Submerged Stem Fitting. Pressure-tight seat against inside wall of holder, no threads exposed to milk or dairy products. Distance from underside of ferrule to the sensitive portion of the bulb to be not less than 76 millimeters (3 inches).

Chart Speed. A circular chart shall make one revolution in not more than 12 hours. Two charts shall be used if operations extend beyond 12 hours in 1 day. Circular charts shall be graduated for a maximum record of 12 hours. Strip-charts may show a continuous recording over a 24-hour period.

Chart Support Drive. The rotating chart support drive shall be provided with a pin to puncture the chart in a manner to prevent its fraudulent rotation.

UTILIZING TEMPERATURES GREATER THAN 71° C (160° F)

Batch pasteurizers used solely for 30-minute pasteurization of dairy products at temperature above 71° C (160° F) may use recording thermometers with the following options:

Scale. Graduated in temperature scale divisions of 1° C (2° F), spaced not less than 1 millimeter (.040 of an inch) apart between 65° C and 77° C (150° F and 170° F), graduated in time-scale divisions of not more than 15 minutes and having a chord of straight-line length of not less than 6.3 millimeters (0.25 inch) between 71° C and 77° C (160° F and 170° F).

Temperature Accuracy. Within 1° C (2° F), plus or minus, between 71° C and 77° C (160° F and 170° F).

Chart Speed. A circular chart shall make one revolution in not more than 24 hours and shall be graduated for a maximum record of 24 hours.

RECORDER/CONTROLLERS FOR CONTINUOUS PASTEURIZERS

Case. Moisture proof under normal operating conditions in pasteurization plants.

Chart Scale. Shall have a span of not less than 17° C (30° F), including the temperature at which diversion is set, plus and minus, 7° C (12° F), graduated in temperature scale divisions of 0.5° C (1° F),

~~spaced not less than 1.6 millimeter (0.0625 of an inch) apart at the diversion temperature, plus or minus, 0.5° C (1° F). Provided, that temperature-scale divisions of 0.5° C (1° F), spaced not less than 1 millimeter (0.040 of an inch) apart, are permitted when the ink line is thin enough to be easily distinguished from the printed line, graduated in time-scale divisions of not more than 15 minutes, and having an equivalent 15 minute chord or straight-line length of not less than 6.3 millimeters (0.25 of an inch) at the diversion temperature, plus or minus 0.5° C (1° F).~~

~~**Temperature Accuracy.** Within 0.5° C (1° F), plus or minus, at the temperature at which the controller is set to divert, plus and minus 3° C (5° F) (Appendix F, Test 2).~~

~~**Power Operated.** All recorder/ controllers for continuous pasteurization shall be electrically operated.~~

~~**Pen-Arm Device.** Easily accessible; simple to adjust.~~

~~**Pen and Chart Paper.** Pen designed to give line not over .07 millimeter (0.025 of an inch) wide; easy to maintain.~~

~~**Temperature Sensing Device.** Bulb, tube, spring or thermistor, protected against damage at a temperature of 105° C (220° F). Provided, that recorder controller temperature sensing devices, used on HHST systems, shall be protected against damage at temperatures of 149° C (300° F).~~

~~**Submerge Stem Fitting.** Pressure-tight seat against inside wall of pipe; no threads exposed to milk or dairy products; and location from underside of ferrule to the sensitive portion of the bulb not less than 76 millimeters (3 inches).~~

~~**Chart Speed.** A circular chart shall make one revolution in not more than 12 hours. Two charts shall be used if operations extend beyond 12 hours in one (1) day. Circular charts shall be graduated for a maximum record of 12 hours. Strip-charts may show a continuous recording over a 24-hour period.~~

~~**Frequency Pen.** The recorder/ controller shall be provided with an additional pen-arm for recording, on the outer edge of the chart, the record of the time at which the flow-control device is in the forward-flow, diverted-flow or stopped position. The chart time line shall correspond with the reference arc, and the recording pen shall rest upon the time line matching the reference arc.~~

~~**Controller.** Actuated by same sensor as recorder pen, but cut-in and cut-out response independent of pen-arm movement.~~

~~**Controller Adjustment.** Mechanism for adjustment of response temperature simple, and so designed that the temperature setting cannot be changed or the controller manipulated without detection.~~

~~**Thermometric Response.** With the recorder/controller bulb at room temperature and then immersed in a well stirred water or oil bath at 4°C (7°F) above the cut-in point, the interval between the moment when the recording thermometer reads 7°C (12°F) below the cut-in temperature and the moment of power cut-in shall be not more than 5 seconds (Appendix F. Test 8).~~

~~**Chart Support Drive.** The rotating chart support drive shall be provided with a pin to puncture the chart in a manner to prevent its fraudulent rotation.~~

~~**INDICATING THERMOMETERS USED IN STORAGE TANKS**~~

~~**Scale Range.** Shall have a span not less than 28° C (50° F), including normal storage temperatures, plus and minus 3° C (5° F), with extension of scale on either side permitted and graduated in not more than 1° C (2° F) divisions.~~

~~**Temperature Scale Division.** Spaced not less than 1.6 millimeters (0.0625 of an inch) apart between 2° C and 13° C (35° F and 55° F).~~

~~**Accuracy.** Within 1° C (2° F), plus or minus, throughout the specified scale range.~~

~~**Stem Fitting.** Pressure-tight seat or other suitable sanitary fittings. No threads exposed.~~

~~**RECORDING THERMOMETERS USED IN STORAGE TANKS**~~

~~**Case.** Moistureproof under operating conditions in processing plants.~~

~~**Scale.** Shall have a scale span of not less than 28° C (50° F) including normal storage temperature, plus and minus 3° C (5° F), graduated in not more than 1° C (2° F) divisions, spaced not less than 1 millimeter (0.040 of an inch) apart, are permitted when the ink line is thin enough to be easily distinguished from the printed line and graduated in time scale divisions of not more than 1 hour, having a chord of straight-line length of not less than 3.2 millimeter (0.125 of an inch) at 5° C (40° F). Chart must be capable of recording temperatures up to 83° C (180° F). (Span specifications do not apply to extensions beyond 38° C (100° F).~~

~~**Temperature Accuracy.** Within 1° C (2° F), plus or minus, between specified range limits.~~

~~**Pen-Arm Setting Device.** Easily accessible; simple to adjust.~~

~~**Pen and Chart Paper.** Designed to give line not over .635 millimeter (0.025 of an inch) thick when in proper adjustment; easy to maintain.~~

~~**Temperature Sensor.** Protected against damage at 100° C. (212° F).~~

~~**Stem Fittings.** Pressure-tight seat or other suitable sanitary fitting. No threads exposed.~~

~~**Chart Speed.** The circular chart shall make one revolution in not more than 7 days and shall be graduated for a maximum record of 7 days. Strip chart shall move not less than 25 millimeter (1 inch) per hour and may be used continuously for 1 calendar month.~~

~~**RECORDING THERMOMETERS ON MECHANICAL CLEANING SYSTEMS**~~

~~**Location.** Temperature sensor in the return solution line downstream from process.~~

~~**Case.** Moistureproof under operation conditions.~~

~~**Scale.** Shall have a range from 16° C to 83° C (60° F to 180° F), with extensions of scale on either side permissible and graduated in time-scale divisions of not more than 15 minutes. Above 44° C (110° F), the chart is to be graduated in temperature divisions of not more than 1° C (2° F), spaced not less than 1.6 millimeters (0.0625 of an inch) apart. Provided, that temperature-scale divisions of 1° C (2° F), spaced not less than 1 millimeter (0.040 of an inch) apart, are permitted when the ink line is thin enough to be easily distinguished from the printed line.~~

~~**Temperature Accuracy.** Within 1° C (2° F), plus or minus, above 44° C (110° F).~~

~~**Pen-Arm Setting Device.** Easily accessible; simple to adjust.~~

~~**Pen and Chart Paper.** Designed to make a line not over .635 millimeter (0.025 of an inch) wide; easy to maintain.~~

~~**Temperature Sensor.** Protected against damage at 100° C (212° F).~~

Stem Fitting. Pressure-tight seat against inside wall of pipe; no threads exposed to solution.

Chart Speed. Circular charts shall make one revolution in not more than 24 hours. Strip charts shall not move less than 25 millimeters (1 inch per hour). More than one record of the cleaning operation shall not overlap on the same section of the chart for either circular- or strip-type charts.

INDICATING THERMOMETERS USED IN REFRIGERATED ROOMS

Indicating thermometers used in refrigerated rooms, where milk and dairy products are stored, shall meet the following specifications:

Scale Range. Shall have a span not less than 28° C (50° F), including normal storage temperatures, plus and minus 3° C (5° F), with extensions of scale on either side permitted if graduated in not more than 1° C (2° F) divisions.

Temperature Scale Divisions. Spaced not less than 1.6 millimeter (0.0625 of an inch) apart between 0° C and 13° C (32° F and 55° F).

Accuracy. Within 1° C (2° F), plus or minus, throughout the specified scale ranges.

CRITERIA FOR THE EVALUATION OF COMPUTERIZED SYSTEMS FOR PUBLIC HEALTH CONTROLS

BACKGROUND

Computers are different from hard-wired controls in three major categories. To provide adequate public health protection, the design of computerized public health controls must address these three major differences.

First, unlike conventional hard-wired systems, which provide full-time monitoring of the public health controls, the computer performs its tasks sequentially, and the computer may be in real time contact with the flow diversion device for only one millisecond. During the next 100 milliseconds (or however long it takes the computer to cycle one time through its tasks), the flow diversion device remains in forward flow, independent of temperature in the holding tube. Normally, this is not a problem, because most computers can cycle through 100 steps in their program, many times during one second. The problem occurs when the public health computer is directed away from its tasks by another computer, or the computer program is changed, or a seldom used JUMP, BRANCH, or GOTO instruction diverts the computer away from its public health control tasks.

Second, in a computerized system, the control logic is easily changed because the computer program is easily changed. A few keystrokes at the keyboard will completely change the control logic of the computer program. Conversely, hard-wired systems required tools and a technician to make wiring changes. Once the hard-wired system was properly installed and working, it was never changed. This problem can be solved by sealing the access to the computer, but some procedure is needed to ensure that the computer has the correct program when the computer is resealed by the public health authority.

Finally, some computer experts have stated categorically that no computer program can be written error-free. They were referring primarily to very large programs, with many conditional jumps and branches, with thousands of lines of program code. For these large systems, the programs actually improve with age (the errors are found and corrected under actual conditions of use). For public health controls, the computer program must and can be made error-free, since the programs required for public health control are relatively brief.

~~**GLOSSARY**~~

~~**Address**: A numerical label on each memory location of the computer. The computer uses this address when communicating with the input or output.~~

~~**Computer**: A very large number of on-off switches arranged in a manner to sequentially perform logical and numerical functions.~~

~~**Default mode**: The pre-described position of some memory locations during start-up and standby operations.~~

~~**EAPROM**: An Electrically Alterable, Programmable, Read-Only Memory. Individual memory locations may be altered without erasing the remaining memory.~~

~~**EEPROM:** An Electrically Erasable Programmable, Read-Only Memory. The entire memory is erased with one electrical signal.~~

~~**EPROM:** An Erasable, Programmable, Read-Only Memory. The entire memory is erased by exposure to ultra-violet light.~~

~~**Fail safe**: Design considerations that cause the instrument or system to move to the safe position upon failure of electricity, air, or other support systems.~~

~~**Field alterable**: A devise having a specific design or function that is readily changed by user and/or maintenance personnel.~~

~~**Force off:** A programmable computer instruction that places any input or output in the "off" state, independently of any other program instructions.~~

~~**Force on**: A programmable computer instruction that places any input or output in the "on" state, independently of any other program instructions.~~

~~**Input**: Electrical signals applied to the computer that are used by the computer to make logical decisions on whether or not to activate one or more outputs. Input consists of data from temperature and pressure instruments, liquid level controls, microswitches, and operator-controlled panel switches.~~

~~**Input/Output Terminals**: An electrical panel that provides for the connection of all inputs and outputs to the computer. The input/output address labels are found on this panel. Indicator lights showing the status (on/off) of all inputs and outputs may be available on this panel.~~

~~**Last state switch**: A manually operated switch or software setting that instructs the computer to place all outputs in the "on", "off", or "last state" condition during a start-up. The "last state" position instructs the computer to place the outputs in whatever state (on or off) occurred during the last loss of power.~~

~~**Operator override switch:** A manually operated switch that permits the operator to place any input or output in the on or off position, independently or any program instructions.~~

~~**Output:** Electrical signals from the computer that turn on or off: valves, motors, lights, horns, and other devises being controlled by the computer. Outputs may also consist of messages and data to the operator.~~

~~**Programmable controller**: A computer, with only limited mathematical ability, that is used to control industrial machines, instruments and processes. Most computers used on HTST pasteurizers will be programmable controllers.~~

RAM: Random Access Memory. Memory used by the computer to run programs, store data, read input and control outputs. The computer may either read data from the memory or write data into the memory.

ROM: Read-Only Memory. A memory used by the computer to run its own internal unchangeable programs. The computer may only read from the memory; it cannot write into the memory or alter the memory in any way.

Standby status: The computer is turned on, running, and waiting for instructions to start processing input data. This instruction is usually accomplished by a manually-operated switch.

Status printing: Some computers are programmed to interrupt printing of the chart record and print the status of key set points and conditions such as: cold milk temperature, holding tube temperature, diversion temperature setting and chart speed.

CRITERIA

The following listed criteria shall be complied with for all computers or programmable controllers when applied to HTST, HHST and UHT pasteurization systems used for milk and dairy products. In addition, all systems shall conform to all other existing requirements of these Regulations.

1. A computer or programmable controller used for public health control of pasteurizers must be a system dedicated only to the public health control of the pasteurizer. The public health computer shall have no other assignments involving the routine operation of the plant.

2. The public health computer and its outputs shall not be under the command or control of any other computer system. It shall not have an address to be addressable by any other computer system. A host computer cannot override its commands or place it on standby status. All addresses of the public health computer must be ready to process data at any time.

3. A separate public health computer must be used on each pasteurizing system.

4. The status of the inputs and outputs of the public health computer may be provided as inputs-only, to other computer systems. The wiring connections must be provided with isolation protection such as relays, diodes, or optical-coupling devises to prevent the public health outputs from being driven by the other computer system. Digital outputs from an other computer may be connected to an input of the public health computer in order to request operation of a device controlled by the public health computer.

5. On loss of power to the computer, all public health controls must assume the fail-safe position. Most computers can be placed in standby status by either a program instruction or manual switches. When the computer is in standby status, all public health controls must assume the fail-safe position. Some computers have internal diagnostic checks that are performed automatically during start-up. During this time, the computer places all outputs in default mode. In this default mode, all public health controls must be in the fail-safe position.

6. Some computers or programmable controllers have Input/Output buses with “last state switches” that permit the operator to decide what state the output bus will take on power-up after a shutdown or loss of power. The choices are on, off, or “last state” occurring when the computer lost power. These “last state switches” must be placed in the fail-safe position.

7. The computer performs its tasks sequentially, and for most of real time, the computer outputs are locked in the ON or OFF position, while waiting for the computer to come back through the cycle. Consequently, the computer program must be written so that the computer monitors all inputs,

and updates all outputs on a precise schedule - at least once every second. Most computers will be capable of performing this function many times in one second.

8. Programs must be stored in some form of read-only memory, and be available when the computer is turned on. Tapes or disks are not acceptable.

9. The computer program access must be sealed. Any telephone modem accesses must also be sealed. If the Input/Output Terminals contain “last state switches”, the Input/Output Terminals must be sealed. The vendor must supply the Regulatory Official with procedures and instructions to confirm that the program currently in use by the computer is the correct program. The Regulatory Official will use this test procedure to confirm that the correct program is in use, during a start-up, and whenever the seal is broken.

10. If the computer contains FORCE-ON, FORCE-OFF functions, the computer must provide indicator lights showing the status of the FORCE-ON, FORCE-OFF function. The vendor instructions must remind the Regulatory Official that all FORCE-ON, FORCE-OFF functions must be cleared before the computer is sealed.

11. The Input/Output Terminals of the public health computer shall contain no operator override switches.

12. Computerized systems which provide for printing the recording chart by the computer must ensure that proper calibration is maintained. During chart printing, the computer must not be diverted from its public health tasks for more than one second. Upon returning to public health control, the computer shall complete at least one full cycle of its public health tasks before returning to chart printing.

13. When printing a chart, some systems provide status reports on the chart paper of selected Input/Output conditions. This is usually done by interrupting the printing of the chart and printing the Input/Output conditions. Such interrupts, for status printing, are permitted only when a continuous record is recorded on the chart. When an interrupt is started, the time of the start of the interrupt will be printed on the chart at the beginning of the interrupt and at the end of the interrupt. The time interval during which the computer is diverted from its public health control tasks for status printing shall not exceed one second. Upon returning to public health control, the computer shall complete at least one full cycle of its public health tasks before returning to status printing.

14. When the computer prints the temperature trace of temperature in the holding tube, at specific intervals, rather than a continuously changing line. temperature readings shall be printed not less than once every five seconds, except that during the thermometric lag test, the temperature shall be printed or indicated fast enough that the Regulatory Official can place the temperature sensor in a bath at a temperature 7EF above the diversion setting and accurately determine the point in time when the temperature rises to a point 12EF below the diversion point setting so that the Regulatory Official can start the timing of the thermometric lag test.

15. When the computer prints the frequency pen position (the position of the flow diversion device, forward or divert) at specific intervals, rather than continuously, all changes of position shall be recognized by the computer and printed on the chart. In addition, the frequency pen position and temperature in the holding tube must be printed on the chart in a manner that the temperature in the holding tube can be determined at the moment of a change of position of the flow diversion device.

16. The vendor shall provide a built-in program for test procedures, or a protocol shall be provided so that all applicable public health tests of Appendix F for each instrument can be performed by the

Regulatory Official; i.e. Recording thermometers: temperature accuracy, time accuracy, check against indicating thermometer, thermometric response; Flow Diversion Devices: valve seat leakage, operation of valve stem(s), device assembly, manual diversion, response time, time delay intervals if used; booster pumps: proper wiring, proper pressure control settings; flow promoting devises of public health significance capable of generating flow through the holding tube: holding time in holder, proper wiring interlocks.

17. Computers require high quality (clean) well regulated power supplies to operate reliably and safely. Spurious voltage spikes can cause unwanted changes in computer random access memory (RAM). Some mechanical and electrical components also deteriorate with age. One solution is to have two permanent programs in the computer; one in RAM and one in read-only memory (ROM). Through a self-diagnostic test, these two programs could be compared routinely. If there were differences in the programs, the computer would go into default mode. Another solution would be to down-load the program from ROM to RAM at every start-up. A third solution would be to have the computer read program directly from ROM, that is unchangeable. However, this approach is practical only in large volume applications such as microwave ovens. For most small volume applications, the read-only memories are field alterable, such as erasable, programmable read-only memories (EPROMS), electrically erasable, programmable, read-only memories (EEPROMS) and electrically alterable, programmable read-only memories (EAPROMS). EPROMS, EEPROMS, and EAPROMS cannot be relied upon to maintain a permanent record. Something is needed to ensure that the proper program is in computer memory when the Regulatory Official seals the computer.

18. Computer programs used for Public Health Controls on Pasteurizers must conform to the attached logic diagrams. Minor modifications to these diagrams are permissible to accommodate or delete items that are unique to a specific HTST Pasteurizer system such as; magnetic flow meters used as replacement for timing pump, the flush cycle on the detect stem of the flow diversion device, and the ten minute delay of booster pump and flow diversion device that permits the timing pump to run during cleaning operations. The vendor must provide a protocol in the user's manual so that the installer, user, and/or Regulatory Official can demonstrate that the program performs as designed under actual production conditions. Similar appropriate logic flow should be followed for HHST and aseptic processing systems based on modifying these diagrams as needed.

19. The logic diagrams for the flow diversion device and booster pump show a programmed mechanical cleaning cycle operation as part of the computerized system. Some plant operators may wish to use another computer for mechanical cleaning operations, so that mechanical cleaning programs may be changed by plant personnel, as needed to achieve good plant sanitation. When this is done, the connections between the flow diversion device, booster pump, and plant computer, must be provided with solenoid relays or similar devices on the outputs to the flow diversion device and booster pump to prevent them from being operated by the plant computer, except when the mode switch of the flow diversion device is in the “CIP” position.

DIAGRAM LEGEND

t = Time
T = Temperature
MS = Microswitch
FDV = Flow Divert Valve
FDD = Flow Diversion Device

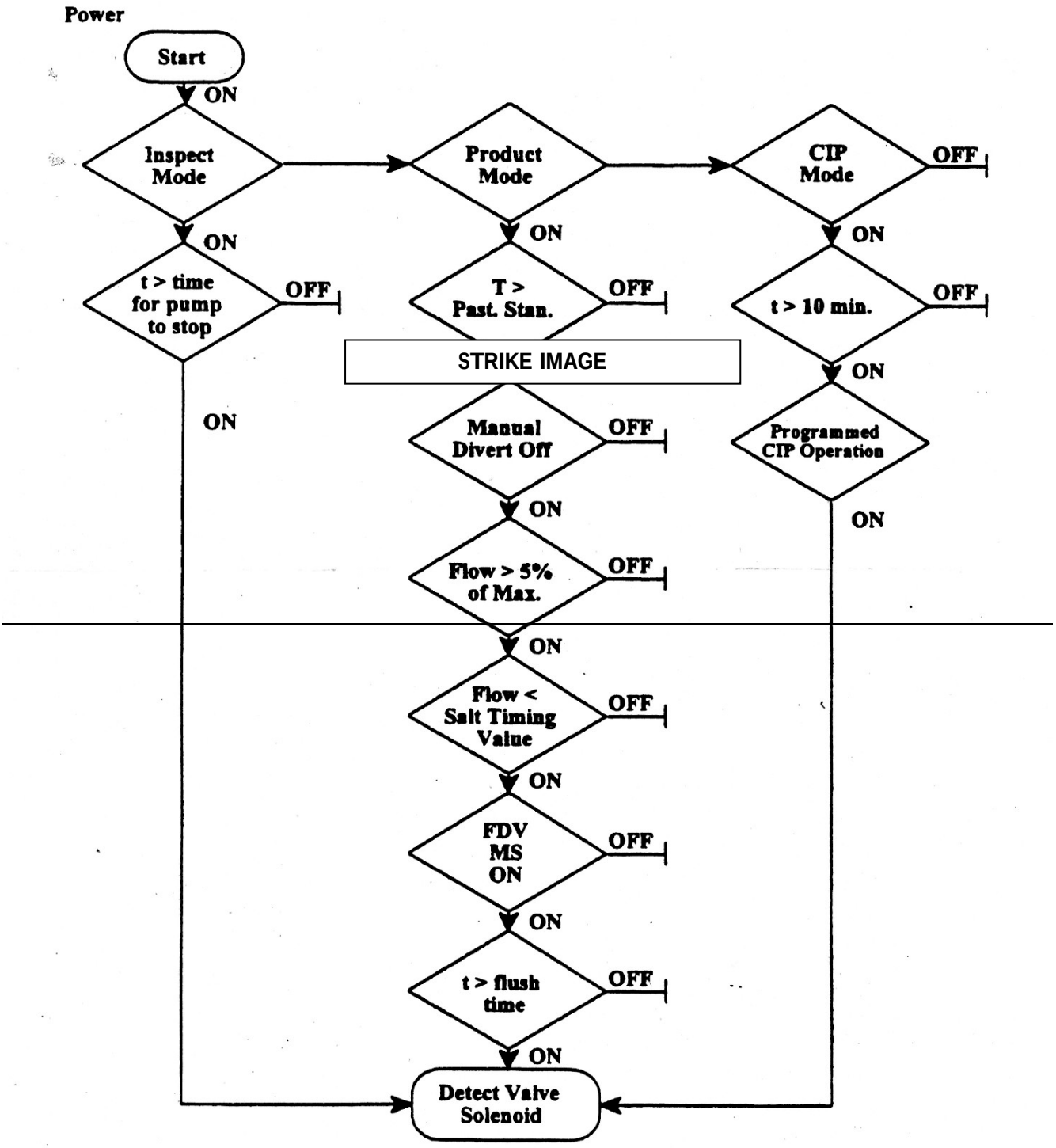

Figure 15. Logic Diagram, Flow Diversion Device, Leak Detect Valve Stem

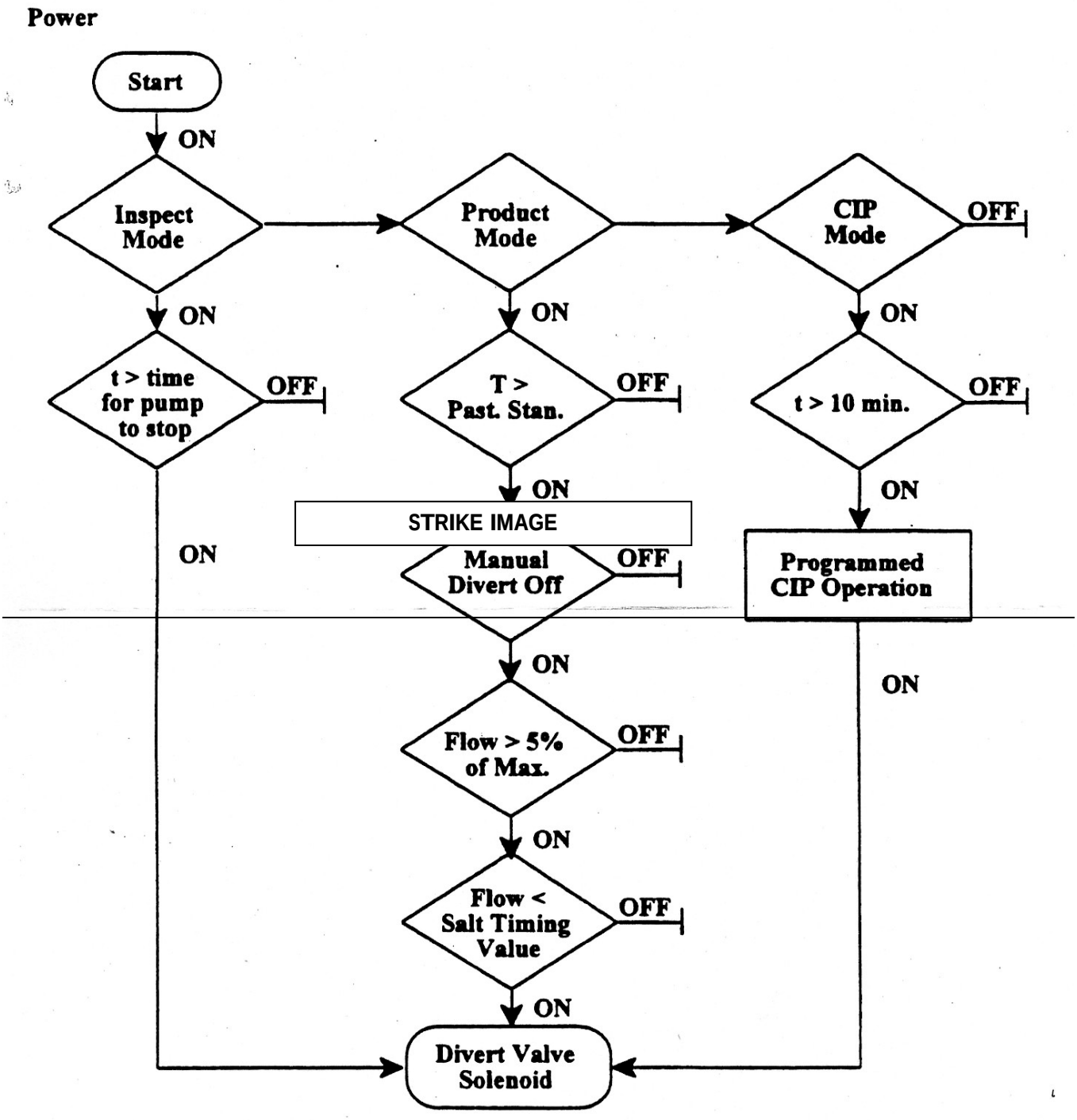

Figure 16. Logic Diagram, Flow Diversion Device, Divert Valve Stem

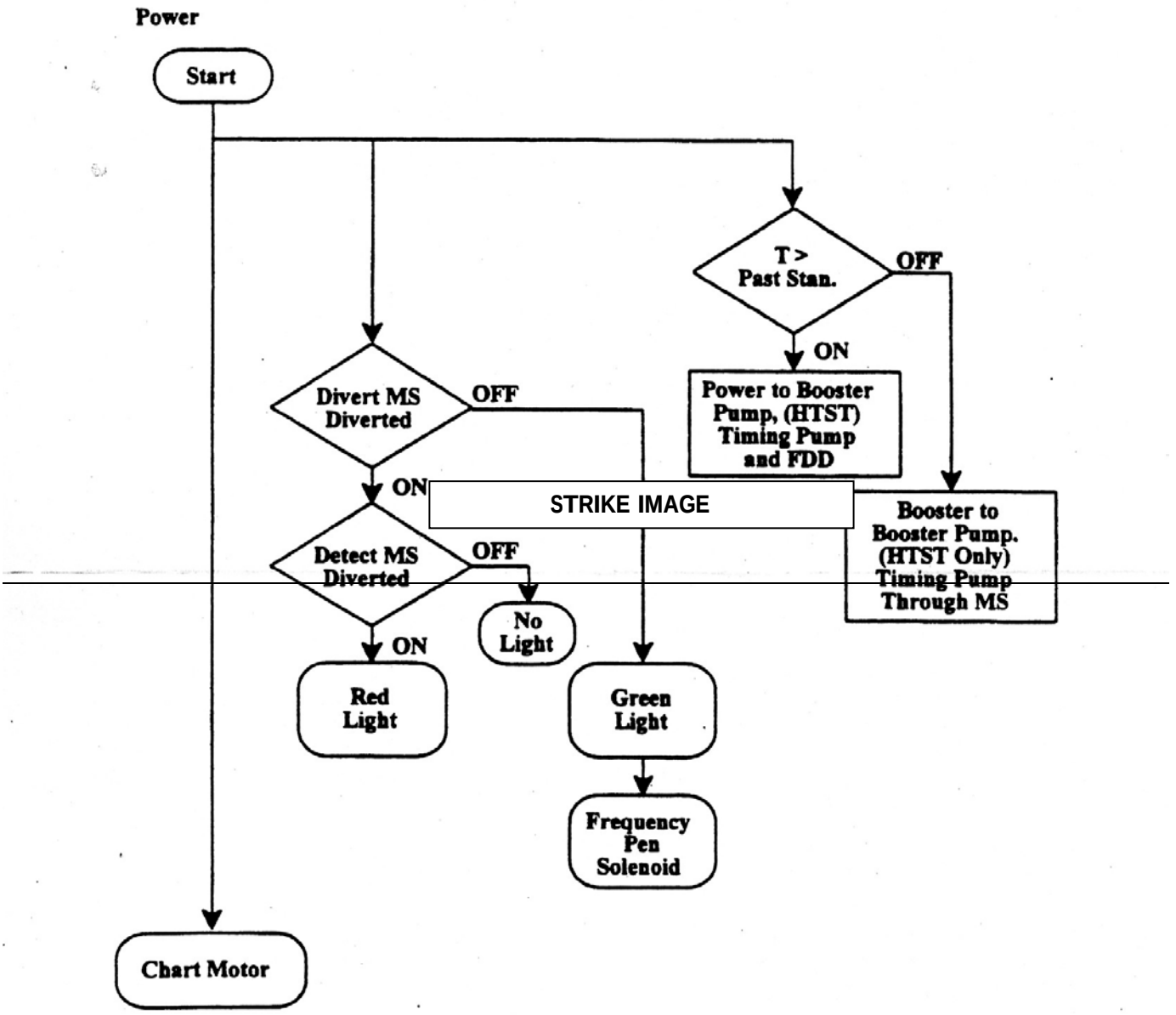

Figure 17. Logic Diagram, Safety Thermal Limit Recorder-Controller

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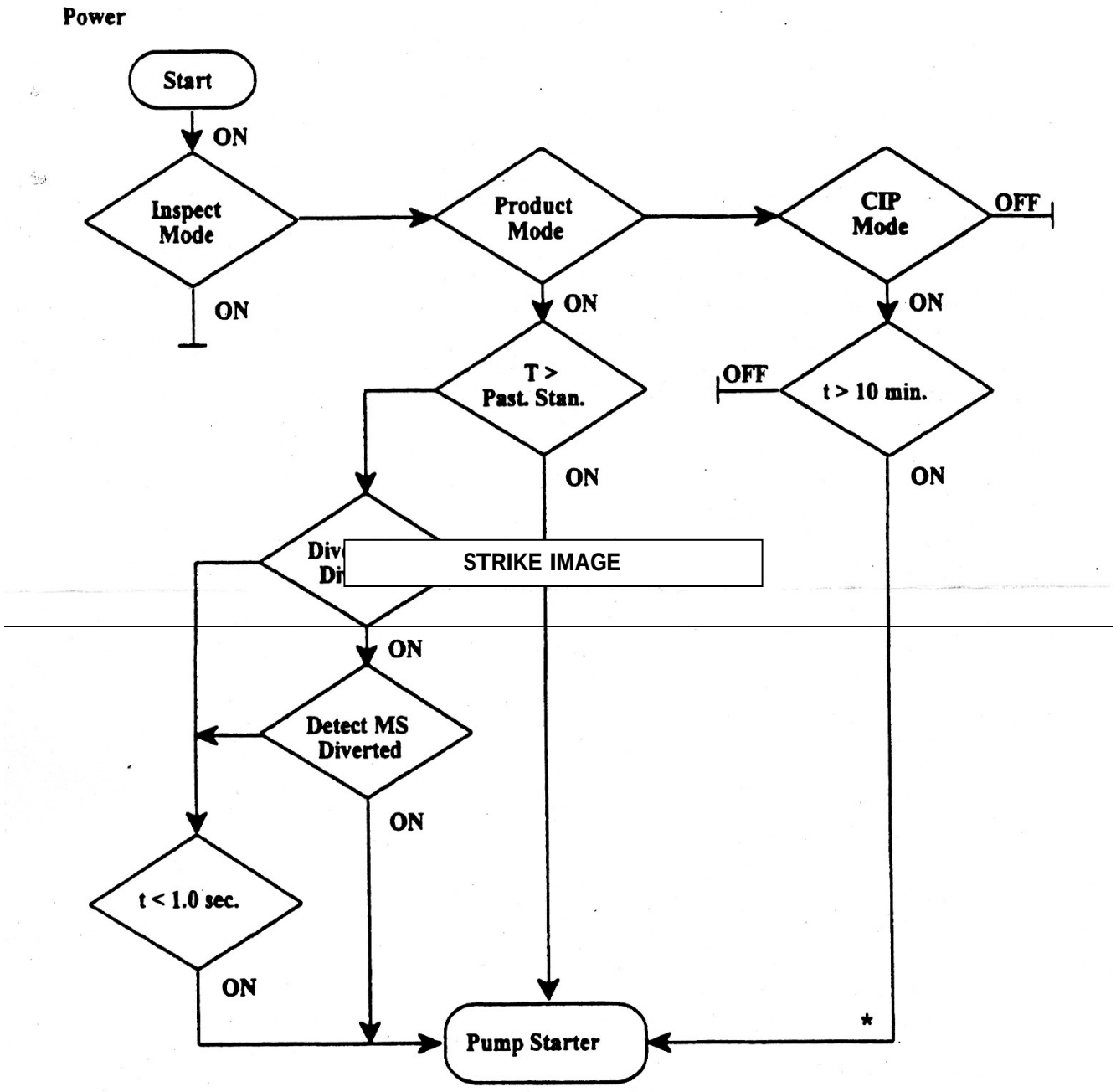
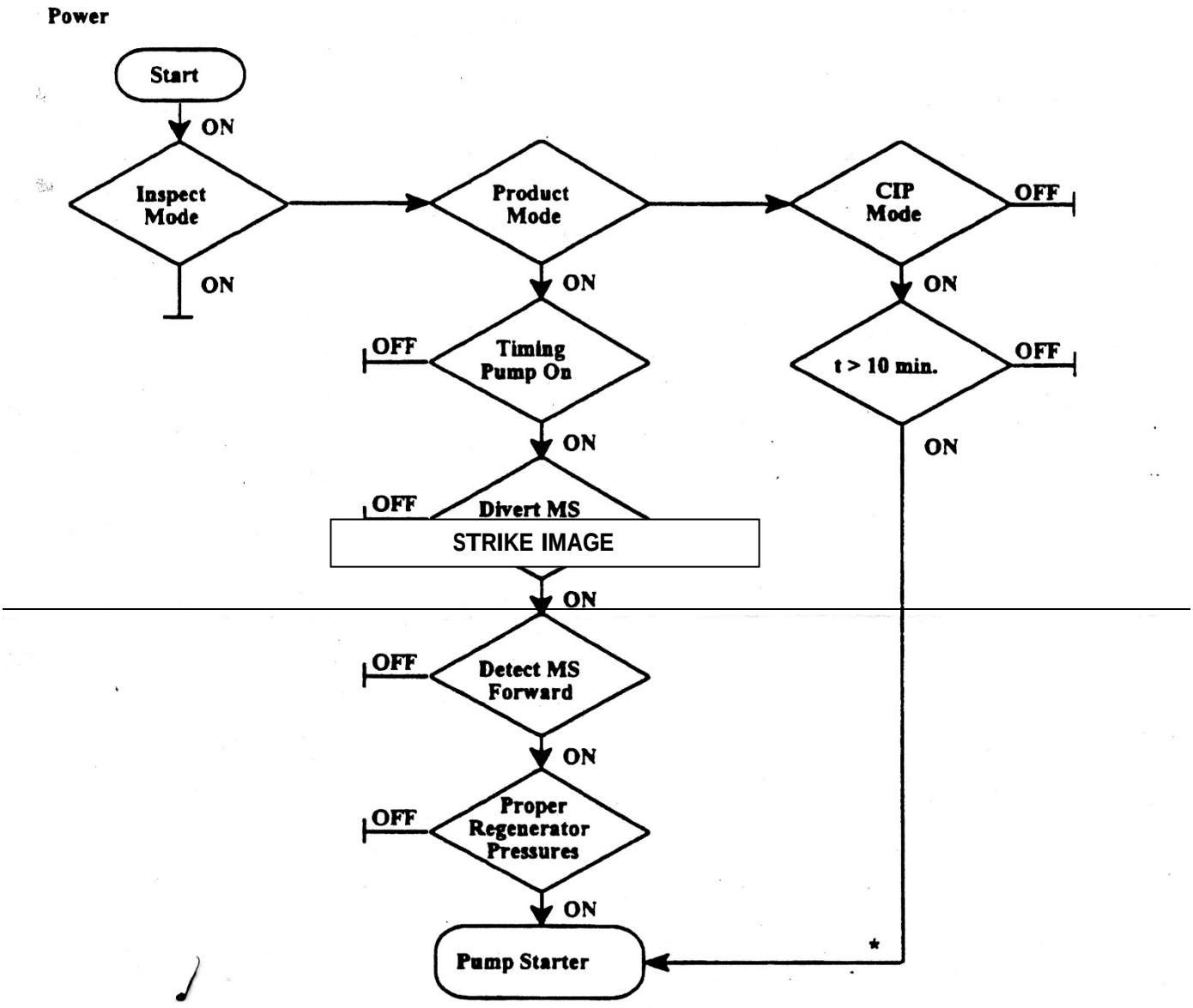


* If the 10 min. time delay is not used when CIP is initiated, this path must be deleted.

Figure 18. Logic Diagram, Timing Pump



* If the 10 min. time delay is not used when CIP is initiated, this path must be deleted.

Figure 19. Logic Diagram, Booster Pump

~~APPENDIX F. PASTEURIZATION EQUIPMENT AND CONTROLS—TESTS~~

~~I. TESTING APPARATUS SPECIFICATIONS~~

~~**TEST THERMOMETER**~~

~~**Type.**~~ ~~Mercury-actuated; readily cleanable; plain front, enameled back; length 305 millimeters (12 inches); immersion point to be etched on stem; mercury to stand in contraction chamber at 0°C (32°F).~~

~~**Scale Range.**~~ ~~At least 7°C (12°F) below and 7°C (12°F) above the pasteurization temperature at which the operating thermometer is used, with extensions of scale on either side permitted; protected against damage at 149°C (300°F).~~

~~**Temperature Represented by Smallest Scale Division.**~~ ~~0.1°C (0.2°F).~~

~~**Number of Degrees per 25 Millimeters (Inch) of Scale.**~~ ~~Not more than 4° C or not more than 6° F.~~

~~**Accuracy.**~~ ~~Within 0.1°C (0.2°F), plus or minus, throughout specified scale range. The accuracy shall be checked against a thermometer which has been tested by the National Institute of Standards and Technology.~~

~~**Bulb.**~~ ~~Corning normal or equally suitable thermometric glass.~~

~~**Case.**~~ ~~Suitable to provide protection during transit and periods when not in use.~~

~~**GENERAL PURPOSE THERMOMETER**~~

~~**Type.**~~ ~~Pocket type~~

~~**Scale Range.**~~ ~~1°C (30°F) to 100°C (212°F), with extension on either side permitted. Protected against damage at 105°C (220°F).~~

~~**Temperature Represented by Smallest Scale Division.**~~ ~~1°C (2°F).~~

~~**Accuracy.**~~ ~~Within 1°C (2°F), plus or minus, throughout the specified scale range. Checked periodically against a known accurate thermometer.~~

~~In the case of mercury actuated general purpose thermometers, the following additional specifications shall apply:~~

~~**Magnification of Mercury Column.**~~ ~~To apparent width of not less than 1.6 millimeter (0.0625 of an inch).~~

~~**Number of Degrees per Inch of Scale.**~~ ~~Not more than 29° C or not more than 52° F.~~

~~**Case.**~~ ~~Metal, provided with a fountain pen clip.~~

~~**Bulb.**~~ ~~Corning normal or equally suitable thermometric glass.~~

~~**ELECTRICAL CONDUCTIVITY MEASURING DEVICES**~~

~~**Type.**~~ ~~Manual or automatic.~~

~~**Conductivity.**~~ ~~Capable of detecting change produced by the addition of 10 ppm of sodium chloride, in water of 100 ppm of hardness.~~

~~**Electrodes.**~~ ~~Standard.~~

~~**Automatic Instruments.**~~ ~~Electric clock, time divisions not over 0.2 of a second.~~

STOPWATCH

Type. Open face, indicating fractional seconds.

Accuracy. Accurate to 0.2 of a second.

Hands. Sweep hand (if applicable), one complete turn every 60 seconds or less.

Scale. Divisions of not over 0.2 of a second.

Crown. Depression of crown or push button starts, stops and resets to zero.

II. TEST PROCEDURES

Equipment and field tests to be performed by the regulatory agency are listed and suitably referenced below. The results of tests shall be recorded on suitable forms and filed as the regulatory agency shall direct.

TEST 1 INDICATING THERMOMETERS— TEMPERATURE ACCURACY

Reference. Item 16p(E).

Application. To all indicating thermometers used for measurement of product temperature during pasteurization or aseptic processing, including airspace thermometers.

Frequency. Upon installation and once each 3 months thereafter or whenever the thermometer has been replaced or the regulatory seal on a digital sensor or the digital control box has been broken.

Criteria. Within 0.25° C (0.5° F) for pasteurization and aseptic processing thermometers and 0.5° C (1° F) for airspace thermometers, plus or minus, in a specified scale range. Provided, that on batch pasteurizers used solely for 30-minute pasteurization of products at temperatures above 71° C (160° F), indicating thermometers shall be accurate to within 0.5° C (1° F) plus or minus.

Apparatus.

A. Test thermometer meeting specifications under Appendix F, Part 1.

B. Water or oil bath and agitator.

C. Suitable means of heating water or oil bath.

Method. Both thermometers exposed to a water or oil medium of uniform temperature. Indicating thermometer reading is compared to the reading of the test thermometer.

Procedure.

A. Prepare a quantity of water in a water bath, or a quantity of oil in an oil bath, or a quantity of other suitable heating media, by raising the temperature of the water, oil or other suitable heating media to within a range of 2°C (3°F) of the appropriate pasteurization or airspace temperature, or aseptic processing temperature.

B. Stabilize the bath temperature and agitate water or oil bath rapidly.

C. Continue agitation. Insert indicating and test thermometers to indicated immersion point during the test.

D. Compare both thermometer readings at the temperature within the test range.

E. Repeat comparison of readings.

F. Record thermometer readings, and thermometer identification or location.

G. Install seals as appropriate on sensors and control boxes of digital thermometers.

Corrective Action. Do not run test if mercury column has been split or capillary tube is broken, as thermometer should be returned to the factory for repair. When the indicating thermometer differs from the test thermometer by more than 0.25°C (0.5°F) and the airspace thermometer by more than 0.5°C (1°F), the indicating thermometer should be adjusted to agree with the test thermometer. Retest the thermometer after adjustment.

TEST 2. RECORDING THERMOMETERS— TEMPERATURE ACCURACY.

Reference. Item 16p(E).

Application. To all recording and recorder/controller thermometers used to record milk temperatures during pasteurization or aseptic processing.

Frequency. Upon installation, at least once each 3 months and whenever the recording penarm setting requires frequent adjustment, when sensing element has been replaced, or when a regulatory seal has been broken.

Criteria. Within 0.5° C (1° F), plus or minus, in specified scale range. Provided, that on batch pasteurizers used solely for 30-minute pasteurization of products at temperatures above 71° C (160° F), recording thermometers shall be accurate to within 1° C (2° F), plus or minus, between 71° C and 77°C (160° F and 170° F).

Apparatus. Pasteurizer or aseptic processor indicating thermometer previously tested against a known accurate thermometer, water baths or suitable vats or containers, agitator, suitable means of heating water baths and ice.

NOTE When this test is performed on recorder/controllers, used with HHST pasteurization or aseptic processing systems operation at or above the boiling point of water, an oil bath shall be substituted for the processing (operating) temperature water mentioned in steps 1,4,5,6, and 7 as well as the boiling water mentioned in steps 2, 3 and 5. The temperature of the oil bath which is used in place of the boiling water shall be above the normal operating range but below the highest temperature division on the chart.

Method. The testing of a recording thermometer for temperature accuracy involves the determination of whether or not the temperature pen-arm will return to within 0.5°C (1°F), or 1° C (2° F) as provided above, of its previous setting, after exposure to high heat and melting ice.

Procedure.

A. Adjust the recording pen to read exactly as the previously tested indicating thermometer, in the temperature range for the process being used after a stabilization period of 5 minutes (two minutes for electronic recording thermometers) at a constant temperature. The bath shall be rapidly agitated throughout the stabilization period.

B. Prepare one water bath by heating to the boiling point and maintain temperature. Prepare a second container with melting ice. Place water baths within working distance of the recorder sensing element.

C. Immerse the sensing element of the recorder in boiling water for not less than 5 minutes (two minutes for electronic recording thermometers).

D. Remove the sensing element from the boiling water and immerse in water at a temperature within the testing range for the process being used. Allow a 5-minute (two minutes for electronic recording thermometers) stabilization period for both indicating and recording thermometers. Compare readings of the indicating and recording thermometers. The recorder reading should be within 0.5°C (1°F) or 1° C (2° F) as provided above, plus or minus, of the indicator thermometer reading.

E. Remove sensing element from the bath, at operating temperatures, and immerse in melting ice for not less than 5 minutes (two minutes for electronic recording thermometers).

F. Remove sensing element from the ice water and immerse in water at a temperature, within the testing range, for the process being used. Allow a 5-minute (two minutes for electronic recording thermometers) stabilization period for both indicating and recording thermometers. Compare readings of the indicating and recording thermometers. The recorder reading should be within 0.5°C (1°F), or 1° C (2° F) as provided above, plus or minus, of the indicator thermometer reading.

G. Re-seal regulatory controls as necessary and record the indicator and recording thermometer readings obtained at steps 1, 4, and 6.

Corrective Action. If the pen does not return to 0.5°C (1°F), or 1° C (2 F) as provided above, plus or minus, of indicating thermometer reading at steps 4 and 6, the recording thermometer should be repaired.

TEST 3. RECORDING THERMOMETERS — TIME ACCURACY

Reference. Item 16p(E).

Application. To all recording and recorder/controller thermometers used to record time of pasteurization or aseptic processing.

Frequency. Upon installation and at least once each 3 months thereafter, or whenever the seal of a programmable recorder/controller has been broken.

Criteria. The recorded time of pasteurization or aseptic processing shall not exceed the true elapsed time.

Apparatus.

A. A watch, graduated at intervals not to exceed 1 minute, and accurate to within 5 minutes in 24 hours.

B. A pair of dividers, or any other suitable device for measuring short distances.

Method. Comparison of the recorded time over a period of not less than 30 minutes with a watch of known accuracy. For recorders utilizing electric clocks, check the cycle on the face plate of clock with a known cycle; observe that the clock is in operating condition.

Procedure.

A. Determine if chart is appropriate to recorder. Insure that the recording pen is aligned with the time arc of the chart at both the center and the outside edge.

B. Inscribe reference mark at the pen point on the recorder chart and record the time.

C. At the end of 30 minutes by the watch, inscribe a second reference mark at the pen point position on the chart.

D. Determine the distance between the two reference marks and compare the distance with the time-scale divisions on the record chart at the same temperature.

E. For electric clocks, remove face plate, compare cycle specification on face plate with the current cycle utilized.

F. Re-seal regulatory controls as necessary and enter finding on chart and initial and record results.

Corrective Action. — If recorded time is incorrect, the clock should be adjusted or repaired.

TEST 4. RECORDING THERMOMETERS — CHECK AGAINST INDICATING THERMOMETERS

Reference. — Item 16p(D).

Application. — To all recording and recording/controller thermometers used to record product temperatures during pasteurization or aseptic processing.

Frequency. — At least once each 3 months by regulatory agency; daily by plant operator.

Criteria. — Recording thermometer shall not read higher than corresponding indicating thermometer.

Apparatus. — No supplementary materials required.

Method. — This test requires only that the reading of the recording thermometer be compared with that of the indicating thermometer at a time when both are exposed to a stabilized pasteurization or aseptic processing temperature.

Procedure. —

A. While the indicating and recording thermometers are stabilized at the same acceptable pasteurization or aseptic processing temperature, read indicating thermometer.

B. Immediately inscribe on the recording thermometer chart a line intersecting the recorded temperature arc at the pen location, record on the chart the indicating thermometer temperature and initial.

C. Record the indicating and thermometer readings.

Corrective Action. — If recording thermometer reads higher than indicating thermometer, the pen should be adjusted by the operator.

TEST 5. FLOW-DIVERSION DEVICE — PROPER ASSEMBLY AND FUNCTION

Reference. — Item 16p(E).

Application. — Test 5 (parts 1 through 9) does not apply to aseptic processing divert systems, valves or other acceptable controls which may be used in place of a flow diversion device. Parts 1 to 4 and 6 to 8 apply to all flow diversion devices used with continuous flow pasteurizers parts 5 and 9 apply only flow diversion devices used with HTST pasteurizers.

Frequency. — Upon installation and at least once each 3 months thereafter, or when a regulatory seal has been broken.

Criteria. The flow-diversion device shall function correctly in operating situations and shall de-energize the metering pump and all other flow promoting devices capable of causing flow through the holding tube in the event of malfunction or incorrect assembly.

5.1 LEAKAGE PAST VALVE SEAT(S)

Apparatus. For single stem flow diversion devices, suitable tools for the disassembly of flow-diversion device and sanitary piping. None for dual stem flow diversion devices.

Method. Observe the valve seat(s) of the flow-diversion device for leakage.

Procedure. With the system operating with water, place the flow-diversion device in diverted-flow position:

In the case of single stem flow diversion devices disconnect the forward flow piping and observe the valve seat for leakage. Check leak escape ports to see if they are open.

In the case of dual stem flow diversion devices, observe the leak detect line discharge or sight glass for leakage.

Corrective Action. If leakage is noted, device must be dismantled and defective gaskets replaced or other suitable repairs made.

5.2 OPERATION OF VALVE STEM(S)

Apparatus. Suitable tools for tightening the packing nut on the stem(s).

Method. Observe flow-diversion device valve stem(s) for ease of movement.

Procedure. When a stem packing nut is used, tighten stem packing nut as much as possible. Operate system at maximum normal operating pressure and place device in forward and diverted flow several times. Note freedom of action of valve stem.

Corrective Action. If valve action is sluggish, suitable adjustment or repair shall be made to permit stem to act freely in all positions, with packing nut, when used fully tightened.

5.3 DEVICE ASSEMBLY- SINGLE STEM DEVICE

Apparatus. Sanitary fitting wrench.

Method. During diverted flow, by temperature, observe function of metering pump and all other flow promoting devices capable of causing flow through the holding tube when flow-diversion device is improperly assembled.

Procedure.

A. With system in operation below the required process temperature, unscrew by one-half turn, the 13H hex nut which holds the top of the valve to the valve body. This should de-energize the metering pump and all other flow promoting devices capable of causing flow through the holding tube. This test should be run with no piping connected to the forward flow port of the device since there can be sufficient force from the piping to keep the forward flow port tightly clamped even though the hex nut is loosened. Re-tighten the 13H hex nut.

B. With the HTST system in operation below the required process temperature, remove the connecting key located at the base of the valve stem. The metering pump and all other flow promoting devices capable of causing flow through the holding tube should be de-energized.

C. Re-seal regulatory controls as necessary and attempt to restart the metering pump and each flow promoting device capable of causing flow through the holding tube. None of these flow promoting devices should start or operate.

Corrective Action. If any flow promoting device fails to respond as indicated, immediate checks of the device assembly and wiring are required to locate and correct the cause.

5.4 DEVICE ASSEMBLY, DUAL STEM DEVICE

Apparatus. None

Method. Observe function of metering pump and all other flow promoting devices capable of causing flow through the holding tube when flow-diversion device is improperly assembled.

Procedure.

A. With the device in diverted-flow, by temperature, when the flow-diversion device is properly assembled.

B. Move the device to the forward-flow position and disconnect stem from actuator.

C. Move the device to the diverted-flow position and turn on the metering pump and all other flow promoting devices capable of causing flow through the holding tube. The metering pump and each of the other flow promoting devices must be de-energized and must not run. If any pump starts momentarily and then stops, it may indicate improper wiring of the one second time delay as allowed in 16p.B.2.b.10. Separators must be effectively valved out of the system.

D. Reassemble the device by moving it to the forward-flow position and reconnecting the stem to the actuator.

E. Re-seal regulatory controls as necessary and repeat the procedure for the other actuator.

Corrective Action. If any of the flow promoting devices fail to respond as indicated, an immediate check of the device assembly and wiring is required to locate and correct the cause.

5.5 MANUAL DIVERSION (when booster pump is installed in the HTST system)

Apparatus. None.

Method. Observe the response of the system to manual diversion.

Procedure.

A. With the HTST system in operation and the flow-diversion device in the forward-flow position, press the manual diversion button. This should (a) cause the valve to assume the divert position, and (b) de-energize the booster pump. The pressure differential between raw and pasteurized milk in the regenerator should be maintained.

B. Operate the HTST system in forward flow and activate the manual divert button until the raw pressure reaches zero (0) psi. Deactivate the manual divert button and observe the raw milk and

pasteurized milk pressures. The pressure differential between raw and pasteurized milk in the regenerator should be maintained. Re-seal regulatory controls as necessary.

Corrective Action. – If the above described actions do not occur when procedures a and b are performed, or the necessary pressure differential between raw and pasteurized milk is not maintained, the assembly and wiring of the HTST system must be immediately reviewed and the indicated deficiencies corrected or proper adjustments made.

5.6 RESPONSE TIME

Apparatus. – Temperature bath, stopwatch. The stopwatch should be used to determine that the response time interval does not exceed 1 second.

Method. – Determine the elapsed time between the instant of the activation of the control mechanism at cut-out temperature on declining temperature and the instant the flow-diversion device takes the fully diverted-flow position.

Procedure. –

A. With the water or oil bath at a temperature above cut-out temperature, allow the water or oil to cool gradually. At the moment the cut-out mechanism is activated, start the watch and the moment the flow-diversion device takes the fully-diverted position, stop the watch.

B. Re-seal regulatory controls as necessary and record results.

Corrective Action. – Should response time exceed 1 second, immediate corrective action must be taken.

5.7 TIME DELAY INTER-LOCK WITH METERING PUMP

Application. – To dual stem flow-diversion devices with a manual forward-flow switch.

Apparatus. – None.

Method. – Determine that the device does not assume a manually induced forward-flow position, while the metering pump or any other flow promoting device capable of causing flow through the holding tube is running.

Procedure. – With the system running in forward flow, move the control switch to the “Inspect” position and observe that the following events automatically occur in sequence:

A. The device immediately moves to the diverted-flow position and the metering pump and all other flow promoting devices capable of causing flow through the holding tube are turned off or in the case of separators, are effectively valved out of the system

B. The device remains in the diverted-flow position while the metering pump and all other flow promoting devices capable of causing flow through the holding tube are running down or in the case of a separator, valving out..

C. After the metering pump stops turning, and all other flow promoting devices capable of causing flow through the holding tube have also stopped, or in the case of separators. have been effectively valved out of the system, the device assumes the forward-flow position.

D. Repeat the above procedure by moving the control switch to the cleaned-in-place (CIP) position.

E. Record test results and seal the control enclosure.

Corrective Action. If the above sequence of events does not occur, either a timer adjustment or wiring change is required.

5.8 CIP TIME DELAY RELAY

Application. To all continuous flow pasteurizer systems in which it is desired to run the timing pump and/or other flow promoting devices during the CIP cycle without the controls required during product processing.

Criteria. When the mode switch on the flow diversion device is moved from process product to CIP, the flow diversion device shall move immediately to the diverted position and remain in the diverted position for at least 10 minutes, with all controls and safe guards required in product mode functioning, before starting its normal cycling in the CIP mode. In HTST systems, the booster pump shall be turned off during the 10 minute time delay.

Apparatus. Stopwatch.

Method. Determine that the set point on the time delay relay is equal to or greater than 10 minutes.

Procedure.

A. Operate pasteurizer in forward flow, with the mode switch on the flow diversion device in the process product position, using water above pasteurization temperature. In systems which are equipped with magnetic flow meter based timing systems, operate the system, at a flow rate below the Flow Alarm set point and above the Loss-of-Signal Alarm set point.

B. Move the mode switch on the flow diversion device to the CIP position. The flow diversion device should move immediately to the diverted position. Start the stopwatch when the flow diversion device moves to the diverted position. Check all controls and safeguards which are required to be in operation when the system is in product mode and in diverted flow. For example, in HTST systems, the booster pump must stop running. Separators located between regenerator sections or on the pasteurized side of the system must be effectively valved out and stuffer pumps for such separators must be de-energized.

C. Stop the stopwatch when the CIP timer times out. On most systems this is when the flow diversion device moves to the forward position for its initial cycle in the CIP mode. At this time the system may be operated without the controls and safe guards normally required during product processing. For example, the booster pump may start at this time.

D. Record results for the office record.

E. Install and seal enclosure over the time delay relay.

Corrective Action. If the flow diversion device does not remain in the diverted position for at least 10 minutes after the mode switch is moved from process product to CIP, increase the set point on the time delay relay and repeat this test procedure. All safe guards and controls which are required to be in operation when the system is in product mode and in diverted flow must be functional during this 10 minutes. If any of these required safeguards or controls are not functional during this 10 minutes, adjustments or repairs are needed. In HTST systems, if the booster pump runs at any time during the 10 minute delay, the booster pump wiring is in need of repair.

5.9 LEAK DETECT VALVE FLUSH - TIME DELAY

~~**Application**. — The minimum one second delay applies to HTST continuous flow pasteurizers in which space between the divert and detect valves is not self draining in the diverted flow position.~~

~~The maximum of five seconds for this delay is not applicable if:~~

~~A. The minimum acceptable holding time in diverted flow can be achieved without the use of a restriction in the divert line, or~~

~~B. The timing system is magnetic flow meter based.~~

~~**Criteria**. — The leak detect valve will be flushed for at least one second and not more that five seconds after the divert valve moves to the forward flow position and before the detect valve moves to the forward position.~~

~~**Apparatus**. — A stop watch.~~

~~**Method**. — Observe the movement of the divert and detect valves to the forward flow position and measure the time interval between the movement of the two valves.~~

~~**Procedure.** —~~

~~A. Move the flow diversion device from the diverted flow position to the forward flow position either by raising the temperature above the cut in set point or by operating the HTST pasteurizer above the cut in temperature in manual divert mode and releasing the manual divert.~~

~~B. When the divert valve begins to move to the forward flow position, start the watch.~~

~~C. When the detect valve begins to move to the forward flow position, stop the watch.~~

~~D. Record the elapsed time.~~

~~E. If the elapsed time is at or above one second and at or below five seconds, seal the time delay.~~

~~**Corrective Action.** — If the elapsed time is less than one second or greater than five seconds, appropriate changes to the system or system controls must be made.~~

~~**TEST 6. LEAK PROTECTOR VALVE**~~

~~**Reference.** — Item 16p(E).~~

~~**Application.** — To all batch (vat) pasteurizer outlet valves and to all batch (vat) pasteurizer inlet valves which are not disconnected and removed during holding, cooling and emptying periods.~~

~~**Frequency.** — Upon installation and at least once each 3 months thereafter.~~

~~**Criteria.** — No leakage of milk past the valve seat in any closed position.~~

~~**Apparatus.** — No supplementary materials required.~~

~~**Method.** — By observing when the piping is disconnected from the valve outlet whether or not leakage past the valve seat occurs when pressure is exerted against the upstream face of the valve.~~

~~**Procedure.** —~~

A. During normal operation, while milk pressure is exerted against the valve inlet, fully close the valve and disconnect the outlet piping.

(Caution: Care must be taken to avoid contamination of the valves or the piping.)

B. Observe whether or not any milk is leaking past the valve seat into the valve outlet.

C. In the case of plug-type valves, turn the valve to the just-closed position, and examine the leakage into the valve outlet.

D. Reconnect the outlet piping.

E. Record identity of the valve, and findings, for the office record.

Corrective Action. — If leakage past the valve seat should occur in any closed position, the valve plug should be re-ground, gaskets replaced, springs replaced or other necessary steps be taken to prevent leakage.

TEST 7. INDICATING THERMOMETERS ON PIPELINES— THERMOMETRIC RESPONSE

Reference. — Item 16p(E).

Application. — To all HTST indicating thermometers located on pipelines and used for determination of milk temperatures during pasteurization.

Frequency. — Upon installation and once each three (3) months thereafter, and whenever the seal on a digital thermometer has been broken.

Criteria. — Four (4) seconds under specified conditions.

Apparatus. — Stopwatch, water bath, agitator, heat supply and indicating thermometer from pasteurizer.

Method. — By measuring the time required for the reading of the thermometer being tested to increase 7°C (12°F) through a specified temperature range (temperature range must include pasteurization temperature). The temperature used in the water bath will depend upon the scale range of the thermometer to be tested.

Procedure. —

A. Immerse indicating thermometer in water bath heated to a temperature at least 11°C (19°F) higher than minimum scale reading on the indicating thermometer. Bath temperature should be 4°C (7°F) higher than maximum required pasteurization temperature for which thermometer is used.

B. Immerse indicating thermometer in bucket of cold water for several seconds to cool it.

NOTE — Continuous agitation of water baths during the performance of steps c, d and e is required. Elapsed time between end of step a and beginning of step c, should not exceed 15 seconds, unless a constant temperature bath is used, so the hot water bath does not cool significantly.

C. Insert indicating thermometer in hot water bath to proper bulb immersion depth.

D. Start stopwatch when indicating thermometer reads 11°C (19°F) below bath temperature.

E. Stop stopwatch when indicating thermometer reads 4°C (7°F) below bath temperature.

F. Record thermometric response time for office record.

Example. For a thermometer used at pasteurization temperature set points of 71.7°C (161°F) and 74.4°C (166°F), a water bath at a temperature of 78.3°C (173°F) could be used. 10.6°C (19°F) lower than 78.3°C (173°F) water bath would be 67.8°C (154°F); 3.9°C (7°F) lower than 78.3°C (173°F) water bath would be 74.4°C (166°F). Hence, after immersing the thermometer which has been previously cooled, in the 78.3°C (173°F) bath, the stopwatch is started when the thermometer reads 67.8°C (154°F) and stopped when it reads 74.3°C (166°F).

NOTE The test included the pasteurization temperature set points of 71.7°C (161°F) and 74.4°C (166°F). If the pasteurization temperature set points had been 71.7°C (161°F) and 79.4°C (175°F), it would not have been possible to include both set points within a 6.7°C (12°F) span. With these set points the test would have to be done separately for each set point.

Corrective Action. If the response time should exceed four (4) seconds, the thermometer should be replaced or returned for repair.

TEST 8. RECORDER/CONTROLLER—THERMOMETRIC RESPONSE

Reference. Item 16p(E).

Application. To all continuous-flow pasteurizers, except those in which the flow-diversion device is located at the end of the cooler section.

Frequency. Upon installation and at least once each 3 months thereafter.

Criteria. Five seconds, under specified conditions.

Apparatus. Previously tested indicating thermometer (on pasteurizers), stopwatch, water bath, agitator and heat supply.

Method. Measure the time interval between the instant when the recording thermometer reads 7°C (12°F) below the cut-in temperature and the moment of cut-in by the controller. This measurement is made when the sensing element is immersed in a rapidly agitated water bath maintained at 4°C (7°F) above the cut-in temperature.

Procedure.

A. Check and, if necessary, adjust the pen-arm setting of the recording thermometer in the proper reference to agree with the indicating thermometer reading at pasteurization temperature.

B. Determine the cut-in temperature of controller (Test 10), either while in normal operation or by using a water bath.

C. Remove sensing element and allow to cool to room temperature.

D. Heat water bath to 4°C (7°F) above the cut-in temperature while vigorously agitating bath to insure uniform temperature.

E. Immerse recorder/controller bulb in bath. Continue agitation during steps f. and g. below.

F. Start stopwatch when the recording thermometer reaches a temperature of 7°C (12°F) below the cut-in temperature.

G. Stop stopwatch when the controller cuts in.

H. Re-seal regulatory controls as necessary and record thermometric response time for office record.

Corrective Action. If the response time should exceed five (5) seconds, the recorder/controller should be repaired.

TEST 9. REGENERATOR PRESSURE CONTROLS

Reference. Item 16p(E).

9.1 PRESSURE SWITCHES. Used to control operation of booster pumps.

Application. To all pressure switches controlling the operations of booster pumps on HTST pasteurizer systems employing regenerators.

Frequency. Upon installation, each 3 months thereafter, after any change in the booster pump or the switch circuit and/or whenever the pressure switch seal is broken.

Criteria. The booster pump shall not operate unless there is at least a 6.9 kPa (1-pound) pressure differential on the pasteurized milk side of the regenerator.

Apparatus. Sanitary pressure gauge and pneumatic testing device, for checking and adjusting pressure switch settings.

A simple inexpensive pneumatic testing device may be made from a discarded 50 millimeter (2 inch) - 7BX sanitary tee, with two additional 13H nuts, one of which is provided with a 16A cap, drilled and tapped for a 13 millimeters (½ inch) galvanized iron nipple for the air connection. A hose connection is made to a compressed air source in the plant by means of a snap-on fitting. The air pressure can be controlled by an inexpensive pressure reducing valve (range 0-60 psi) followed by a 13 millimeters (½ inch) globe type bleeder valve connected into the side outlet of a 13 millimeters (½ inch) tee installed between the pressure reducing valve and the testing device. The pressure switch to be tested is disconnected from the pasteurizer and connected to another of the outlets of the sanitary tee, and the pressure gauge is connected to the third outlet of the sanitary tee. By careful manipulation of the air pressure reducing valve and the air bleeder valve, the air pressure in the testing device may be regulated slowly and precisely. (In operating the device, care should be taken to avoid exposing the pressure switch and the sanitary pressure gauge to excessive pressure which might damage them. This can be done by first closing off the air pressure regulating valve and opening fully the bleeder valve; these may then be manipulated slowly to bring the air pressure in the testing device within the desired range.) A test light of proper voltage can be placed in series with the pressure switch contact and in parallel with the electrical load (booster pump starter) so the actuation point may be readily determined.

Method. Check and make adjustment of pressure switch so as to prevent the operation of the booster pump unless the pressure of the pasteurized milk side of the regenerator is greater by at least 6.9 kPa (1 psi) than any pressure that may be generated on the raw side.

Procedure.

A. Determine maximum pressure of the booster pump.

(1) Install sanitary pressure gauge in tee at discharge of booster pump.

(2) Operate the pasteurizer with water with the flow-diversion device in forward-flow position, the metering pump operating at minimum speed possible and the booster pump operating at its rated speed. If vacuum equipment is located between the raw outlet from the regenerator and the metering pump, it should be bypassed while this determination is made.

(3) Note maximum pressure indicated by pressure gauge under these conditions.

B. Check and set the pressure switch.

(1) Install a sanitary pressure gauge of known accuracy on the pneumatic testing device to which the pressure switch sensing element should also be connected.

(2) Remove the seal and cover to expose adjustment mechanism on pressure switch.

(3) Operate the testing device and determine the pressure gauge reading at the cut-in point of the pressure switch which will light the test lamp. (If the switch is short circuited, the lamp will be lighted before air pressure is applied.)

(4) The cut-in point should be adjusted, if necessary, so as to occur at a pressure gauge reading at least 6.9 kPa (1 psi) greater than the maximum booster pump operating pressure, as determined under section a. of this method. Where adjustment is necessary, refer to the manufacturer's instructions for adjusting procedures. After adjustment, recheck actuation point and readjust if necessary.

(5) Replace cover, seal the pressure switch and restore sensing element to original location.

(6) Record test the maximum booster pump pressure developed and the pressure switch setting for the office record.

9.2 DIFFERENTIAL PRESSURE CONTROLLER

Application. Part 2.1 applies to all differential pressure controllers used to control the operation of booster pumps on HTST and HHST systems, or used to control the operation of flow-diversion devices on HHST systems and aseptic processing systems, when no vacuum breaker is located downstream from the holding tube.

Part 2.2 Applies only to HTST systems. Part 2.3 Applies to the testing of HHST systems in which the differential pressure controller is used to control the operation of the flow-diversion device. Test 2.3 also applies to aseptic processing systems in which the differential pressure controller is used to control the flow diversion device, product divert system, product divert valve or other acceptable control system.

Frequency. Upon installation, each 3 months thereafter and whenever the differential pressure controller is adjusted or repaired.

Criteria. The booster pump shall not operate, or the pasteurizer shall not operate in forward flow, unless the product pressure in the pasteurized side of the regenerator is at least 6.9 kPa (1 psi) greater than the product pressure in the raw side of the regenerator. When the differential pressure controller is used to control the flow-diversion device on HHST or aseptic processing systems, and improper pressure occurs in the regenerator, the flow-diversion device shall move to the diverted-flow position and remain in diverted flow until proper pressures are re-established in the regenerator and all product-contact surfaces between the holding tube and flow-diversion device have been held at or above the required pasteurization or aseptic processing temperature, continuously and simultaneously for at least the required time.

Apparatus. A sanitary pressure gauge and a pneumatic testing device, described under PRESSURE SWITCHES (Test 9.1) above can be used for checking and adjusting the differential pressure switch setting.

Method. The differential pressure switch is checked and adjusted to prevent the operation of the booster pump, or prevent forward flow, unless the product pressure in the pasteurized, or aseptic, side of the regenerator is at least 6.9 kPa (1 psi) greater than the pressure in the raw side of the regenerator.

9.2.1 CALIBRATION OF DIFFERENTIAL PRESSURE CONTROLLER PROBES

Procedure.

A. Loosen the process connection at both pressure sensors and wait for any liquid to drain through the loose connections. Both pointers, or digital displays, should be within 3.5 kPa (0.5 psi) of .0 kPa (0 psi). If not, adjust pointer(s), or digital display(s), to read 0 kPa (0 pounds psi).

B. Remove both sensors from the processor and mount them in a tee, either at the discharge of the booster pump, or connected to the pneumatic testing device. Note the separation between the two pointers or digital displays. The change in elevations of the sensors will have caused some change in the zero readings.

Turn on the booster pump switch and depress the test push button to operate the booster pump. If the pneumatic testing device is used in lieu of the booster pump, adjust air pressure to the normal operating pressure of the booster pump. Note that the pointer, or digital display reading separation is within 6.9 kPa (1 psi) of that observed before pressure was applied. If not, the instrument requires adjustment or repair.

Record the test results for the office record.

9.2.2 HTST—INTERWIRING OF THE PRESSURE DIFFERENTIAL CONTROLLER WITH THE BOOSTER PUMP

Method. Determine if the booster pump stops when the pressure differential is not properly maintained in the regenerator.

Procedure.

A. Connect the pasteurized pressure sensor to a testing tee with the other end of the tee capped.

(Caution: If there is water in the HTST system, ensure that the recorder/controller probe and the pasteurized sensor ports are capped before the metering pump is turned on.)

B. Turn on the metering pump and the booster pump.

C. Place the recorder/controller probe in hot water which is above the cut-in temperature.

D. Turn up the air supply on tee to provide an adequate pressure differential to start the booster pump.

E. Decrease the air supply to the testing tee until the pressure is less than 14 kPa (2 psi) of the pressure on the raw milk pressure sensor. The booster pump should have stopped. Ensure that the flow diversion device remains in the forward flow position and the metering pump continues to operate.

F. Reseal regulatory controls as necessary and record test results for the office record.

Corrective Action. If the booster pump fails to stop when the pressure differential is not maintained, have the plant maintenance personnel determine and correct the cause.

9.2.3 HHST AND ASEPTIC PROCESSING — INTERWIRING OF THE PRESSURE DIFFERENTIAL CONTROLLER WITH THE FLOW DIVERSION DEVICE IN AN HHST SYSTEM OR AN ACCEPTABLE ALTERNATIVE DEVICE OR SYSTEM IN ASEPTIC PROCESSING EQUIPMENT

Application.—

A. To all differential pressure controllers used to control the operation of flow-diversion devices on HHST systems when no vacuum breaker is located downstream from the holding tube, and:

B. To all differential pressure controllers used to control the operation of flow-diversion devices, product divert systems, product divert valve(s) or other acceptable control systems used in aseptic processing equipment.

C. **Apparatus.**—A sanitary pressure gauge and a pneumatic testing device, described under PRESSURE SWITCHES (Test 9.1) above can be used for checking and adjusting the differential pressure switch setting.

Method.—The differential pressure switch is checked and adjusted to prevent forward flow, unless the product pressure in the pasteurized side of the regenerator is at least 6.9 kPa (1 psi) greater than the pressure in the raw product side of the regenerator. In the case of product to water to product regenerators protected on the pasteurized or aseptic side, the water side of the regenerator shall be considered to be the "raw product" for purposes of this test.

Procedure.—

A. Wire the test lamp in series with the signal from the pressure differential switch to the flow-diversion device.

B. Calibrate the pressure switch and probes (using test 9.2.1).

C.

(1) Adjust the pressure on the pressure switch sensors to their normal operating pressures (with the pasteurized, or aseptic pressure at least 14 kPa (2 psi) higher than the raw product pressure.

(2) The test lamp should be lit. If the test light is not lit increase the pasteurized, or aseptic pressure (or lower the raw product pressure) until the test light is lit.

(3) Gradually lower the pasteurized, or aseptic side (or raise the raw product pressure) until the test light turns off.

(4) The test light should turn off when the pasteurized, or aseptic pressure is 14 kPa (2 psi) or more higher than the raw product pressure.

(5) Note the differential pressure at the point the light turns off.

(6) Gradually raise the pasteurized, or aseptic pressure (or lower the raw product pressure) until the test light turns on.

(7) The test light not should turn on until the pasteurized, or aseptic pressure is greater than 14 kPa (2 psi) higher than the raw product pressure. Note the differential pressure at the point the light turns off.

NOTE—This test may be completed using a pneumatic testing device capable of producing differential pressures on the probes. This device should be capable of being operated (and be operated) in a manner so as to duplicate the conditions described above.

D. Seal the instrument and record the test results for the office record.

9.3. ADDITIONAL HTST TESTS FOR BOOSTER PUMPS

Application.—To all booster pumps used for HTST systems.

Criteria.—The booster pump shall be wired so it cannot operate if the flow-diversion device is in the diverted position or if the metering pump is not in operation.

Apparatus.—A sanitary pressure gauge and pneumatic testing device as described in Test 9.1 and water with a heat source.

9.3.1 BOOSTER PUMPS—INTERWIRED WITH FLOW-DIVERSION DEVICE

Method.—Determine if the booster pump stops by dropping the temperature and causing the flow-diversion device to divert.

Procedure.—

A. Connect the pasteurized pressure sensor to a testing tee with the other end of the tee capped.

(Caution: If there is water in the HTST system, ensure that the recorder/controller probe and the pasteurized sensor ports are capped before the metering pump is turned on.)

B. Turn on the metering pump and the booster pump.

C. Place the recorder/controller probe in hot water which is above the cut-in temperature.

D. Turn up the air supply on tee to provide an adequate pressure differential to start the booster pump.

E. Remove the recorder/controller probe from the hot water.

F. When the flow-diversion device moves to the diverted flow position, the booster pump must stop. Ensure that the pressure differential remains adequate and the metering pump continues to operate.

G. Reseal regulatory controls as necessary and record the test results for office records.

Corrective Action.—If the booster pump fails to stop when the flow-diversion device is in the diverted flow position, have the plant maintenance personnel check the wiring and correct the cause.

9.3.2 BOOSTER PUMPS—INTERWIRED WITH THE METERING PUMP

Method.—Determine if the booster pump stops when the metering pump is off.

Procedure.—

A. Connect the pasteurized pressure sensor to a testing tee with the other end of the tee capped.

(Caution: If there is water in the HTST system, ensure that the recorder/controller probe and the pasteurized sensor ports are capped before the metering pump is turned on.)

B. Turn on the metering pump and the booster pump.

C. Place the recorder/controller probe in hot water which is above the cut-in temperature.

D. Turn up the air supply on tee to provide an adequate pressure differential to start the booster pump.

E. Turn off the metering pump. The booster pump must stop. Ensure that the pressure differential remains adequate and the flow-diversion device remains in the forward flow position.

G. Reseal regulatory controls as necessary and record the test results for the office record.

Corrective Action. If the booster pump fails to stop when the metering pump has been turned off, have the plant maintenance personnel determine and correct the cause.

TEST 10. MILK-FLOW CONTROLS—MILK TEMPERATURE AT CUT-IN AND CUT-OUT

References. Item 16p(B), 16p(E).

Milk-flow controls shall be tested for milk temperature at cut-in and cut-out by one of the following applicable tests at the frequency prescribed:

10.1 HTST PASTEURIZERS

Application. All recorder/controllers used in connection with HTST pasteurizers except those in which the flow-diversion device is located at the end of the cooler section.

Frequency. Upon installation and at least once each three months thereafter by the regulatory agency; daily by the plant operator, or when a regulatory seal has been broken.

Criteria. No forward flow until pasteurization temperature has been reached. Flow diverted before temperature drops below minimum pasteurization temperature.

Apparatus. No supplemental materials needed.

Method. By observing the actual temperature of the indicating thermometer at the instant forward flow starts (cut-in) and stops (cut-out).

Procedure.

A. Cut-in temperature.

(1) While milk or water is completely flooding the sensing element of the recorder/controller and the indicating thermometer, increase the heat gradually so as to raise the temperature of the water or milk at a rate not exceeding 0.5°C (1°F) every 30 seconds. If a water bath is used in place of water or milk flowing through the system, the water bath shall be adequately agitated during this test.

(2) Observe the indicating thermometer reading at the moment the forward flow starts (i.e., flow-diversion device moves). Observe that the frequency pen reading is synchronized with the recording pen on the same reference arc.

(3) Record the indicating thermometer reading on the recorder chart and initial. The regulatory agency shall record test findings.

B. Cut-out temperature.

(1) After the cut-in temperature has been determined, and while the milk or water is above the cut-in temperature, allow the water to cool slowly at a rate not exceeding (0.5°C) 1°F per 30 seconds. Observe the indicating thermometer reading at the instant forward flow stops.

(2) Re-seal regulatory controls as necessary and record the indicating thermometer reading on the recorder chart and initial.

Corrective Action. Should the reading be below the minimum pasteurization temperature, the cut-in and cut-out mechanism and/or the differential temperature mechanism should be adjusted to obtain proper cut-in and cut-out temperatures by repeated tests. When compliance is achieved, seal the controller mechanism.

10.2 HHST PASTEURIZERS AND ASEPTIC PROCESSING SYSTEMS USING INDIRECT HEATING

Application. All HHST pasteurizers and aseptic processing systems using indirect heating. When testing aseptic processing systems, the "product divert system"or "product divert valve" or "acceptable control system" may be substituted for the "flow-diversion device" when it is referenced in this test.

Frequency. Upon installation, and every 3 months thereafter; whenever the thermal controller seal is broken.

Criteria. The pasteurizer or aseptic processor shall not operate in forward flow unless pasteurization or aseptic processing temperature has been achieved. The product flow shall be diverted at a temperature no lower than the chosen pasteurization or aseptic processing standard.

Apparatus. No supplemental materials needed.

Method. The cut-in and cut-out temperatures are determined by observing the actual temperature in the constant temperature bath at which the two sensing elements signal for forward flow (cut-in) and diverted flow (cut-out).

Procedure.

A. Wire the test lamp in series with the control contacts of the sensing element (holding tube). Immerse this sensing element in the constant temperature bath. Raise the bath temperature at a rate not exceeding 0.5°C (1°F) every 30 seconds. Observe the temperature reading at the cut-in temperature. Record the temperature for the office record.

B. After the cut-in temperature has been determined and while the bath is above the cut-in temperature, allow the bath to cool slowly at a rate not exceeding 0.5°C (1°F) per 30 seconds. Observe the temperature reading on the controller when the test lamp goes out (cut-out temperature). Determine that the cut-out temperature on the thermal limit controller is equivalent to or greater than the chosen pasteurization or aseptic processing standard. Where adjustment is necessary, refer to the manufacturer's instructions. After adjustment, repeat the procedure above, and when the results are satisfactory, record the results for the office records.

C. Repeat the procedure for the other sensing element, (flow-diversion device). When proper cut-out temperature has been verified for both sensing elements, seal the controller system.

10.3 HHST PASTEURIZERS AND ASEPTIC PROCESSING SYSTEMS USING DIRECT HEATING

Application. — All HHST pasteurizers and aseptic processing systems using direct heating. When testing aseptic processing systems, the "product divert system" or "product divert valve" or "acceptable control system" may be substituted for the "flow-diversion device" when it is referenced in this test.

Frequency. — Upon installation, every three (3) months thereafter and whenever the thermal limit controller seal is broken.

Criteria. — The pasteurizer or aseptic processor shall not operate in forward flow unless pasteurization or aseptic processing temperature has been achieved. The product flow shall be diverted at a temperature no lower than the chosen pasteurization or aseptic processing standard.

Apparatus. — No supplemental materials needed.

Method. — The cut-in and cut-out temperatures are determined by observing the actual temperature in the constant temperature bath at which each of the three sensing elements signals for forward flow (cut-in) and diverted flow (cut-out).

Procedure. —

A. Wire the test lamp in series with the control contacts of the sensing element (the holding tube). Immerse this sensing element in the constant temperature bath. Raise the bath temperature at a rate not exceeding 0.5°C (1°F) every 30 seconds. Observe the temperature reading on the controller when the test lamp lights (cut-in temperature). Record the temperature for the office record.

B. After the cut-in temperature has been determined, and while the bath is above the cut-in temperature, allow the bath to cool slowly at a rate not exceeding 0.5°C (1°F) per 30 seconds. Observe the temperature reading on the controller when the test lamp goes out (cut-out temperature). Determine that the cut-out temperature, on the thermal limit controller, is equivalent to or greater than the chose pasteurization or aseptic processing standard. Where adjustment is necessary, refer to the manufacturer's instructions. After adjustment, repeat the procedure above and when the results are satisfactory, record the results for the office record.

C. Repeat the procedure for the other two sensing elements, i.e., the vacuum chamber and flow-diversion device. Rewire the test lamp in series with the control contacts from each sensing element, respectively. When proper cut-out temperatures have been verified for all three sensing elements, seal the controller system.

TEST 11. CONTINUOUS FLOW HOLDERS — HOLDING TIME

Reference. — Item 16p(B).

Continuous flow holders shall be tested for holding times by one of the applicable tests.

11.1 HTST PASTEURIZERS — (except for magnetic flow meter systems)

Application. — To all HTST pasteurizers employing a holding time of 15 seconds or longer.

Frequency. — Upon installation, semiannually thereafter; whenever the seal on the speed setting is broken; any alteration is made affecting the holding time, the velocity of the flow (such as, replacement of pump, motor, belt, drive or driven pulleys, or decrease in number of HTST plates or the capacity of holding tube), or whenever a check of the capacity indicates a speedup.

~~**Criteria.** Every particle of milk shall be held for at least 15 seconds in both the forward- and diverted-flow positions.~~

~~**Apparatus.** Electrical conductivity measuring device, capable of detecting change in conductivity, equipped with standard electrodes; table salt (sodium chloride); 50 ml. syringe; stopwatch; and suitable container for salt solution.~~

~~**Method.** The holding time is determined by timing the interval for an added trace substance to pass through the holder. Although the time interval of the fastest particle of milk is desired, the conductivity test is made with water. The results found with water are converted to the milk flow time, by formulation, since a pump may not deliver the same amount of milk as it does water.~~

~~**Procedure.**~~

~~A. Examine the entire system to insure that all flow promoting equipment is operating at maximum capacity and all flow impeding equipment is so adjusted or bypassed as to provide the minimum of resistance to the flow. There shall be no leakage on the suction side of the timing pump.~~

~~B. Adjust variable speed pump to its maximum capacity (preferably with a new belt and full size impellers). Check homogenizers for seals, and/or gears or pulley identification. Check AC variable speed timing pump control boxes for seals.~~

~~C. Install one electrode at the inlet to the holder and the other electrode in the holder outlet. Close the circuit to the electrode located at the inlet to the holder.~~

~~D. Operate the pasteurizer, using water at pasteurization temperature, with the flow-diversion device in the forward-flow position.~~

~~E. Quickly inject 50 ml. of saturated sodium chloride solution into the holder inlet.~~

~~F. Start the stopwatch with the first movement of the indicator of a change in conductivity. Open the circuit to the inlet electrode and close the circuit to the electrode at the outlet of the holder.~~

~~G. Stop the stopwatch with the first movement of the indicator of a change in conductivity.~~

~~H. Record results.~~

~~I. Repeat the test six (6) or more times, until six (6) successive results are within 0.5 seconds of each other. The average of these six (6) tests is the holding time for water in forward flow. When consistent readings cannot be obtained, purge the equipment, check instruments and connections and check for air leakage on the suction side. Repeat tests. Should consistent readings not be obtained, use the fastest time as the holding time for water.~~

~~J. Repeat steps d. through i. for the testing time on water in diverted flow.~~

~~K. With the pump at the same speed and equipment adjusted as in a. above, time the filling of a 38 liter (10-gallon) can with a measured weight of water, using the discharge outlet with the same head pressure as in normal operation. Average the time of several trials. (Since flow rates of the large capacity units make it very difficult to check by filling a 38 liter (10-gallon) can, it is suggested, that a calibrated tank of considerable size be used.)~~

~~L. For all gear type timing pumps, repeat procedure 'k' using milk.~~

NOTE. For those homogenizers used as timing pumps repeat procedure 'k' using milk when the measured holding time for water is less than 120% of the legal holding time.

M. Compute the holding time for milk from one of the following formulas either by volume or by weight. Compute separately for forward flow and diverted flow. Re-seal regulatory controls as necessary.

BY VOLUME

The holding time for milk is equal to the holding time for water times quotient of the time it takes to deliver a volume of milk divided by the time it takes to deliver the same volume of water.

Tm = Tw(Vm/Vw)

In which: Tm = Adjusted product holding time for milk.
Tw = Holding time for water (the salt test results).
Vw = Time (usually in seconds) that it takes to pump a volume of water.
Vm = Time (usually in seconds) that it takes to pump the same volume of milk.

or

BY WEIGHT (Using specific gravity)

The holding time for milk is equal to the specific gravity of milk times the holding time for water times quotient of the time it takes to deliver a measured weight of milk divided by the time it takes to deliver the same weight of water.

Tm = 1.032xTw(Wm/Ww)

In which: 1.032 = the specific gravity of milk
Tm = Adjusted product holding time for milk.
Tw = Holding time for water (the salt test results).
Wm = Time (usually in seconds) that it takes to pump he a measured weight of milk.
Ww =Time (usually in seconds) that it takes to pump the same measured weight of water.

N. Record results for the office record.

Corrective Action. When the computed holding time for milk is less than that required, either in forward flow or diverted flow, the speed of the timing pump shall be reduced or an adjustment made in the holding tube and the timing test repeated until satisfactory holding time is achieved. Should an orifice be used, to correct the holding time in diverted flow, there should be no excessive pressure exerted on the underside of the valve seat of the flow-diversion device. Governors shall be sealed on motors that do not provide a constant speed as provided in Item 16p(B)5b.

Application. To all high-temperature short-time pasteurizers with a Magnetic Flow Meter System, used in lieu of a metering pump.

Frequency. Upon installation, semiannually thereafter, whenever a seal on the Flow Alarm is broken, any alteration is made affecting the holding time, the velocity of the flow or the capacity of holding tube or whenever a check of the capacity indicates a speed up.

Criteria. Every particle of milk shall be held for at least a minimum holding time in both the forward and diverted flow positions.

~~**Apparatus.**~~ ~~Electrical conductivity measuring device, capable of detecting change in conductivity, equipped with standard electrodes, table salt (sodium chloride), 50-ml syringe, stopwatch and a suitable container for salt solution.~~

~~**Method.**~~ ~~The holding time is determined by timing the interval for an added trace substance to pass through the holder.~~

~~**Procedure.**~~

~~A. Examine the entire system to insure that all flow promoting equipment is operating at maximum capacity and all flow impeding equipment is so adjusted or bypassed as to provide the minimum resistance to the flow.~~

~~B. Adjust the set point on the Flow Alarm to its highest possible setting.~~

~~C. Adjust the set point on the Flow Controller to a flow rate estimated to yield an acceptable holding time.~~

~~D. Install one electrode at the inlet to the holder and the other electrode to the holder outlet. Close the circuit to the electrode located at the inlet to the holder.~~

~~E. Operate the pasteurizer, using water, above the pasteurization temperature, with the flow diversion device in the forward flow position.~~

~~F. Quickly inject 50-ml of saturated sodium chloride solution into the holder inlet.~~

~~G. Start the stopwatch with the first movement of the indicator of a change in conductivity. Open the circuit to the inlet electrode and close the circuit to the electrode at the outlet of the holder.~~

~~H. Stop the stopwatch with the first movement of the indicator of a change in conductivity.~~

~~I. Record results.~~

~~J. Repeat the test six (6) or more times, until six (6) successive results are within 0.5 seconds of each other. The average of these six tests is the holding time for water in forward flow. When consistent readings cannot be obtained, purge the equipment, check instruments and connections and check for air leakage on the suction side of the pump, located at the raw product supply tank. Repeat tests. If six (6) consecutive readings cannot be achieved within 0.5 seconds, in forward and diverted flow, the pasteurizing system is in need of repair.~~

~~K. With the Flow Controller at the same set point as in c. above, time the filling of a 38 liter (10-gallon) can with a measured volume of water using the discharge outlet, with the same head pressure as in normal operation. Average the time of several trials. (Since flow rates of the large capacity units make it very difficult to check by filling a 38 liter (10-gallon) can, it is suggested that a calibrated tank of considerable size be used.)~~

~~L. Re-seal regulatory controls as necessary and record this result for the office record.~~

~~**Corrective Action.**~~ ~~When the computed holding time for milk is less than that required, either in forward flow or diverted flow, the set point on the Flow Controller shall be decreased, or adjustment made in the holding tube and the timing test repeated until a satisfactory holding time is achieved. Should an orifice be used to correct the holding time in diverted flow, there should be no excessive pressure exerted on the underside of the valve seat of the flow diversion device.~~

~~**11.2B CONTINUOUS FLOW HOLDERS—FLOW ALARM**~~

Application. To all continuous flow pasteurization and aseptic processing systems using a Magnetic Flow Meter System to replace a metering pump. When testing aseptic processing systems, the "product divert system" or "product divert valve" or "acceptable control system" may be substituted for the "flow-diversion device" when it is referenced in this test.

Frequency. Upon installation, semiannually thereafter, whenever the seal on the Flow Alarm is broken, any alteration is made affecting the holding time, the velocity of the flow or the capacity of holding tube or whenever a check of the capacity indicates a speedup.

Criteria. When flow rate equals or exceeds the value at which the holding time was measured, the Flow Alarm shall cause the flow diversion device to assume the diverted position, even though the temperature of the milk in the holding tube is above pasteurization or aseptic processing temperature.

Apparatus. None.

Method. Adjust the set point of the Flow Alarm so that flow is diverted when the flow rate equals or exceeds the value at which the holding time was measured or calculated (see parts 3 or 4 of this test).

Procedure.

A. Operate the pasteurizer or aseptic processing equipment in forward flow, at the flow rate at which holding time was measured, using water above the pasteurization or aseptic processing temperature.

B. Adjust set point on the Flow Alarm slowly downward until the frequency pen on the Recorder indicates that flow has been diverted.

NOTE. when performing this test on systems which operate above the boiling point of water, be sure that the system is cooling is engaged to avoid the possibility of serious burns.

C. Observe that the flow diversion device moved to the diverted position, while water passing through the holding tube remained above pasteurization or aseptic processing temperature.

D. Re-seal regulatory controls as necessary and record the set point of the Flow Alarm, the occurrence of flow diversion and the temperature of the water in the holding tube, for the office record.

Corrective Action. If the flow diversion device does not move to the diverted position, when the frequency pen of the recorder indicates a diversion, a modification or repair of the control wiring is required.

11.2C CONTINUOUS FLOW HOLDERS—LOW FLOW/LOSS-OF-SIGNAL ALARM

Application. To all continuous flow pasteurization and aseptic processing systems using a Magnetic Flow Meter System to replace a metering pump. When testing aseptic processing systems, the "product divert system" or "product divert valve" or "acceptable control system" may be substituted for the "flow-diversion device" when it is referenced in this test.

Frequency. Upon installation, semiannually thereafter, whenever the seal on the Flow Alarm is broken, or any alteration is made affecting the holding time.

Criteria. Forward flow occurs only when flow rates are above the Loss-of-Signal Alarm set point.

Apparatus. None.

Method. By observing the actions of the frequency pens on the recorder and the position of the flow diversion devise.

Procedure.

A. Operate the pasteurizer or aseptic processing equipment in forward flow, at a flow rate below the Flow Alarm set point and above the loss-of-signal alarm set point, using water.

B. Disrupt power to the magnetic flow meter or decrease the flow through the flow meter below the low flow alarm set point. Observe that the flow diversion devise and both the safety thermal limit recorder frequency pen and the flow rate frequency pen assume the diverted flow position.

C. Re-seal regulatory controls as necessary and record results for the office record.

Corrective Action. If the valve does not divert or the pens do not move. Adjustment of low flow alarm or modification or repair of control wiring is required.

11.2D CONTINUOUS FLOW HOLDERS—FLOW OUT-IN AND CUT-OUT

Application. To all high-temperature short-time pasteurizers using a Magnetic Flow Meter System to replace a metering pump.

Frequency. Upon installation, semiannually thereafter, whenever the seal on the Flow Alarm is broken, any alteration is made affecting the holding time, the velocity of the flow or the capacity of holding tube, or whenever a check of the capacity indicates a speedup.

Criteria. Forward flow occurs only when flow rates are below the Flow Alarm set point and above the Loss-of-Signal Alarm set point.

Apparatus. None.

Method. By observing the recorder readings along with the action of the frequency pen on the recorder.

Procedure.

A. Operate the pasteurizer in forward flow, at a flow rate below the Flow Alarm set point and above the Loss-of-Signal Alarm set point, using water above pasteurization temperature.

B. Using the Flow Controller, increase flow rate slowly until the frequency pen on the recorder indicates a flow diversion (flow cut-out point). The flow diversion device will also assume the diverted position. Observe the reading of flow rate from the recorder, the instant flow cut-out occurs, as indicated by the frequency pen.

C. With the pasteurizer operating on water, above the pasteurization temperature, and with the flow diversion device diverted because of excessive flow rate, slowly decrease flow rate until the frequency pen on the Flow Recorder indicates the start of a forward flow movement (flow cut-in point). Because of the time delay relay described in Test E, the flow diversion device will not move immediately to the forward flow position. Observe the reading from the recorder, the instant flow cut-in occurs, as indicated by the frequency pen.

D. Re-seal regulatory controls as necessary and record results for the office record.

Corrective Action. If the cut-in or cut-out point occurs at a flow rate equal to or greater than the value at which holding time was measured, adjust the Flow Alarm to a lower set point and repeat the test.

~~**11.2E CONTINUOUS FLOW HOLDERS—TIME DELAY RELAY**~~

~~**Application.**—To all high-temperature short-time pasteurizers using a Magnetic Flow Meter System to replace a metering pump.~~

~~**Frequency.**—Upon installation, semiannually thereafter, whenever the seal on the Flow Alarm is broken, any alteration is made affecting the holding time, the velocity of the flow or the capacity of the holding tube, or whenever a check of the capacity indicates a speedup.~~

~~**Criteria.**—Following the flow cut-in, as described in the test for flow cut-in and cut-out, forward flow shall not occur until all product in the holding tube has been held at or above pasteurization temperature for at least the minimum holding time.~~

~~**Apparatus.**—Stopwatch.~~

~~**Method.**—Set time delay equal to or greater than the minimum holding time.~~

~~**Procedure.**—~~

~~A. Operate the pasteurizer in forward flow, at a flow rate below the Flow Alarm set point and above the Loss-of Signal Alarm set point, using water above pasteurization temperature.~~

~~B. Using the Flow Controller, increase flow rate slowly until the frequency pen on the Flow Recorder indicates a diversion movement and the flow diversion device moves to the diverted position. There shall be no time delay between the movements of the frequency pen and the flow diversion device.~~

~~C. With the pasteurizer operating on water, above the pasteurization temperature, with the flow diversion device diverted because of excessive flow rate, slowly decrease flow rate.~~

~~D. Start the stopwatch the instant the frequency pen on the Flow Recorder indicates the start of a forward flow movement.~~

~~E. Stop the stopwatch the instant the flow diversion device starts to move to the forward flow position.~~

~~F. Record results for the office record.~~

~~G. Install and seal enclosure over the time delay relay.~~

~~**Corrective Action.**—If the time delay is less than the minimum holding time, increase the time setting on the time delay and repeat this test procedure.~~

~~**11.3 CALCULATED HOLD FOR INDIRECT HEATING**~~

~~**Application.**—To all HHST pasteurizers using indirect heating.~~

~~**Frequency.**—When installed, semiannually thereafter, whenever the seal on speed setting is broken, whenever any alteration is made affecting the holding time, the velocity of the flow, e.g., replacement of pump, motor, belt, driver or driven pulley, decrease in number of heat-exchange plates or the capacity of holding tube and whenever a check of the capacity indicates a speedup.~~

~~**Criteria.**—Every particle of product shall be held for the minimum holding time in both the forward and diverted-flow positions.~~

~~**Apparatus.**—No supplemental materials needed.~~

Method. Fully developed laminar flow is assumed and holding tube length is calculated. An experimental determination of pumping rate is required; this is accomplished by determining the time required for the pasteurizer to fill a vessel of known volume, converting these data by division to obtain flow rate in gallons per second and multiplying this value by the proper number in Table 5. of this paragraph to obtain the required length of the holding tube. Holding tube lengths for HHST pasteurizers with indirect heating for a pumping rate of one (1) gallon/second are:

Procedure.

Table 5. Holding Tube Length—HHST Pasteurizers—Indirect Heating					
	Tubing Size (inches)				
Holding Time (sec.)	**1**	**1-1/2**	**2**	**2-1/2**	**3**
	Holding Tube Length (inches)				
1.0	723.0	300.0	168.0	105.0	71.4
0.5	362.0	150.0	84.0	52.4	35.7
0.1	72.3	30.0	16.8	10.5	7.14
0.05	36.2	15.0	8.4	5.24	3.57
0.01	7.23	3.0	1.68	1.05	.714

A. Examine the entire system to ensure that all flow promoting equipment is operating at maximum capacity and all flow impeding equipment is so adjusted or bypassed to provide the minimum of resistance to the flow. This means that inline filters must be removed, booster pumps must be in operation and vacuum equipment in the system must be operating at a maximum vacuum. Also, before the tests are begun, the pasteurizer should be operated at maximum flow for a sufficient time to purge air from the system (about 15 minutes) and pipe connections on the suction side of the metering pump should be made tight enough to exclude the entrance of air. With the pasteurizer operating with water, adjust the metering pump to its maximum capacity, preferably with a new belt and full-size impellers.

B. Determine that no flow exists in the diverted line, and measure the time required to deliver a known volume of water at the forward-flow discharge line. Repeat the test at least once to determine that the measurements are consistent.

C. Repeat the steps in paragraphs a. and b. of this procedure in diverted flow by collecting the effluent at the discharge of the divert line.

D. Select the greatest flow rate (shortest delivery time for the known volume) and calculate the flow rate in gallons per second by dividing the known volume by the time required to collect he known volume. Multiply this value with the appropriate value in Table 5. to determine the required holding tube length.

E. Determine the number and type of fittings in the holding tube and convert these to equivalent lengths of straight pipe with the use of Table 6. of this paragraph. Determine the total length of the holding tube by adding the equivalent lengths of the fittings to the measured straight lengths of pipe. Record the number and type of fittings, the number and length of straight pipe and the holding tube configuration for the office record. If the temperature sensor is located at the beginning of the holding tube, the holding tube shall be protected against heat loss by material that is impervious to water. Re-seal regulatory controls as necessary.

Alternate procedure. For pasteurizers of large capacity, the method of measuring flow rate at the discharge of the pasteurizer is inconvenient, the following alternate test procedure may be used. Remove the divert line from the raw-product supply tank and turn off the product pump feeding the raw-product

supply tank. Suspend a sanitary dip stick in the raw-product supply tank and operate the pasteurizer at maximum capacity. Record the time required for the water level to move between two graduations on the dip stick. The volume of water is calculated from the dimensions of the raw-product supply tank and the drop in water level. Flow rate is determined as follows: Divide the volume of water removed from the raw-product supply tank by the time required to remove it.

Corrective Action. If the length of the holding tube is shorter than the calculated length, reseal the metering pump at a slower maximum speed, or lengthen the holding tube, or both, and repeat the above determination.

Table 6. Centerline Distances of 3-A Fittings

3-A (inches) designation				Fitting size	
	1	1-1/2	2	2-1/2	3
Centerline distance (inches)					
2C 90° bend	3.4	4.8	6.2	8.0	9.7
2CG 90° bend	3.1	4.5	5.8	7.6	9.3
2C 90° bend	3.4	4.8	6.2	8.0	9.7
2CG 90° bend	3.1	4.5	5.8	7.6	9.3
2C 90° bend	3.4	4.8	6.2	8.0	9.7
2CG 90° bend	3.2	4.6	6.0	7.7	9.4

11.4 CALCULATED HOLD FOR DIRECT HEATING

Application. To all HHST pasteurizers using direct contact heating.

Frequency. When installed, semiannually thereafter, whenever the seal on the speed setting is broken, whenever any alteration is made affecting the holding time, the velocity of the flow, e.g., replacement of pump, motor, belt, driver or driven pulley, or decrease in the number of heat exchange plates, or the capacity of the holding tube and whenever a check of the capacity indicates a speedup.

Apparatus. No supplemental materials needed.

Criteria. Every particle of product shall be held for the minimum holding time in both forward- and diverted-flow positions.

Method. Fully developed laminar flow and a temperature increase by steam injection of 67°C (120°F) are assumed, the temperature-time standard is chosen by the processor and the required holding tube length is calculated from an experimental determination of pumping rate.

Procedure.

A. Examine the entire system to ensure that all flow promoting equipment is operating at a maximum capacity and all flow impeding equipment is so adjusted or bypassed as to provide the minimum resistance to the flow. Remove in-line filters, make certain booster pumps are operating and that vacuum equipment in the system is operating at maximum vacuum. Also, before the tests are begun, operate the pasteurizer at maximum flow for a sufficient time to purge the air from the system (about 15 minutes) and tighten pipe connections on the suction side of the metering pump

to exclude entrance of air. With the pasteurizer operating on water, adjust the metering pump to its maximum capacity. Determine that no flow exists in the diverted line, and measure the time required to deliver a known volume of water at the discharge of the pasteurizer in forward flow. Repeat the test at least twice to determine that the measurements are consistent.

B. Repeat the last step (a. above) in diverted flow by collecting the effluent at the discharge of the divert line. Select the greatest flow rate, the shortest delivery time for the known volume and calculate the flow rate in gallons per second, by dividing the tube lengths for direct contact heating pasteurizers with a pumping rate of 1 gallon/second are:

Table 7. Holding Tube Length, HHST Pasteurizers, Direct Heating

Tubing Size (inches)					
Holding Time (sec.)	**1**	**1-1/2**	**2**	**2-1/2**	**3**
	Holding Tube Length (inches)				
1.0	810.0	336.0	188.0	118.0	80.0
0.5	405.0	168.0	94.0	59.0	40.0
0.1	81.0	33.6	18.8	11.8	8.0
0.05	40.5	16.8	5.90	5.90	4.0
0.01	8.10	3.0	1.68	1.18	0.8

c. Determine the number and type of fittings in the holding tube, and convert these to equivalent lengths of straight pipe with the use of Table 6. Determine the total length of the holding tube by adding the equivalent lengths of the fittings to the measured lengths of straight pipe. If the actual holding tube length is equivalent to or greater than the required holding tube length, record the number and type of fittings, the number and length of straight pipes and the holding tube configuration, for the office record. Make sure that the holding tube slopes upward at least 6.35 millimeters (0.25 inch) per foot. The holding tube shall also be protected against heat loss with insulation that is impervious to water if the temperature sensor is located at the beginning of the holding tube. Re-seal regulatory controls as necessary.

Alternate procedure. – For pasteurizers of large capacity, the method of measuring flow rate at the discharge of the pasteurizer is inconvenient and the following alternate test procedure may be used. Remove the divert line from the raw product supply tank and turn off the product pump feeding the raw-product supply tank. Suspend a sanitary dip stick in the raw-product supply tank and operate the pasteurizer at maximum capacity. Record the time required for the water level to move between two graduations on the dip stick. Calculate the volume of water from the dimensions of the raw-product supply tank and the drop in water level. Determine flow rate as follows: Divide the volume of water, in gallons, removed from the raw product supply tank by the time, in seconds, required to remove it. Then use Table 7. to calculate the required holding tube length.

Corrective Action. – If the length of the holding tube is shorter than the calculated length. reseal the metering pump at a slower maximum speed, or lengthen the holding tube, or both, and repeat the procedure.

11.5 HOLDING TIME – STEAM INFUSERS WITH STEAM POP OFF VALVE AND VACUUM CHAMBER ORIFICE USED IN PLACE OF A TIMING PUMP

Application. – To all HHST pasteurizers using direct steam infusion heating and using a steam pop off valve and a vacuum chamber orifice in place of a timing pump.

Frequency. – Upon installation, and every 3 months thereafter, or when a regulatory seal has been broken.

Apparatus. – No supplemental materials needed.

~~**Criteria.** Every particle of product shall be held for the minimum holding time in both forward- and diverted-flow positions.~~

~~The following controls are required:~~

~~A. The steam infuser shell or feed line shall be equipped with a pressure relief popoff valve. This pressure relief valve shall be located and sized so that the total pressure inside the infuser can never exceed the set point on this pressure relief valve.~~

~~B. An orifice or restriction, permanently installed in a noticeable fitting, shall be placed in the holding tube just prior to the vacuum chamber. The opening in the orifice or restriction, shall be sized to insure a minimum product residence time at least as long as that specified in the chosen HHST standard.~~

~~C. The size of the opening in the orifice or restriction and the setting of the steam pressure relief valve shall be determined by trial and error. Once an appropriate maximum flow rate has been determined and a legal minimum holding time has been calculated, both the restriction or orifice and the steam pressure setting on the pressure relief valve shall be sealed so that neither can be changed.~~

~~D. The state regulatory authority shall keep records of the orifice or restriction size. They shall also keep records of the location, size, setting and manufacturer of the pressure relief valve.~~

~~**Procedure.**~~

~~A. Examine the entire system to ensure that all flow promoting equipment is operating at a maximum capacity and all flow impeding equipment is so adjusted or bypassed as to provide the minimum resistance to the flow.~~

~~B. The steam pressure in the infuser shall be raised to a level just below the pressure relief point on the pop off valve.~~

~~C. Any back-pressure valves or other variable restrictions in the holding tube shall be normally placed into the fully open position.~~

~~D. All air bleeds to the vacuum chamber shall be closed so that the chamber will be operating under maximum vacuum.~~

~~E. Before the tests are begun, operate the pasteurizer at maximum flow for a sufficient time to purge the air from the system (about 15 minutes) and tighten pipe connections on the suction side of the metering pump to exclude entrance of air.~~

~~F. Determine that no flow exists in the diverted line, and measure the time required to deliver a known volume of water at the discharge of the pasteurizer in forward flow.~~

~~G. Repeat the test at least twice to determine that the measurements are consistent.~~

~~H. Repeat the last step (a. through e. above) in diverted flow by collecting the effluent at the discharge of the divert line.~~

~~I. Select the greatest flow rate, the shortest delivery time for the known volume and calculate the flow rate in gallons per second, by dividing the known volume by the time required to collect the known volume.~~

J. Multiply this value, gallons per second, with the appropriate value in Table 7, to determine the required holding tube length.

K. Holding tube lengths for direct contact heating pasteurizers with a pumping rate of one (1) gallon/second are specified in Table 5.

L. Determine the number and type of fittings in the holding tube, and convert these to equivalent lengths of straight pipe with the use of Table 6. Determine the total length of the holding tube by adding the equivalent lengths of the fittings to the measured lengths of straight pipe.

M. Make sure that the holding tube slopes upward at least 6.35 millimeters (0.25 inch) per foot.

N. The holding tube shall also be protected against heat loss with insulation that is impervious to water if the temperature sensor is located at the beginning of the holding tube.

O. If the actual holding tube length is equivalent to or greater than the required holding tube length, record the number and type of fittings, the number and length of straight pipes and the holding tube configuration, for the office record. Re-seal regulatory controls as necessary.

Corrective Action. – If the length of the holding tube is shorter than the calculated length, lengthen the holding tube and repeat the above determination.

TEST 12. THERMAL LIMIT CONTROLLER FOR CONTROL-SEQUENCE LOGIC

References. – Items 16p(B), 16p(E).

Thermal limit controllers used with HHST and aseptic processing systems that have the flow-diversion device located downstream from the regenerator and/or cooler shall be tested by one of the following applicable tests at the frequency specified.

12.1 HHST PASTEURIZATION AND ASEPTIC PROCESSING—INDIRECT HEATING

Application. – To all HHST pasteurizers and aseptic processing systems using indirect heating. When testing aseptic processing systems, the "product divert system" or "product divert valve" or "acceptable control system" may be substituted for the "flow-diversion device" when it is referenced in this test.

Frequency. – Upon installation, and every three (3) months thereafter, or when a regulatory seal has been broken.

Criteria. – The pasteurizer, or aseptic processing equipment, shall not operate in forward flow until the product surfaces downstream from the holding tube have been sanitized, or in the case of aseptic processing equipment, sterilized. On start up, surfaces shall be exposed to fluid at pasteurization, or in the case of aseptic processing equipment, sterilizing temperature for at least the required pasteurization or sterilization time. If the product temperature falls below the pasteurization or sterilization standard in the holding tube, forward flow shall not be reachieved until the product surfaces downstream from the holding tube have been re-sanitized, or in the case of aseptic processing equipment, re-sterilized.

Apparatus. – A constant temperature bath of water, or oil, and the test lamp from the pneumatic testing device described in Test 9.1 can be used to check the control-sequence logic of the thermal limit controller.

Method. – The control-sequence logic of the thermal limit controller is determined by monitoring the electric signal from the thermal limit controller during a series of immersions and removals of the two sensing elements from a bath heated above the cut-in temperature.

Procedure.—

A. Heat a constant temperature water or oil bath a few degrees above the cut-in temperature on the thermal limit controller. Wire the test lamp in series with the signal from the thermal limit controller to the flow-diversion device. If some processors have time delays built into their control logic, in excess of that required for public health reasons, by pass these timers or account for their effect in delaying forward flow.

B. Immerse the sensing element of the flow-diversion device in the bath, which is above the cut-in temperature. The test lamp should remain unlighted, i.e., diverted flow. Leave the sensing element in the bath.

C. Immerse the sensing element from the holding tube in the bath. The test lamp should light up, i.e., forward flow after a minimum time delay of 1 second for continuous flow pasteurization systems. For aseptic processing systems no delay is required if the filed process includes a documented sterilization period.

D. Remove the sensing element of the flow-diversion device from the bath. The test lamp should remain lighted, i.e., forward flow.

E. Remove the holding tube sensing element from the bath. The test lamp should go out immediately, i.e., diverted flow.

F. Re-immerse the sensing element of the holding tube in the bath. The test lamp should remain unlighted, i.e., diverted flow. Re-seal regulatory controls as necessary.

Corrective Action.—If the control-sequence logic of the thermal limit controller does not follow this pattern, the instrument shall be rewired to conform to this logic.

12.2 HHST PASTEURIZATION AND ASEPTIC PROCESSING—DIRECT HEATING

Application.—To all HHST pasteurizers and aseptic processing systems using direct contact heating. When testing aseptic processing systems, the “product divert system”or “product divert valve” or “acceptable control system” may be substituted for the “flow-diversion device” when it is referenced in this test.

Frequency.—Upon installation and every three (3) months thereafter, or when a regulatory seal has been broken.

Criteria.—The pasteurizer, or aseptic processing equipment, shall not operate in forward flow until the product surfaces downstream from the holding tube have been sanitized, or in the case of aseptic processing equipment, sterilized. On start up, surfaces shall be exposed to fluid at pasteurization, or in the case of aseptic processing equipment, sterilizing temperature for at least the required pasteurization or sterilization time. If the product temperature falls below the pasteurization or sterilization standard in the holding tube, forward flow shall not be reachieved until the product surfaces downstream from the holding tube have been re-sanitized, or in the case of aseptic processing equipment, re-sterilized.

Apparatus.—A constant temperature bath of water, or oil, and the test lamp from the pneumatic testing device described in Test 9.1 can be used to check the control-sequence logic of the thermal limit controller.

Method.—The control-sequence logic of the thermal limit controller is determined by monitoring the electric signal from the thermal limit controller during a series of immersions and removals of the three sensing elements from a bath heated above the cut-in temperature.

Procedure.—

A. Heat a water or oil bath to a constant temperature, a few degrees above the cut-in temperature on the thermal limit controller. Wire the test lamp in series with the signal from the thermal limit controller to the flow-diversion device. If some processors have time delays built into their control logic, in excess of that required for public health reasons, bypass these timers or account for their effect in delaying forward flow. Before performing this test, make sure the pressure switches, which must be closed to achieve forward flow, have also been bypassed.

B. Immerse the sensing element from the flow-diversion device in the bath which is above the cut-in temperature. The test lamp should remain unlighted, i.e., diverted flow. Remove this sensing element from the bath.

C. Immerse the sensing element, from the vacuum chamber, in the bath. The test lamp should remain unlighted, i.e., diverted flow. Remove the sensing element from the bath.

D. Immerse two sensing elements, from the vacuum chamber and flow-diversion device, in the bath. The test lamp should remain unlighted, i.e., diverted flow. Leave the two sensing elements in the bath.

E. Immerse the third sensing element, from the holding tube, in the bath. The test lamp should light up, i.e., forward flow, after a minimum time delay of 1 second for continuous flow pasteurization systems. For aseptic processing systems no delay is required if the filed process includes a documented sterilization period.

F. Remove one sensing element, the flow-diversion device, from the bath. The test lamp should remain lighted, i.e., forward flow.

G. Remove another sensing element, the vacuum chamber, from the bath. The test lamp should remain lighted, i.e., forward flow.

H. Remove the last sensing element, the holding tube, from the bath. The test lamp should go out, i.e., diverted flow, immediately.

I. Re-immerse the sensing element, holding tube, in the bath. The test lamp should remain unlighted, i.e., diverted flow. Re-seal regulatory controls as necessary.

Corrective Action.—If the control-sequence logic of the thermal limit controller does not follow the pattern set out in the procedure section, the instrument shall be rewired to conform to this logic.

TEST 13. SETTING OF CONTROL SWITCHES FOR PRODUCT PRESSURE IN THE HOLDING TUBE

Reference.—Item 16p(B).

Application.—To all HHST pasteurizers and aseptic processing systems which are capable of operating with product in forward flow mode, with less than 518 kPa (75 psig) pressure in the holding tube. When testing aseptic processing systems, the “product divert system”or “product divert valve” or “acceptable control system” may be substituted for the “flow-diversion device” when it is referenced in this test.

Frequency.—Upon installation, every three (3) months thereafter, whenever the pressure switch seal is broken and whenever the operating temperature is changed.

Criteria.—The pasteurizer or aseptic processor shall not operate in forward flow unless the product pressure in the holding tube is at least 69 kPa (10 psi) above the boiling pressure of the product.

~~**Apparatus.** A sanitary pressure gauge and a pneumatic testing device described in Test 9.1 can be used for checking and adjusting the pressure switch setting.~~

~~**Method.** The pressure switch is checked and adjusted so as to prevent forward flow unless the product pressure in the holding tube is at least 69 kPa (10 psi) above the boiling pressure of the product.~~

~~**Procedure.**~~

~~A. From Figure 20 determine the pressure switch setting necessary for the operating temperature (not the diversion temperature) being used in the process. Install the sanitary pressure gauge, of known accuracy, and the pressure switch sensing element on the pneumatic testing device.~~

~~B. Remove the seal and cover to expose the adjustment mechanism on the pressure switch. Place the test lamp in series with the pressure switch contacts or use some other method to monitor the cut-in signal.~~

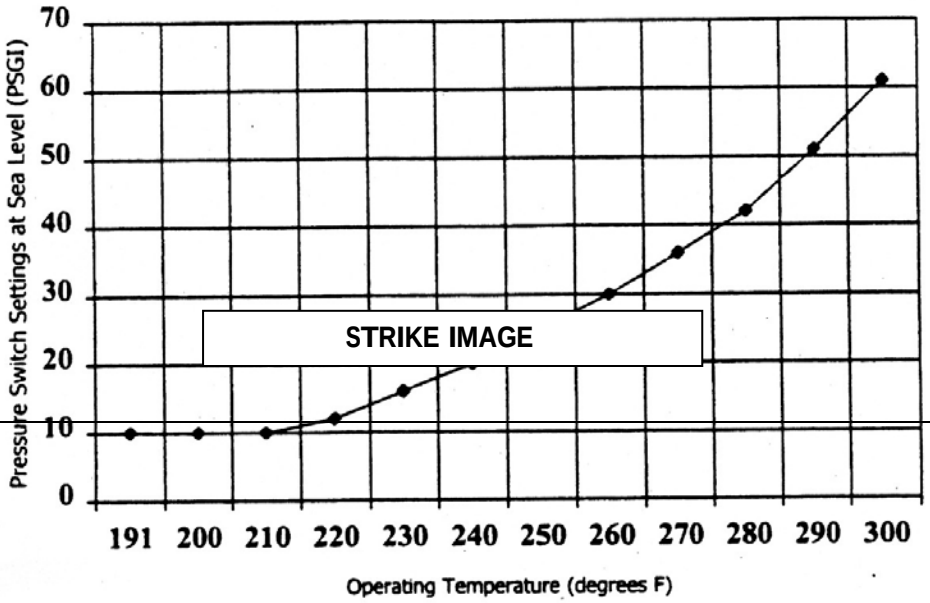
~~C. Apply air pressure to the sensing element and determine the pressure gauge reading at the cut-in point of the switch which sill light the test lamp. If the switch is short circuited, the lamp will be lit before air pressure is applied.~~

~~D. Determine that the cut-in pressure on the switch is equivalent to or greater than the required pressure from Figure 20. Where adjustment is necessary, refer to the manufacturer's instructions.~~

~~E. After adjustment, repeat the procedure.~~

~~F. When the results are satisfactory, seal the pressure switch setting and record the results for the office record.~~

~~For each operating temperature on HHST pasteurizers or aseptic processing systems using direct contact heating, the product pressure switch setting is as follows:~~



This pressure setting shall be adjusted upward by the difference between local normal atmospheric pressure and sea level.

Figure 20. Pressure Switch Setting

5806

5807 ~~**TEST 14. SETTING OF CONTROL SWITCHES FOR DIFFERENTIAL PRESSURE ACROSS THE**~~
5808 ~~**INJECTOR**~~

5809 ~~**Application.** To all HHST pasteurizers and aseptic processing systems using direct contact heating.~~
5810 ~~When testing aseptic processing systems, the "product divert system" or "product divert valve" or~~
5811 ~~"acceptable control system" may be substituted for the "flow-diversion device" when it is referenced in this~~
5812 ~~test.~~

5813 ~~**Frequency.** Upon installation, every three (3) months thereafter and whenever the differential pressure~~
5814 ~~controller seal is broken.~~

5815 ~~**Criteria.** The pasteurizer or aseptic processor shall not operate in forward flow unless the product~~
5816 ~~pressure drop across the injector is at least 69 kPa (10 psi).~~

5817 ~~**Apparatus.** A sanitary pressure gauge and a pneumatic testing device described in Test 9.1 can be~~
5818 ~~used for checking and adjusting the differential pressure controller.~~

5819 ~~**Method.** Check the differential pressure switch and adjust it so as to prevent forward flow, unless the~~
5820 ~~differential pressure across the injector is at least 69 kPa (10 psi).~~

5821 ~~**Procedure.**~~

A. Remove both pressure sensing elements from their original locations on the pasteurizer, or aseptic processor. Install a sanitary pressure gauge of known accuracy and the pressure sensing element, that is installed prior to the steam injection, on the pneumatic testing device.

B. Leave the other pressure sensing element open to the atmosphere, but at the same height as the sensing element connected to the pneumatic testing device.

C. Wire the test lamp in series with the microswitch of the differential pressure controller or use the method provided by the instrument manufacturer to monitor the cut-in signal.

D. Apply air pressure to the sensing element and determine the pressure gauge reading at the cut-in point of the differential pressure switch that will light the test lamp.

E. Determine that the differential pressure cut-in on the controller is at least 69 kPa (10 psi).

F. After adjustment, repeat the procedure.

G. When the results are satisfactory, seal the instrument and record the results for the office record.

APPENDIX G. DEFINITIONS AND STANDARDS OF IDENTITY FOR MILK AND DAIRY PRODUCTS AND FEDERAL FOOD, DRUG, AND COSMETIC ACT (1998)

DEFINITIONS

The following definitions and standards of identity are contained in Title 21 Code of Federal Regulations (CFR) 1999, and the Colorado Revised Statutes (C.R.S.) 1998.

21 CR 101 Food Labeling

21 CFR 130.10 - Requirements for Foods Named by Use of a Nutrient Content Claim and a Standardized Term.

21 CFR 110 - Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food

21 CFR 113 - Thermally Processed Foods Packaged In Hermetically Sealed Containers.

21 CFR 113.5 - Current Good Manufacturing Practice.

21 CFR 113.10 Personnel.

21 CFR 113.40 Equipment and Procedures.

21 CFR 113.60 Containers.

21 CFR 113.83 Establishing Scheduled Processes.

21 CFR 113.89 - Deviations in Processing, Venting, or Control of Critical Factors.

21 CFR 113.100 Processing and Production Records.

21 CFR 173.310 Boiler Water Additives.

21 CFR 133.3 Milk, Non-Fat Milk and Cream

21 CFR 133.102 - 133.127 & 133.133- 133.196 Cheese and Related Cheese Products Standards

~~21 CFR 135.110 Ice Cream and Frozen Custard~~

~~21 CFR 135.115 Goat's Milk Ice Cream~~

~~21 CFR 135.130 Mellorine~~

~~21 CFR 135.160 Water Ices~~

~~§25-5.5-102 C.R.S., Butter Standards~~

~~§25-5.5-108 C.R.S., Condensed Milk and Cream~~

~~§25-5.5-110 C.R.S., Milk, Cream and Cheese Standards~~

~~§25-5.5-203-204 C.R.S., Imitation Dairy Products~~

~~§25-5.5-303 C.R.S., Ice Cream Standards~~

~~§25-5.5-304 C.R.S., French Ice Cream and Custards Standards~~

~~§25-5.5-305 C.R.S., Ice Milk Standards~~

~~§25-5.5-305.5 C.R.S., Low-Fat Frozen Dairy Dessert Standards~~

~~§25-5.5-306 C.R.S., Sherbet Standards~~

~~§25-5.5-307 C.R.S., Water Ice Standards~~

~~APPENDIX N. DRUG RESIDUE TESTING~~

~~I. INDUSTRY RESPONSIBILITIES~~

~~A. Monitoring and Surveillance~~

~~Industry shall screen all bulk milk pickup tankers for beta lactam drug residues. Additionally, other drug residues shall be screened for by employing a random sampling program on bulk milk pickup tankers. Samples collected under this random sampling program shall be analyzed as specified by FDA. (See M-a-75).~~

~~Bulk milk pickup tanker testing shall be completed prior to processing the milk. Industry samplers shall be evaluated according to the requirements specified in Section 6. – The Examination of Milk and Dairy Products. Bulk milk pickup tanker samples found to be positive for drug residues shall be retained as determined necessary by the regulatory agency. Industry shall also record all sample results and retain such records for a period of six months.~~

~~B. Reporting and Farm Traceback~~

~~When a bulk milk pickup tanker is found to be positive for drug residues, the regulatory agency shall be immediately notified of the results and the ultimate disposition of the raw milk.~~

~~The producer samples from the bulk milk pickup tanker, found to be positive for drug residues, shall be individually tested to determine the farm of origin. The samples shall be tested as directed by the regulatory agency.~~

~~Further pickups of the violative individual producer shall be immediately discontinued, until such time, that subsequent tests are no longer positive for drug residues.~~

II. REGULATORY AGENCY RESPONSIBILITIES

A. Monitoring and Surveillance

State regulatory agencies shall monitor industry surveillance activities by making unannounced, on-site inspections to collect samples from bulk milk pickup tankers and to review industry records of the random sampling program. A review shall include, but not be limited to, the following:

1. Is the program an appropriate routine monitoring program for the detection of drug residues? Is the program utilizing appropriate test methods?

2. Is each producer's milk represented in a testing program for drug residues and tested at the frequency prescribed in I. A. above for drug residues?

3. Is the program assuring timely notification to the appropriate regulatory agency of positive results, the ultimate disposition of the bulk milk pickup tanker milk and of the trace back to the farm of origin? Is farm pickup suspended until subsequent testing establishes the milk is no longer positive for drug residues?

The regulatory agency shall also perform routine sampling and testing for drug residues determined to be necessary as outlined in Section 6 and M-a-75.

B. Enforcement

If testing reveals milk positive for drug residues, the milk shall be disposed of in a manner that removes it from the human or animal food chain, except where acceptably reconditioned under FDA compliance policy guidelines. The regulatory agency shall determine the producer responsible for the violation.

Suspension. — Any time milk is found to test positive for a drug residue, the regulatory agency shall immediately suspend the producer's permit or equally effective measures shall be taken to prevent the sale of milk containing drug residues.

Penalties. — Future pick-ups are prohibited until subsequent testing reveals the milk is free of drug residue. The penalty shall be for the value of all milk on the contaminated load plus any costs associated with the disposition of the contaminated load. The State Regulatory Authority may accept certification from the violative producer's milk marketing cooperative or purchaser of milk as satisfying the penalty requirements.

Reinstatement. — The Producer permit may be reinstated, or other action taken, to allow sale of milk for human food, when a representative sample taken from the producer's milk, prior to commingling with any other milk, is no longer positive for drug residue.

Follow-Up. — Whenever a drug residue test is positive an investigation shall be made to determine the cause:

Farm inspection is completed by athe regulatory agency or its agent to determine the cause of the residue and actions taken to prevent future violations including:

(a) On farm changes in procedures necessary to prevent future occurrences as recommended by the state regulatory agency.

Permit Revocation. — After a third violation in a 12 month period the regulatory agency shall initiate administrative procedures pursuant to revocation of the producer's permit under the authority of “Section 3, Permits”, due to repeated violations.

Reinstatement. — The producer permit may be reinstated, or other such similar action taken, to allow sale of milk for human food, 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. ESTABLISHED TOLERANCES AND/OR SAFE LEVELS OF DRUG RESIDUES

"Safe levels" are used by FDA as guides for prosecutorial discretion. They do not legalize residues found in milk that are below the safe level. In short, FDA uses the "safe levels" as prosecutional guidelines and in full consistency with CNI v. Young stating, in direct and unequivocal language, that the "safe levels" are not binding — that they do not dictate any result, that they do not limit the agency's discretion in any way, and that they do not protect milk producers (or milk) from court enforcement action.

"Safe levels" are not and cannot be transformed into tolerances that are established for animal drugs under section 512 (b) of the *Federal Food, Drug, and Cosmetic Act* (1998). "Safe levels" do not (1) bind the courts, the public (including milk producers), or the agency, and (2) do not have the "force of law" of tolerances (or of binding rules).

Notification, changes or additions of "safe levels" will be transmitted via Memoranda of Information (M-I's).

IV. APPROVED METHODS

Drug residue detection methods shall be evaluated at the safe level or tolerance. Regulatory action based on each test kit method may be delayed until the evaluation is completed and the method is found to be acceptable to FDA and complies with the provisions of Section 6.

One year after test(s) have been evaluated by FDA and accepted by the NCIMS for a particular drug or drug family, other unevaluated tests are not acceptable for screening milk. The acceptance of evaluated tests does not mandate any additional screening by industry with the evaluated method.

Editor's Notes

History