Grade "A"

Pasteurized

Milk

Ordinance

2001 Revision

U.S. Department of Health and Human Services

Public Health Service

Food and Drug Administration

LIST OF PREVIOUS EDITIONS OF PHS/FDA MILK ORDINANCE

1924. *Ordinance* only. Reprint No. 971 from *Public Health Reports* of November 7, 1924.
1926. *Ordinance* only. Reprint No. 1099 from *Public Health Reports* of July 30, 1926.
1927. *Ordinance and Code.* Mimeographed tentative draft, November 1927.
1929. *Ordinance and Code.* Mimeographed, July 1929.
1929. *Ordinance and Code.* Mimeographed, September 1929.
1931. *Ordinance and Code.* Mimeographed, September 1931.
1933. *Ordinance* only. Mimeographed, July 1933.
1933. *Ordinance and Code.* Mimeographed, July 1933.
1933. *Ordinance* only. Rotoprinted, December 1933.
1933. *Ordinance and Code.* Rotoprinted, December 1933.
1934. *Ordinance and Code.* Rotoprinted, August 1934.
1934. *Ordinance* only. Rotoprinted, August 1934.
1935. *Ordinance and Code.* Printed as *Public Health Bulletin No. 220,* 1935 Edition, July 1935.
1936. *Ordinance* only. Mimeographed, December 1936.
1936. *Ordinance and Code.* Printed as *Public Health Bulletin No. 220,* 1936 Edition, January 1937.
1939. *Ordinance and Code.* Mimeographed, January 1939.
1939. *Ordinance* only. Mimeographed, February 1939.
1939. *Ordinance* only. Mimeographed, November 1939.
1939. *Ordinance and Code.* Printed as *Public Health Bulletin No. 220*, 1939 Edition, February 1940.
1947. *Ordinance* only. Mimeographed tentative draft, August 1947.
1949. *Ordinance* only. Multilthed, April 1949.
1951. *Ordinance* only. Multilthed, November 1951.
1953. *Ordinance and Code.* Printed as *Public Health Service Publication No. 229.*
1965. *Pasteurized Milk Ordinance. Public Health Service Publication No. 229.*
1978. *Pasteurized Milk Ordinance. Public Health Service/Food and Drug Administration Publication No. 229.*
1983. *Pasteurized Milk Ordinance. Public Health Service/Food and Drug Administration Publication No. 229.*
1985. *Pasteurized Milk Ordinance. Public Health Service/Food and Drug Administration Publication No. 229*.
1989. *Pasteurized Milk Ordinance. Public Health Service/Food and Drug Administration Publication No. 229.*
1993. *Pasteurized Milk Ordinance. Public Health Service/Food and Drug Administration Publication No. 229.*
1995. *Pasteurized Milk Ordinance. Public Health Service/Food and Drug Administration Publication No. 229.*
1997. *Pasteurized Milk Ordinance. Public Health Service/Food and Drug Administration Publication No. 229.*
1999. *Pasteurized Milk Ordinance. Public Health Service/Food and Drug Administration Publication No. 229.*
2001. *Pasteurized Milk Ordinance. Public Health Service/Food and Drug Administration Publication No. 229.*

PUBLIC HEALTH SERVICE/FOOD AND DRUG ADMINISTRATION
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FOREWORD

The milk sanitation program of the United States Public Health Service is one of its oldest and most respected activities. The interest of the Public Health Service in milk sanitation stems from two important public health considerations. First, of all foods, none surpasses milk as a single source of those dietary elements needed for the maintenance of proper health, especially in children and older citizens. For this reason, the Service has for many years promoted increased milk consumption. Second, milk has a potential to serve as a vehicle of disease and has, in the past, been associated with disease outbreaks of major proportions.

The incidence of milkborne illness in the United States has been sharply reduced in recent years. In 1938, milkborne outbreaks constituted twenty-five percent (25%) of all disease outbreaks due to infected foods and contaminated water. Our most recent information reveals that milk and fluid milk products continue to be associated with less than one percent (<1%) of such reported outbreaks. Many groups have contributed to this commendable achievement, including Public Health and Agricultural Agencies, dairy and related industries, several interested professional groups, educational institutions and the consuming public. The Public Health Service/Food and Drug Administration is proud to have contributed to the protection and improvement of the milk supply of the nation through technical assistance, training, research, standards development, evaluation and certification activities.

Despite the progress that has been made, occasional milkborne outbreaks still occur, emphasizing the need for continued vigilance at every stage of production, processing, pasteurization and distribution of milk and milk products. Problems associated with the sanitary control of milk and milk products have become extremely complex because of new products, new processes, new chemicals, new materials and new marketing patterns, which must be evaluated in terms of their public health significance. The *Grade "A" Pasteurized Milk Ordinance* (PMO), 2001 Revision translates this new knowledge and technology into effective and practicable public health practices.

The responsibility for insuring the ready availability and safety of milk and milk products is not confined to an individual community or a State, or to the Federal Government, it is the concern of the entire nation. With the continued cooperation of all interested groups engaged in the sanitary control of milk and milk products, including Government and industry, such responsibility can be accepted with confidence.

PREFACE

Public Health Service activities in the area of milk sanitation began at the turn of the century with studies on the role of milk in the spread of disease. These studies led to the conclusion that effective public health control of milkborne disease requires the application of sanitation measures throughout the production, handling, pasteurization, and distribution of milk. These early studies were followed by research to identify and evaluate sanitary measures, which might be used to control disease, including studies that led to improvement of the pasteurization process.

To assist States and Municipalities in initiating and maintaining effective programs for the prevention of milkborne disease, the Public Health Service, in 1924, developed a model regulation, known as the *Standard Milk Ordinance* for voluntary adoption by State and Local Milk Control Agencies. To provide for the uniform interpretation of this *Ordinance*, an accompanying *Code* was published in 1927, which provided administrative and technical details as to satisfactory compliance. This model milk regulation, now titled the *Grade "A" Pasteurized Milk Ordinance* (PMO), 2001 Revision, represents the 24th revision since 1924 and incorporates new knowledge into public health practice.

The Public Health Service/Food and Drug Administration alone did not produce the Grade “A” PMO. As with every preceding edition, it was developed with the assistance of Milk Sanitation and Regulatory Agencies at every level of Federal, State, and Local Government including both Health and Agriculture Departments; all segments of the dairy industry including producers, plant operators, equipment manufacturers, and associations; many educational and research institutions; and with helpful comments from many individual sanitarians and others.

The Public Health Service/Food and Drug Administration's recommended Grade "A" PMO is the basic standard used in the voluntary Cooperative State-PHS/FDA Program for the Certification of Interstate Milk Shipments, a program participated in by all fifty (50) States, the District of Columbia and U.S. Trust Territories. The National Conference on Interstate Milk Shipments (NCIMS) in accordance with the Memorandum of Understanding with the Food and Drug Administration has at its biennial conferences recommended changes and modifications to the Grade "A" PMO. These changes have been incorporated into this 2001 revision. The counsel and guidance rendered by the Conference in preparation of this edition of the Grade "A" PMO is deeply appreciated.

The Grade "A" PMO is incorporated by reference in Federal specifications for procurement of milk and milk products; is used as the sanitary regulation for milk and milk products served on interstate carriers; and is recognized by the Public Health Agencies, the milk industry, and many others as a national standard for milk sanitation. The Grade "A" PMO adopted and uniformly applied will continue to provide effective public health protection without being unduly burdensome to either Regulatory Agencies or the dairy industry. It represents a "grass-roots" consensus of current knowledge and experiences and as such represents a practical and equitable milk sanitation standard for the nation.

INTRODUCTION

The following Grade "A" PMO, with Appendices, is recommended for legal adoption by States, Counties, and Municipalities, in order to encourage a greater uniformity and a higher level of excellence of milk sanitation practice in the United States. An important purpose of this recommended standard is to facilitate the shipment and acceptance of milk and milk products of high sanitary quality in interstate and intrastate commerce.

This edition of the *Ordinance* contains sanitary standards for only Grade "A" raw milk for pasteurization and Grade "A" pasteurized milk and milk products defined in Section 1. The following form is suggested for adoption by States, Municipalities, and Counties subject to the approval of the appropriate legal authority. Adoption of this form will reduce the cost of publishing and printing, and will enable the Grade "A" PMO to be easily kept current. The adoption of this form is considered legal in many States and has been so adopted. The Council of State Governments has prepared a model State law, *Milk and Food Codes Adoption-by-Reference Act*,[1] which is recommended for enactment by States to enable communities to adopt milk and food ordinances by reference.

An ordinance to regulate the production, transportation, processing, handling, sampling, examination, labeling, and sale of Grade "A" milk and milk products; the inspection of dairy farms, milk plants, receiving stations, transfer stations, milk tank truck cleaning facilities, milk tank trucks and bulk milk hauler/samplers; the issuing and revocation of permits to milk producers, 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.

The.....of.....[2] ordains:

SECTION 1. The production, transportation, processing, handling, sampling, examination, labeling and sale of all Grade "A" milk and milk products sold for the ultimate consumption within the ..... of .....[2] or its jurisdiction; the inspection of dairy farms, milk plants, receiving stations, transfer stations, milk tank truck cleaning facilities, milk tank trucks and bulk milk hauler/samplers; and the issuing and revocation of permits to milk producers, bulk milk hauler/samplers, milk tank trucks, milk transportation companies, milk plants, receiving stations, transfer stations, milk tank truck cleaning facilities, haulers, and distributors shall be regulated in accordance with the provisions of the current edition of the Grade "A" PMO, a certified copy[3] of which is filed in the office of the appropriate governing official. Provided, that Sections 15 and 16 of this *Ordinance* shall be replaced, respectively by Sections 2 and 3 below.

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[1] A copy of the model act is included in Suggested State Legislation Programs for 1950, developed by the Council of State Governments, Box 11910, Iron Works Pike, Lexington, KY 40578.

[2] Substitute proper legal jurisdiction here and in all similar places throughout the Ordinance.

[3] A certified copy may be secured from the Department of Health and Human Services, Public Health Service, Food and Drug Administration, Milk Safety Branch (HFS-626), 5100 Paint Branch Parkway, College Park, MD 20740-3835.

SECTION 2. Any person who shall violate any of the provisions of this *Ordinance* shall be guilty of a misdemeanor and, upon conviction thereof, shall be punished by a fine of not more than $....., and/or such persons may be enjoined from continuing such violations. Each day upon which such a violation occurs shall constitute a separate violation.

SECTION 3. All Ordinances and parts of ordinances in conflict with this *Ordinance*, shall be repealed 12 months after the adoption of this *Ordinance*, at which time this *Ordinance* shall be in full force and effect, as provided by law.

Legal Aspects: Recommendations concerning legal aspects have been suggested from time to time by the Office of the Chief Counsel and have been incorporated into the *Ordinance*. Other changes have also been incorporated on the advice of various State and Local legal counsel.

The *Ordinance* has been widely adopted and used for many years and has been upheld by court actions. One of the most comprehensive decisions upholding the various provisions of the *Ordinance* was that of the District Court, Reno County, Kansas, in the case of *Billings et al. v. City of Hutchinson et al.,* decided May 1, 1934. In this action, the plaintiffs unsuccessfully sought to enjoin the enforcement of the Hutchinson ordinance on the grounds that: (a) it was unreasonable; (b) it conflicted with State statutes; (c) the license fees provided in the local ordinance (but not in the *Ordinance* recommended by the Public Health Service) were in excess of expenses; and (d) the milk inspector was clothed with arbitrary powers. (Reprint No. 1629 from *Public Health Reports* of June 8, 1934.)

The model ordinance discourages the use of public health regulations to establish unwarranted trade barriers against the acceptance of high quality milk from other milksheds (Section 11). On repeated requests from the Association of State and Territorial Health Officers and the National Conference on Interstate Milk Shipments (NCIMS), the Public Health Service/Food and Drug Administration is actively cooperating in the voluntary program for the certification of interstate milk shippers. Such a program would be impossible without widespread agreement on uniform standards, such as those of the recommended *Ordinance*.

The value of these standards as a means of overcoming interstate trade barriers was recognized by the U.S. Supreme Court in the case of the *Dean Milk Company v. City of Madison.* (No. 258--October term, 1950). The Court reversed the decision of the Wisconsin Supreme Court which had sustained an ordinance requirement imposing a 5-mile limit on the location of pasteurization plants selling milk in Madison and pointed out that Madison consumers would be adequately safeguarded if the city relied upon the provisions of Section 11 of the Public Health Service's recommended *Milk Ordinance*.

The Public Health Service/Food and Drug Administration does not have legal jurisdiction in the enforcement of milk sanitation standards, except on interstate carriers and milk and milk products shipped in interstate commerce. Elsewhere, it serves solely in an advisory and stimulative capacity. Its program is designed primarily to assist State and Local Regulatory Agencies. Its aim is to promote the establishment of effective and well-balanced milk sanitation programs in each State; to stimulate the adoption of adequate and uniform State and Local milk

control legislation; and to encourage the application of uniform enforcement procedures through appropriate legal and educational measures.

When this *Ordinance* is adopted locally, its enforcement becomes a function of the Local or State authorities. Consequently, the *Ordinance* should be adopted only if adequate provisions can be made for qualified personnel and for suitable laboratory facilities. Small Municipalities which cannot afford to provide these services should arrange for supervision by the County or State Health Department, or seek cooperation with neighboring Municipalities in organizing a milk-control district or area.

The charter and the legal counsel of the government unit involved should be consulted for information or advice on proper legal procedures, such as the recording and advertising of the *Ordinance* after passage.

Adoption: In the interest of national uniformity, it is recommended that no changes be made in this *Ordinance* when adopted by a State or Local community, unless changes are necessary to avoid conflict with State law. Modifications should be contemplated with extreme caution so as not to render the *Ordinance* unenforceable. In order to promote uniformity, it is recommended that all of the Administrative Procedures be adopted as well.

Amendment of Existing Regulations: States and Communities that have adopted the 1999 or earlier editions of the Public Health Service/Food and Drug Administration recommended Grade "A" PMO are urged to bring such *Ordinance* up-to-date in order to take advantage of the most current developments in milk sanitation and administration. States and Communities whose milk sanitation law or regulations are not based on a previous Public Health Service/Food and Drug Administration recommended Grade "A" PMO are urged to consider the attendant public health benefits, as well as those economic in nature, which can accrue upon adoption and implementation of the Grade "A" PMO.

TABLE OF CONTENTS

ILLUSTRATIONS

Page

TABLES

Page

GRADE "A" PASTEURIZED MILK ORDINANCE (PMO)
2001 Revision

An ordinance defining "milk" and certain "milk products", "milk producer", "pasteurization", etc.; prohibiting the sale of adulterated and misbranded milk and milk products; requiring permits for the sale of milk and milk products; regulating the inspection of dairy farms and milk plants, the examination, labeling, pasteurization, aseptic processing and packaging and distribution and sale of milk and milk products; providing for the construction of future dairy farms and milk plants; and the enforcement of this *Ordinance* and the fixing of penalties.

Be it ordained by the ... of ...[1] as follows:

SECTION 1. DEFINITIONS

Terms used in this document, not specifically defined herein, are those within Title 21, *Code of Federal Regulations* (CFR) and/or the *Federal Food, Drug, and Cosmetic Act* (FFD&CA) as amended.

The following additional definitions shall apply in the interpretation and the enforcement of this *Ordinance*:

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 milk products to or from a milk 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 bulk milk hauler/sampler to transport bulk raw milk for pasteurization from a dairy farm to a milk plant, receiving station, or transfer station.

C. **BUTTERMILK**: Buttermilk is a fluid product resulting from the manufacture of butter from milk or cream. It contains not less than 8¼ percent of milk solids not fat.

D. **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 label, results in a product conforming with the milkfat and milk solids not fat levels of milk as defined in this Section.

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

F. **DAIRY FARM:** A dairy farm is any place or premises where one (1) or more lactating animals (cows, goats or sheep) are kept for milking purposes, and from which a part or all of the milk or milk product(s) is provided, sold or offered for sale to a milk plant, receiving station or transfer station.

G. **DAIRY PLANT SAMPLER:** A person responsible for the collection of official samples for regulatory purposes outlined in Section 6 of this *Ordinance*. This person is an employee of the Regulatory Agency and is evaluated at least once every two (2)-year period by a State Sampling Surveillance Officer.

H. **EGGNOG OR BOILED CUSTARD:** Eggnog or boiled custard is the product defined in 21 CFR 131.170.

I. **FOOD ALLERGENS:** Are proteins in foods that are capable of inducing an allergic reaction or response in some individuals. There is scientific consensus that the following foods account for more than 90% of all food allergies: peanuts, soybeans, milk, eggs, fish, crustacea, tree nuts, and wheat.

Reference: FDA Compliance Policy Guide 555.250 - Statement of Policy for Labeling and Preventing Cross-Contact of Common Food Allergens available on the Internet at: http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg555-250.htm

J. **FROZEN MILK CONCENTRATE:** Frozen milk concentrate is a frozen milk 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.

K. **GOAT MILK:** Goat milk is the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one (1) or more healthy goats. Goat milk sold in retail packages shall contain not less than 2½ percent milkfat and not less than 7½ percent milk solids not fat. Goat milk shall be produced according to the sanitary standards of this *Ordinance*. The word "milk" shall be interpreted to include goat milk.

L. **GRADE "A" DRY MILK AND WHEY PRODUCTS:** Grade "A" dry milk and whey products are products which have been produced for use in Grade "A" pasteurized or aseptically processed milk products and which have been manufactured under the provisions of the most current revision of the *Grade "A" Condensed and Dry Milk Products and Condensed and Dry Whey - Supplement I to the Grade "A" Pasteurized Milk Ordinance* (DMO).

M. **MILK DISTRIBUTOR:** A milk distributor is any person who offers for sale or sells to another any milk or milk products.

N. **MILK PLANT:** A milk plant is any place, premises; or establishment where milk or milk products are collected, handled, processed, stored, pasteurized, ultra-pasteurized, aseptically processed, packaged, or prepared for distribution.

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

P. **MILK PRODUCTS:** Milk products include cream, light cream, light whipping cream, heavy cream, heavy whipping cream, whipped cream, whipped light cream, sour cream, acidified sour cream, cultured sour cream, half-and-half, sour half-and-half, acidified sour half-and-half, cultured sour half-and-half, reconstituted or recombined milk and milk products, concentrated milk, concentrated milk products, nonfat (skim) milk, reduced fat or lowfat milk, frozen milk concentrate, eggnog, buttermilk, cultured milk, cultured reduced fat or lowfat milk, cultured nonfat (skim) milk, yogurt, lowfat yogurt, nonfat yogurt, acidified milk, acidified reduced fat or lowfat milk, acidified nonfat (skim) milk, low-sodium milk, low-sodium reduced fat or lowfat milk, low-sodium nonfat (skim) milk, lactose-reduced milk, lactose-reduced reduced fat or lowfat milk, lactose-reduced nonfat (skim) milk, aseptically processed and packaged milk and milk products as defined in this Section, milk, reduced fat, lowfat milk or nonfat (skim) milk with added safe and suitable microbial organisms and any other milk product made by the addition or subtraction of milkfat or addition of safe and suitable optional ingredients for protein, vitamin or mineral fortification of milk products defined herein.[2,3]
Milk products also include those dairy foods made by modifying the federally standardized products listed in this Section in accordance with 21 CFR 130.10-Requirements for foods named by use of a nutrient content claim and a standardized term.
This Definition shall include those milk and milk products, as defined herein, which have been aseptically processed and then packaged.
Milk and milk products which have been retort processed after packaging or which have been concentrated, condensed or dried are included in this Definition only if they are used as an ingredient to produce any milk or milk product defined herein or if they are labeled as Grade "A" as described in Section 4.
This Definition is not intended to include dietary products (except as defined herein), infant formula, ice cream or other frozen desserts, butter or cheese.

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

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

S. **MILK TANK TRUCK DRIVER:** A milk tank truck driver is any person who transports raw or pasteurized milk products to or from a milk 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.

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

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

V. **OFFICIAL LABORATORY:** An official laboratory is a biological, chemical or physical laboratory, which is under the direct supervision of the Regulatory Agency.

W. **OFFICIALLY DESIGNATED LABORATORY:** An officially designated laboratory is a commercial laboratory authorized to do official work by the Regulatory Agency, or a milk industry laboratory officially designated by the Regulatory Agency for the examination of producer samples of Grade "A" raw milk for pasteurization and commingled milk tank truck samples of raw milk for drug residues and bacterial limits.

X. **PASTEURIZATION:** The terms "pasteurization", "pasteurized" and similar terms shall mean the process of heating every particle of milk or milk product, in properly designed and operated equipment, to one (1) 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
63ºC (145ºF)*	30 minutes
72ºC (161ºF)*	15 seconds
89ºC (191ºF)	1.0 second
90ºC (194ºF)	0.5 seconds
94ºC (201ºF)	0.1 seconds
96ºC (204ºF)	0.05 seconds
100ºC (212ºF)	0.01 seconds

*If the fat content of the milk product is ten percent (10%) or more, or if it contains added sweeteners, the specified temperature shall be increased by 3ºC (5ºF).

Provided, that eggnog shall be heated to at least the following temperature and time specifications:

69ºC (155ºF)	30 minutes
80ºC (175ºF)	25 seconds
83ºC (180ºF)	15 seconds

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

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

Z. **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.

AA. **RECONSTITUTED OR RECOMBINED MILK AND MILK PRODUCTS:** Reconstituted or recombined milk and/or milk products shall mean milk or milk products defined in this Section which result from reconstituting or recombining of milk constituents with potable water when appropriate.[4]

BB. **REGULATORY AGENCY:** The Regulatory Agency shall mean the ... of the …[1]or their authorized representative. The term, "Regulatory Agency", whenever it appears in the *Ordinance* shall mean the appropriate agency having jurisdiction and control over the matters embraced within this *Ordinance*.

CC. **SHEEP MILK:** Sheep milk is the normal lacteal secretion practically free of colostrum, obtained by the complete milking of one (1) or more healthy sheep. Sheep milk shall be produced according to the sanitary standards of this *Ordinance*. The word "milk" shall be interpreted to include sheep milk.

DD. **TRANSFER STATION:** A transfer station is any place, premises, or establishment where milk or milk products are transferred directly from one (1) milk tank truck to another.

SECTION 2. ADULTERATED OR MISBRANDED MILK OR MILK PRODUCTS

No person shall, within the ... of ...[1], or its jurisdiction, produce, provide, sell, offer, or expose for sale or have in possession with intent to sell any milk or milk product which is adulterated or misbranded. Provided, that in an emergency, the sale of pasteurized milk and milk products, which do not fully meet the requirements of this *Ordinance*, may be authorized by the Regulatory Agency.

Any adulterated or misbranded milk or milk product may be impounded by the Regulatory Agency and disposed of in accordance with applicable laws or regulations.

ADMINISTRATIVE PROCEDURES

This Section of the *Ordinance* shall be used in impounding the products of, or preferring charges against, persons who adulterate or misbrand their milk or milk products; or label them with any grade designation not authorized by the Regulatory Agency under the terms of this *Ordinance;* or who sell or deliver ungraded milk or milk products, except as may be permitted under this Section in an emergency. An emergency is defined as a general and acute shortage in the milk shed, not simply one (1) distributor's shortage.

SECTION 3. PERMITS

It shall be unlawful for any person who does not possess a permit from the Regulatory Agency of the ... of ...[1] to bring into, send into or receive into the ... of ...[1] or its jurisdiction, for sale, or to sell, or offer for sale therein or to have in storage any milk or milk products defined in this *Ordinance*. Provided, that grocery stores, restaurants, soda fountains and similar establishments where milk or milk 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 this *Ordinance* 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 this *Ordinance*; 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 milk product involved creates, or appears to create, an imminent hazard to the public health; or in any case of a willful refusal to permit authorized inspection, serve upon the holder a written notice of intent to suspend permit, which 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 forty-eight (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 seventy-two (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 tank truck[5], milk transportation company and each milk plant, receiving station, milk tank truck cleaning facility and transfer station operator shall hold a valid permit. The permit for a milk tank truck(s) may be issued to the milk transportation company. Milk producers who transport milk or milk products, only from their own dairy farms; employees of a milk distributor or milk plant operator who possesses a valid permit; and employees of a milk transportation company that possesses a valid permit and transports milk from a milk plant, receiving station or transfer station shall not be required to possess a bulk milk hauler/sampler's permit. Grocery stores, restaurants, soda fountains and similar establishments where milk and milk products are served or sold at retail, but not processed, may be exempt from the requirements of this Section.

SUSPENSION OF PERMIT: When any requirement(s) of this *Ordinance* is violated, the permit holder is subject to the suspension of their permit.
The Regulatory Agency may forego suspension of the permit, provided the product or products in violation are not sold or offered for sale as Grade "A" product. A Regulatory Agency may allow the imposition of a monetary penalty in lieu of a permit suspension, provided product or products in violation are not sold or offered for sale as Grade "A" product.

HEARINGS: If a State Administrative Procedures 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 the *Ordinance*. If such Administrative Procedures Act is not available, appropriate procedures, including provision for notice, hearing officer, their 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 plant operator whose permit has been suspended may make written application for the reinstatement of their permit.
When the permit suspension has been due to a violation of any of the bacterial, coliform or cooling temperature standards, the Regulatory Agency, within one (1) 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, 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 (2) per week on separate

days within a three (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 this *Ordinance*.

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 (1) 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 containing milk or milk products defined in Section 1 of this *Ordinance* shall be labeled in accordance with the applicable requirements of the FFD&CA, the *Nutrition Labeling and Education Act* (NLEA) of 1990, and regulations developed thereunder, the CFR, and in addition, shall comply with applicable requirements of this Section as follows:

All bottles, containers and packages containing milk or milk 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 plant where pasteurized, ultra-pasteurized or aseptically processed.
2. The words "keep refrigerated after opening" in the case of aseptically processed milk and milk products.
3. The word "Goat" or "Sheep" shall precede the name of the milk or milk product when the product is or is made from goat or sheep milk respectively.
4. The words "Grade “A” on the exterior surface. Acceptable locations shall include the principal display panel, the secondary or informational panel, or the cap/cover.
5. The word "reconstituted" or "recombined" if the product is made by reconstitution or recombination.

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

Milk tank trucks transporting raw, heat-treated or pasteurized milk and milk products to a milk plant from another milk plant, receiving station or transfer station are required to be marked with the name and address of the milk 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 number. Each milk tank truck containing milk shall include the IMS Bulk Tank Unit (BTU) identification number(s) or the IMS listed Plant Number, for farm groups listed with a plant, on the weight ticket or manifest.
2. Permit identification of hauler, if not an employee of the shipper.
3. Point of origin of shipment.

4. Tanker identification number.
5. Name of product.
6. Weight of product.
7. Temperature of product when loaded.
8. Date of shipment.
9. Name of supervising Regulatory Agency at the point of origin of shipment.
10. Whether the contents are raw, pasteurized, or in the case of cream, lowfat or skim milk, whether it has been heat-treated.
11. Seal number on inlet, outlet, wash connections and vents.
12. Grade of product.

All cans of raw milk from individual dairy farms shall be identified by the name or number of the individual milk producer.
Each milk tank truck containing milk shall be accompanied by documentation, weigh ticket or manifest, which shall include the IMS BTU Identification Number(s) or the IMS Listed Plant Number, for farm groups listed with a plant.

ADMINISTRATIVE PROCEDURES

LABELING OF EMERGENCY SUPPLIES: When the sale of ungraded milk or milk products is authorized during emergencies, under the terms of Section 2, the label must bear the designation "ungraded". When such labeling is not available, the Regulatory Agency shall take immediate steps to inform the public that the particular supply is ungraded and that the supply will be properly labeled as soon as the distributor can obtain the required labels.

IDENTITY LABELING: "Identity", as used in this Section, is defined as the name and address of the milk plant at which the pasteurization, ultra-pasteurization or aseptic processing takes place. It is recommended that the voluntary national uniform coding system for the identification of pasteurization plants, at which milk and milk products are packaged, be adopted in order to provide a uniform system of codes throughout the country.
In cases where several plants are operated by one firm, the common firm name may be utilized on milk bottles or containers. Provided, that the location of the plant at which the contents were 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 pasteurized, ultra-pasteurized, or aseptically processed milk. The street address of the plant need not be shown when only one plant of a given name is located within the municipality.
The identity labeling requirement may be interpreted as permitting plants and persons to purchase and distribute, under their own label, milk and milk products processed and packaged at another 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 bottle cap or label, when, in their opinion, they are not misleading and are not so used as to obscure the labeling required by this *Ordinance*. The use of super grade designations shall not be permitted. Grade designations such as “Grade AA Pasteurized”,

"Selected Grade A Pasteurized", "Special Grade A Pasteurized", etc., give the consumer the impression that such a grade is significantly safer than Grade "A". Such an implication is false, because the *Ordinance* requirements for Grade "A" pasteurized, ultra-pasteurized, or aseptically processed milk when properly enforced, will ensure that this grade of milk will be as safe as milk can practically be made. Descriptive labeling terms must not be used in conjunction with the Grade "A" designation or name of the milk or milk product and must not be false or misleading.

SECTION 5. INSPECTION OF DAIRY FARMS AND MILK PLANTS

Each dairy farm, milk plant, receiving station, milk tank truck cleaning facility and transfer station whose milk or milk products are intended for consumption within ...of...[1] or it's jurisdiction, and each bulk milk hauler/sampler who collects samples of raw milk for pasteurization, for bacterial, chemical or temperature standards and hauls milk from a dairy farm to a milk plant, receiving station or transfer station and each milk tank truck 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 pasteurization for bacterial, chemical or temperature standards and hauls milk from a dairy farm to a milk plant, receiving station or transfer station, at least once every twelve (12) months;
2. Inspect each such bulk milk hauler/sampler's pickup and sampling procedures at least once every twenty-four (24) months;
3. Inspect each milk plant and receiving station at least once every three (3) months;
4. Inspect each milk tank truck cleaning facility and transfer station at least once every six (6) months; and
5. Inspect each dairy farm at least once every six (6) months.[6]

Should the violation of any requirement set forth in Section 7, or in the case of a bulk milk hauler/sampler or milk tank truck also Section 6 and Appendix B, 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 three (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 also Section 6 and Appendix B. 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 and Appendix B 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 milk 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 milk product is occurring; or
3. Conditions exist whereby direct contamination of pasteurized milk or milk product is occurring.

The Regulatory Agency shall take immediate action to prevent further movement of such milk or milk 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 this *Ordinance.* Provided, that in the case of dairy plants producing aseptically processed milk and milk 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 milk products in conformance with Section 3 of this *Ordinance*.

One (1) copy of the inspection report shall be handed to the operator, or other responsible person or be posted in a conspicuous place on an inside wall of 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 this *Ordinance*. 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 milk products of each grade purchased and sold, a list of all sources of such milk and milk products, records of inspections, tests and pasteurization time and temperature records.

It shall be unlawful for any person who, in an official capacity, obtains any information under the provisions of this *Ordinance* which is entitled to protection as a trade secret, including information as to the quantity, quality, source or disposition of milk or milk 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 and transfer stations the interval shall include the designated six (6) month period plus the remaining days of the month in which the inspection is due.

For the purposes of determining the inspection frequency for milk plants and receiving stations the interval shall include the designated three (3) month period plus the remaining days of the month in which the inspection is due.

One (1) milk tank truck inspection every twelve (12) months, or bulk milk hauler/sampler pickup and sampling procedures inspection each twenty-four (24) months, or one (1) producer inspection every six (6) months or one (1) plant inspection every three (3) months is not a desirable frequency, it is instead a legal minimum. Bulk milk hauler/ samplers, milk tank trucks, milk tank truck cleaning facilities, dairy farms, milk plants, receiving stations and transfer stations 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 milk 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 this *Ordinance*.

ENFORCEMENT PROCEDURES: This Section provides that a dairy farm, bulk milk hauler/sampler, milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station or distributor, except those processing aseptically processed milk and milk products, shall be subject to suspension of permit and/or court action, if two (2) successive inspections disclose a violation of the same requirement.

Experience has demonstrated that strict enforcement of the *Ordinance* leads to a better and friendlier relationship between the Regulatory Agency and the milk industry than does a policy of enforcement, which seeks to excuse violations and to defer penalty thereof. The sanitarian's criterion of satisfactory compliance should be neither too lenient nor unreasonably stringent. When a violation is discovered, the sanitarian should point out to the milk producer, bulk milk hauler/sampler, responsible person for the milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station or distributor the requirement that has been violated, discuss a method for correction and set a time for correcting the violated requirement.

The penalties of suspension or revocation of permit, and/or court action, are provided to prevent continued violation of the provisions of this *Ordinance*, 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 milk producer, bulk milk hauler/sampler, responsible person for the milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station or distributor upon the first violation of any of the sanitation requirements listed in Section 7. A milk producer, bulk milk hauler/sampler, responsible person for the milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station 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 (3) 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 milk producer, bulk milk hauler/sampler, responsible person for the milk tank truck, milk tank truck cleaning facility, milk plant, receiving station, transfer station or distributor shall have an opportunity to appeal the sanitarian's interpretation to the Regulatory Agency or request an extension of the time allowed for correction.

ENFORCEMENT PROCEDURES - ASEPTIC PROCESSING MILK PLANTS: Because aseptically processed milk and milk 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 underprocessed product and follow at least the minimum requirements of 21 CFR 113.89 before releasing any product. (See Appendix L.)

CERTIFIED INDUSTRY INSPECTION: The Regulatory Agency may certify industry personnel, with their consent, to carry out cooperatively the provisions of this *Ordinance* with respect to the supervision of dairy farms, bulk milk haul/sampler's pickup and sampling

procedures, and/or milk tank trucks. States utilizing certified industry inspections shall have on file and available for review, a written program that describes how the requirements of this *Ordinance* and related documents shall be implemented. Delegation of the inspection and evaluation of bulk milk hauler/sampler's pickup and sampling procedures shall be done by the Sampling Surveillance Officer in accordance with the *Evaluation of Milk Laboratories* (EML).
Reports of all inspections conducted by such personnel to determine compliance with the provisions of this *Ordinance* shall be maintained by the industry at a location acceptable to the Regulatory Agency. The Certified Industry Inspector may perform all punitive actions and all inspections for the issuance or reinstatement of permits. Initial inspections and change of market inspections are required and shall be conducted by the Regulatory Agency in conjunction with the Certified Industry Inspector.
When a producer changes market, the producer records for the preceding twenty-four (24) months shall be transferred with the producer, through the Regulatory Agency, and will continue to be a part of the producer's record.
Industry personnel shall be certified every three (3) years by the Regulatory Agency.
At least annually, the Certified Industry Inspector shall attend an educational seminar provided by the Regulatory Agency, or equivalent training acceptable to the Regulatory Agency.
At least once in each six (6) month period, the Regulatory Agency shall inspect the records maintained by the Industry for the Certified Industry Inspection Program and conduct farm field work to assure the program meets the provisions of the Regulatory Agency's written plan and requirements of this *Ordinance* and related documents.
Initial certification by the Regulatory Agency shall not be made during the course of an official inspection. Re-certification by the Regulatory Agency may be conducted during the course of an official inspection.

Purpose of Certification: The purpose of certification is to have the applicant formally demonstrate their inspection ability to apply proper interpretations of this *Ordinance*, related documents, and the Regulatory Agency's procedures.

Designation of Individuals to Be Certified: Candidates shall submit requests for certification to the Regulatory Agency. The applicant for certification shall have had experience in the field of milk sanitation, and shall be an employee of a milk plant, a producer association, officially designated laboratory or shall be employed on a consulting basis.

Recording of Qualification Data: Prior to conducting the certification procedure, background information shall be secured on the applicant. This shall include academic training, experience in milk sanitation and related fields, in-service courses attended, etc. This information is to be retained by the Regulatory Agency as part of the applicant's file, along with appropriate records of the applicant's performance during the certification examination.

Field Procedure: Only one (1) applicant shall be certified at a time. The certification is to be conducted without prompting from the Regulatory Agency or comparison of inspection results in any way until the entire procedure is completed. Initial certification shall not be made during the course of an official inspection by the Regulatory Agency.
At least twenty-five (25) randomly selected dairy farms and/or five (5) milk tank trucks shall be visited. After the necessary inspections have been completed, the Regulatory Agency shall

compare their results with those of the candidate. The percentage agreement for each Item of sanitation shall be determined by dividing the number of agreements by the total number of dairy farms and/or milk tank trucks inspected.

Criteria for Certification: In order to be certified, an industry inspector shall agree with the Regulatory Agency eighty percent (80%) of the time on individual Items of sanitation and shall further agree to comply with the administrative procedures established by the Regulatory Agency for the program of dairy farm and/or milk tank truck supervision. The Regulatory Agency should allow sufficient time to discuss the findings with the applicant.

Duration of Certification: Certification of industry inspection personnel shall be for a period not exceeding three (3) years from the date of formal certification or re-certification unless revoked.

Re-certification: The Regulatory Agency shall notify the certified industry inspector of the need for certification renewal at least sixty (60) days prior to its expiration. If re-certification is desired, the inspector will make appropriate arrangements for the renewal procedure. Re-certification can be made for the succeeding three (3) year period, by following the procedures outlined above. Provided, that re-certification may be conducted during the course of an official inspection by the Regulatory Agency.

Reports and Records: Upon satisfactory completion of certification or re-certification, the certified industry inspector shall be issued a certificate. The milk plant(s) or officially designated laboratory(ies) employing the inspector shall be formally notified by letter of the certification. The letter shall outline the purpose of the certification and the conditions under which the certification may be retained. A copy of the notification letter, together with a copy of the qualification data above and a resume of the percentage agreement on individual items, shall be retained by the Regulatory Agency.

Revocation of Certification: The certification of an industry inspector may be revoked by the Regulatory Agency upon a finding that the inspector is:

1. Not in agreement with the Regulatory Agency at least eighty percent (80%) of the time on Items of sanitation in a field examination conducted as described in the **Field Procedure** outlined above; or
2. Not complying with the established administrative procedures of the Regulatory Agency for the program; or
3. Failing to carry out the provisions of this *Ordinance* in the course of the inspector's work.

INSPECTION REPORTS: A copy of the inspection report shall be filed as directed by the Regulatory Agency and retained for at least twenty-four (24) months. The results shall be entered on appropriate ledger forms. The use of a computer or other information retrieval system may be used. Examples of field inspection forms are included in Appendix M.

SECTION 6. THE EXAMINATION OF MILK AND MILK 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 milk plant, receiving station, transfer station or other location approved by the Regulatory Agency.

1. During any consecutive six (6) months, at least four (4) samples of raw milk for pasteurization shall be collected from each producer, in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. These samples shall be obtained under the direction of the Regulatory Agency or shall be taken from each producer under the direction of the Regulatory Agency and delivered in accordance with this Section.

2. During any consecutive six (6) months, at least four (4) samples of raw milk for pasteurization, ultra-pasteurization or aseptic processing, shall be collected in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. These samples shall be obtained by the Regulatory Agency, from each milk plant after receipt of the milk by the plant and prior to pasteurization, ultra-pasteurization or aseptic processing.

3. During any consecutive six (6) months, at least four (4) samples of heat-treated milk products, from plants offering such products for sale, shall be collected by the Regulatory Agency in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days.

4. During any consecutive six (6) months, at least four (4) samples of pasteurized milk, flavored milk, flavored reduced fat or lowfat milk, flavored nonfat (skim) milk, each fat level of reduced fat or lowfat milk and each milk product defined in this *Ordinance*, (including aseptically processed milk and milk products for drug residue tests) shall be collected by the Regulatory Agency in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days from every milk plant.

Samples of milk and milk products shall be taken while in the possession of the producer, milk plant or distributor at any time prior to delivery to the store or consumer. Samples of milk and milk products from dairy retail stores, food service establishments, grocery stores and other places where milk and milk products are sold shall be examined periodically as determined by the Regulatory Agency and the results of such examination shall be used to determine compliance with Sections 2, 4 and 10. Proprietors of such establishments shall furnish the Regulatory Agency, upon request, with the names of all distributors from whom milk or milk products are obtained.

Required bacterial counts, somatic cell counts and cooling temperature checks shall be performed on raw milk for pasteurization. In addition, drug tests on each producer's milk shall be conducted at least four (4) times during any consecutive six (6) months.

Required bacterial counts, drug tests, coliform determinations, phosphatase and cooling temperature checks shall be performed on pasteurized milk and milk products. Required drug residue tests shall be performed on aseptically processed milk and milk products.

Whenever two (2) of the last four (4) consecutive bacterial counts, except those for aseptically processed milk and milk products, somatic cell count, coliform determinations, or cooling temperatures, taken on separate days, exceed the standard for the milk and/or milk products, the Regulatory Agency shall send a written notice thereof to the person concerned. This notice shall be in effect so long as two (2) of the last four (4) consecutive samples exceed the standard. An additional sample shall be taken within twenty-one (21) days of the sending of such notice, but not before the lapse of three (3) 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) of the last five (5) bacterial counts (except those for aseptically processed milk and milk products), somatic cell counts, coliform determinations or cooling temperatures.

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 milk 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 milk 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 confirmed 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 milk 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 milk plant for the sale of aseptically processed milk and milk products. No aseptically processed milk and milk 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 products from the lot that were found to contain one (1) or more unsterile units shall be recalled and disposed of as directed by the Regulatory Agency.

Samples shall be analyzed at an official or appropriate officially designated laboratory. All sampling procedures and required laboratory examinations shall be in substantial compliance with the most current edition of *Standard Methods for the Examination of Dairy Products* (SMEDP) of the American Public Health Association, and the most current edition of *Official Methods of Analysis of AOAC INTERNATIONAL* (OMA). Such procedures, including the certification of sample collectors and examinations shall be evaluated in accordance with the EML. Aseptically processed milk and milk products packaged in hermetically sealed containers shall be tested in accordance with FDA's *Bacteriological Analytical Manual* (BAM). Examinations and tests to detect adulterants, including pesticides, shall be conducted, as the Regulatory Agency requires. Assays of milk and milk products to which vitamin(s) A and/or D have been added, shall be made at least annually in a laboratory which has been accredited by FDA and which is acceptable to the Regulatory Agency, using test methods acceptable to FDA or other official methodologies which gives statistically equivalent results to the FDA methods. Vitamin testing laboratories are accredited if they have one (1) or more certified analysts and

meet the quality control requirements of the program established by FDA. Laboratory accreditation and analyst certification parameters are specified in the EML manual.
In addition, all facilities fortifying products with vitamins must keep volume control records. These volume control records must cross reference the form and amount of vitamin D, vitamin A and/or vitamin A and D used with the amount of products produced and indicate a percent of expected use, plus or minus.

ADMINISTRATIVE PROCEDURES

ENFORCEMENT PROCEDURES: All violations of bacteria, coliform, confirmed somatic cell counts and cooling temperature standards should be followed promptly by inspection to determine and correct the cause. (See Appendix E - Examples of Three (3)-out-of-Five (5) Compliance Enforcement Procedures).
Aseptically processed milk and milk products packaged in hermetically sealed containers are exempt from the refrigerated storage requirements of this *Ordinance.* Therefore, whenever a breakdown in the processing or packaging of these products occurs an imminent hazard to public health exists. Prompt action is needed by the Regulatory Agency. Dairy plants aseptically processing milk and milk products in hermetically sealed containers should be encouraged to perform bacterial and other quality tests on each lot of aseptically processed milk and milk 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 milk 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 FDA 2400 series forms, SMEDP and OMA. The procedures shall be those specified therein for:

1. Standard plate count at 32ºC (agar or Petrifilm method).
2. Alternate methods, including the Plate Loop Count and the BactoScan FC for viable counts for raw milk, and the Petrifilm method for pasteurized milk and milk products at 32ºC.
3. Coliform test with solid media or Petrifilm method at 32ºC for all milk and milk products, and the Petrifilm High Sensitivity Coliform Count method for all milk and milk products, except unflavored whole, reduced or low fat and nonfat (skim) milk.
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 milk product at current safe or tolerance levels shall be used for each drug of concern.
Regulatory action shall be taken on all confirmed 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 and accepted by the NCIMS 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: 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.

5a. Milk (Non-Goat): Any of the following confirmatory or screening tests shall be used: Direct Microscopic Somatic Cell Counting Single Strip Procedure, Electronic Somatic Cell Counting or Flow Cytometry/Opto-Electronic Somatic Cell Counting.

5b. Goat Milk: In addition to the above mentioned tests, the Wisconsin Mastitis Test or California Mastitis Test may be used for screening raw goat milk samples, to indicate a range of somatic cell levels, as long as the somatic cell standard for goat milk remains 1,000,000/mL. Laboratories using the Wisconsin Mastitis Test or California Mastitis Test for goat milk shall confirm samples of herd milk that exceeds 18mm, or a value of one (1), respectively.

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

6. APHA, AOAC, or Electronic Phosphatase Tests: 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, or if any doubt should arise as to the compliance of the equipment, standards or methods outlined in Section 7, Item 16p, the Regulatory Agency should immediately conduct field phosphatase test at the plant. (See Appendix G.)

7. Vitamin testing shall be performed using test methods acceptable to FDA or other official methodologies, which give statistically equivalent results to the FDA methods.

8. Any other tests, which have been approved by FDA to be equally accurate, precise and practical.

9. All standards used in the development and use of drug residue detection methods designed for Grade "A" PMO 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.

10. Procedural or reagent changes for official tests must be submitted to FDA for acceptance prior to being used by certified NCIMS milk laboratories.

SAMPLING PROCEDURES: SMEDP contains guidance for sampling of products. (See Appendix G. 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. See Appendix B. for reference to farm bulk milk hauling programs regarding training, licensing/permitting, routine inspection and the evaluation of sampling procedures.)

SECTION 7. STANDARDS FOR GRADE "A" MILK AND MILK PRODUCTS

All Grade “A” raw milk for pasteurization, ultra-pasteurization, or aseptic processing and all Grade "A" pasteurized, ultra-pasteurized or aseptically processed milk and milk products shall be produced, processed and pasteurized, ultra-pasteurized, or aseptically processed to conform to

the following chemical, bacteriological and temperature standards and the sanitation requirements of this Section.

No process or manipulation other than pasteurization, ultra-pasteurization or aseptic processing; processing methods integral therewith; and appropriate refrigeration shall be applied to milk and milk 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 52ºC (125ºF) but less than 72ºC (161ºF), 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 75ºC (166ºF) in a continuing heating process and immediately cooled to 7ºC (45ºF) or less when necessary for enzyme deactivation (such as lipase reduction) for a functional reason.

Table 1. Chemical, Bacteriological and Temperature Standards		
GRADE "A" RAW MILK AND MILK PRODUCTS FOR PASTEURIZATION, ULTRA-PASTEURIZATION OR ASEPTIC PROCESSING	Temperature.....	Cooled to 10ºC (50ºF) or less within four (4) hours or less, of the commencement of the first milking, and to 7°C (45ºF) or less within two (2) hours after the completion of milking. Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 10ºC (50ºF).
	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.
GRADE "A" PASTEURIZED MILK AND MILK PRODUCTS AND BULK SHIPPED HEAT-TREATED MILK PRODUCTS	Temperature.....	Cooled to 7ºC (45ºF) or less and maintained thereat.
	Bacterial Limits**…....	20,000 per mL, or gm.***
	Coliform****.....	Not to exceed 10 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 milk 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 milk products.
GRADE "A" ASEPTICALLY PROCESSED MILK AND MILK PRODUCTS	Temperature.....	None.
	Bacterial Limits.....	Refer to 21 CFR 113. 3(e)(1)*****
	Drugs**.....	No positive results on drug residue detection methods as referenced in Section 6 - Laboratory Techniques that have been found to be acceptable for use with aseptically processed milk and milk products.

* Goat Milk 1,000,000 per mL

** 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 current edition of the SMEDP)

**** Not applicable to bulk shipped heat-treated milk products

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

STANDARDS FOR GRADE "A" RAW MILK FOR PASTEURIZATION, ULTRA-PASTEURIZATION OR ASEPTIC PROCESSING

ITEM 1r. ABNORMAL MILK

Lactating animals which show evidence of the secretion of abnormal milk in one (1) 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 judgment 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 lactating animals 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 a staphylococcus or other infectious agent often causes the disease. Occasionally lactating 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, (EPA) 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 animals 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 animals.
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 at least those requirements contained in the Model Regulations for Processed Animal Wastes developed by the Association of American Feed Control Officials; 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 C., III.
2. Have walls and ceilings, which are smooth, painted or finished in an approved manner; in good repair; and 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 become 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 lactating 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 C., II. or acceptable to the Regulatory Agency.
4. Stall barns, when used with gutter grates over manure storage pits, are designed and constructed in accordance with the specifications of Appendix C., IV. or acceptable to the Regulatory Agency.
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, calf and horse stalls 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 calves, 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.

ITEM 3r. MILKING BARN, STABLE OR 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, or belly straps, 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 the potential for the spread of disease. Clean milk stools and surcingles reduce the likelihood of contamination of the milker's hands between the milking of one (1) lactating 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 reasonably clean.
5. Gutter cleaners are reasonably clean.
6. All pens, calf stalls and bull pens, 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 C., II.
10. Stall barns, when used with gutter grates over manure storage pits, are operated and maintained in accordance with the specifications of Appendix C., IV.

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 sanitarian should require cleaning with water.

ITEM 4r. COWYARD

The cowyard shall be graded and drained and shall have no standing pools of water or accumulations of organic wastes. Provided, that in loafing or lactating animal-housing areas, lactating animal droppings and soiled bedding shall be removed, or clean bedding added, at sufficiently frequent intervals to prevent the soiling of the lactating 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 cowyard 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 lactating animal's udders and flanks. The grading and drainage of the cowyard, as far as is practicable, is 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 cowyard, 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 cowyard, 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 lactating animal's 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 cowyard. Cowyards, 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 cow'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 and free-stall housing, shall be considered as part of the cowyard. Manure packs shall be solid to the footing of the animals. (See Appendix C.)
5. Cowyards 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 - CONSTRUCTION AND FACILITIES

A milkhouse 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 parlor 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 (2) 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 milkhouse and shall comply with the requirements of the milkhouse with respect to construction items; lighting; drainage; insect and rodent control; and general maintenance. In addition, the following minimum criteria shall be met:

1. 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. An indicating thermometer shall be installed as close as possible to the recording device for verification of recording temperatures. This indicating thermometer will comply with all applicable requirements in Appendix H. This thermometer shall be used to check the recording thermometer during the regulatory inspection and the results recorded on the recording chart.
2. 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 an acceptable milk sample collector.
3. 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 tank truck 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 milkhouse. 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. 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. An indicating thermometer shall be installed as close as possible to the recording device for verification of recording temperatures. This indicating thermometer will comply with all applicable requirements in Appendix H. This thermometer shall be used to check the recording thermometer during the regulatory inspection and the results recorded on the recording chart.
5. The milk shall be sampled at the direction of the Regulatory Agency, in a manner so as to preclude contaminating the milk tank truck 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.
6. The milk tank truck shall be parked on a self-draining concrete or equally impervious surface during filling and storage.

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 milkhouse that is separated from the barn, stable or parlor and the living quarters provides a safeguard against the exposure of milk and milk equipment and utensils to contamination.

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. 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 twenty (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 parlor 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 milk 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 C.)

15. The milkhouse is equipped with a wash-and-rinse vat having at least two (2) 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 (1) part of the two (2) 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 milkhouse and shall comply with the prerequisites of the milkhouse with respect to construction items: lighting; drainage; insect and rodent control; and general maintenance. (See Appendix C. 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 that cools the milk to 7°C (45°F) or less. An indicating thermometer shall be installed as close as possible to the recording device for verification of recording temperatures. This indicating thermometer will comply with all applicable requirements in Appendix H**.** This thermometer shall be used to check the recording thermometer during the regulatory inspection and the results recorded on the recording chart.

b. The milk shall be sampled at the direction of the Regulatory Agency in a manner so as to preclude contaminating the milk tank truck or sample, by an acceptable 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 tank truck can be adequately protected and sampled without contamination, a shelter need not be provided if the following minimum criteria are met:

a. The milk hose connection is accessible to, and made from within, the milkhouse. The milk hose connection to the milk tank truck is completely protected from the outside environment at all times.

b. To assure continued protection of the milk, the milk tank truck manhole must be sealed after the truck has been cleaned and sanitized.
c. 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.
d. An accurate, accessible temperature recording device shall be installed in the milk line downstream from an effective cooling device, which cools the milk to below 7°C (45°F). An indicating thermometer shall be installed as close as possible to the recording device for verification of recording temperatures. This indicating thermometer will comply with all applicable requirements in Appendix H**.** This thermometer shall be used to check the recording thermometer during the regulatory inspection and the results recorded on the recording chart.
e. The milk shall be sampled at the direction of the Regulatory Agency, in a manner so as to preclude contaminating the milk tank truck 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.
f. The milk tank truck shall be parked on a self-draining concrete or equally impervious surface during filling and storage.

ITEM 6r. MILKHOUSE - CLEANLINESS

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

PUBLIC HEALTH REASON

Cleanliness in the milkhouse reduces the likelihood of contamination of the milk.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. The milkhouse structure, equipment and other milkhouse 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 milkhouse provided they are kept clean and ample space is available to conduct the normal operations in the milkhouse and will not cause contamination of the milk.
3. Vestibules, if provided, are kept clean.
4. Animals and fowl are kept out of the milkhouse.

ITEM 7r. TOILET

Every dairy farm shall be provided with one (1) or more toilets, conveniently located; properly constructed; operated; and maintained in a sanitary manner. The waste shall be inaccessible to insects 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 (1) 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 C., or when a Regulatory Agency has more effective standards designed specifically for that region, these standards may apply, provided, there is no mixing of animal and human waste.
2. A toilet or privy is convenient to the milking barn and the milkhouse. There shall be no evidence of human defecation or urination about the premises.
3. No privy opens directly into the milkhouse.
4. The toilet room, including all fixtures and facilities, is kept clean and free of insects 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 insects.
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 dairy utensils and containers, may be more dangerous than a similar water supply that 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 State Water Control Authority and, in the case of individual water systems, complies with the specifications outlined in Appendix D., and the Bacteriological Standards outlined in Appendix G.
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 D) 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 groundwater storage at the dairy farm, a suitable pump, hose and fittings shall be provided. When the pump, hose and fittings are not being used, the outlets shall be capped and stored in a suitable dust-proof enclosure so as to prevent their contamination. The storage tank at the dairy farm shall be constructed of impervious material; provided with a dust and rainproof cover; and also provided with an approved vent and roof hatch. All new reservoirs or reservoirs which have been cleaned shall be disinfected prior to placing them into service. (See Appendix D.)
7. Samples for bacteriological examination are taken upon the initial approval of the physical structure, based upon the requirements of this *Ordinance*; when any repair or alteration of the water supply system has been made; and at least every three (3) 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 (6) 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 (4) 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, non-corrodible 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 milk products, or from which liquids may drip, drain or be drawn into milk or milk products, are made of smooth impervious, nonabsorbent, safe materials of the following types:
   a. Stainless steel of the American Iron and Steel Institute (AISI) 300 series; or
   b. Equally corrosion-resistant, non-toxic metal; 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, relatively insoluble; do not release component chemicals or impart flavor or odor to the product; and which maintain their original properties under repeated use conditions.
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 screwdriver 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 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 for Food Protection 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 this *Ordinance*.

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 milking or once every twenty-four (24) hours for continuous operations.
3. There shall be no partial removal of milk from milk storage/holding tanks by the bulk milk hauler/sampler, except partial pickups may be permitted when the milk storage/holding tank is equipped with a seven (7) day recording device complying with the specifications of Appendix H. or other recording device acceptable to the Regulatory Agency, provided the milk storage/holding tank shall be clean and sanitized when empty and shall be emptied at least every seventy-two (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 inclement weather, natural disaster, etc., a variance may be permitted at the discretion of the 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 that 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, utensils and equipment 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 77ºC (170ºF) for at least five (5) minutes; or exposure to a flow of hot water at a temperature of at least 77ºC (170ºF), as determined by the use of a suitable accurate thermometer, at the outlet, for at least five (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 and shall be used in accordance with label directions. (See Appendix F. 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 FDA, which meets these criteria, may be stored in the milking barn or parlor, provided this equipment is designed, installed and operated to protect the product and solution-contact surfaces from contamination at all times.

PUBLIC HEALTH REASON

Careless storage of milk containers, utensils and equipment, 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 FDA, 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 surfaces from contamination at all times. Some of the parameters to be considered in determining protection are:
   a. Proper location of equipment;
   b. Proper drainage of equipment; and
   c. Adequate and properly located lighting and ventilation.
2. 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. Provided, in the case of a milking parlor that opens directly into an enclosed housing area, through a covered holding area, the holding area may be seasonally enclosed when:
   a. There are no manure pit openings in the parlor, holding area or in the housing area close enough to affect the milking parlor.
   b. The cattle holding and housing areas are maintained in good repair and reasonably clean.
   c. With respect to dust, odors, rodents and insects, the entire area meets milking parlor standards and the parlor is free of evidence of birds.

In addition, construction and cleanliness items identified above shall be evaluated in the appropriate *Ordinance* Sections.

3. Means are provided to effect complete drainage of equipment when such equipment cannot be stored to drain freely.
4. Clean cans or other containers are stored in the milkhouse within a reasonable time after delivery to the dairy farm.
5. Strainer pads, parchment papers, gaskets and similar single-service articles are stored in a suitable container or cabinet, in a location convenient to their use, and protected against contamination.

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 they 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 by FDA 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 milk 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 overcrowded. The quality of any air that is used for the agitation or movement of milk or is directed at a milk 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, utensils and equipment by splash, condensation or manual contact.
2. During processing, pipelines and equipment, used to contain or conduct milk and milk products, shall be effectively separated from tanks or circuits containing cleaning and/or sanitizing solutions.
3. All milk that has overflowed, leaked, been spilled or improperly handled is discarded.
4. All product-contact surfaces of containers, utensils and equipment are covered or otherwise protected to prevent the access of insects, dust, condensation and other contamination. All openings, including valves and piping attached to milk storage and milk tank trucks, 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 bulk milk 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 barn, stable or parlor. 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 H.

9. Sanitized product contact surfaces, including bulk milk 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 milk 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. (See Items 10p. and 11p. and Appendix B. 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 drug 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 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 drugs 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 occurs 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 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. Drugs intended for treatment of non-lactating dairy animals are segregated from those drugs used for lactating animals. Separate shelves in cabinets, refrigerators or other storage facilities satisfy this Item.

4. Drugs shall be properly labeled to include the name and address of the manufacturer or distributor for OTC drugs, or veterinary practitioner dispensing the product for Rx and extra label use drugs.
5. Drug 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 drugs are not used to treat dairy animals and are not stored in the milkhouse, milking barn, stable or parlor.
7. Drugs are stored in such a manner that they cannot contaminate the milk or milk product-contact surfaces of the containers, utensils or equipment.

NOTE: Topical antiseptics and 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 milk product surfaces of containers, utensils or equipment.

ITEM 16r. PERSONNEL - HANDWASHING FACILITIES

Adequate handwashing 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

Adequate handwashing facilities are essential to personal cleanliness and minimize the likelihood of contamination of the milk. Handwashing facilities are required in order to increase the assurance that milker's and bulk milk hauler/sampler's hands will be washed.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. Handwashing facilities are located convenient to the milkhouse, milking barn, stable, parlor and flush toilet.
2. Handwashing 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 handwashing 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 bulk milk hauler/samplers 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 lactating animal's udder. The milker's hands may have been exposed to contamination during the course of their 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 bulk milk hauler/samplers wear clean outer garments while milking or handling milk containers, utensils or equipment.

ITEM 18r. RAW MILK COOLING

Raw milk for pasteurization shall be cooled to 10ºC (50ºF) or less within four (4) hours or less, of the commencement of the first milking, and to 7ºC (45ºF) or less, within two (2) hours after the completion of milking. Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 10ºC (50ºF).

PUBLIC HEALTH REASON

Milk produced by disease-free lactating 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 7ºC (45ºF) 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, however, 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 this *Ordinance* 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 the milk, will not multiply.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. Raw milk for pasteurization shall be cooled to 10ºC (50ºF) or less within four (4) hours or less, of the commencement of the first milking, and to 7ºC (45ºF) or less, within two (2) hours

after the completion of milking. Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 10ºC (50ºF).

2. Recirculated cooling 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 G.

3. 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 every six months and documented 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.

ITEM 19r. INSECT AND RODENT CONTROL

Effective measures shall be taken to prevent the contamination of milk, containers, utensils and equipment by insects and rodents and by chemicals used to control such vermin. Milkhouses 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 pathogenic organisms on their bodies and they may carry living bacteria for as long as four (4) 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 microorganisms, which may multiply and become sufficiently numerous to present a public health hazard. The surroundings of a dairy should be kept neat and clean in order to 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 (4) days in a pile on the ground surface and then spread on the fields; or stored for not more than seven (7) days in an impervious-floored bin, or on an impervious-curbed platform and then spread; or stored in a tight-screened and trapped manure shed; or effectively treated with larvicides; or disposed of in any other manner which controls insect breeding.
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. Milkhouses are free of insects and rodents.
4. Milkhouses 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 EPA are used for insect and rodent control. (See Appendix C. for further information about insect and rodent control).
8. Insecticides and rodenticides are used only in accordance with the manufacturer's label directions and are used so as to prevent the contamination of milk, milk containers, utensils and equipment, feed and water.
9. Covered boxes, bins or separate storage facilities for ground, chopped or concentrated feeds are provided.
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.

NOTE: See Appendix M. for an inspection form for producer dairy farms, which summarizes the applicable sanitation requirements.

STANDARDS FOR GRADE "A" PASTEURIZED, ULTRA-PASTEURIZED AND ASEPTICALLY PROCESSED MILK AND MILK 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, 17p, 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 milk products are handled, processed, or stored, or in which milk containers, utensils and equipment 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 milk products need not be provided with floor drains when the floors are sloped to drain to one (1) 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 milk 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 milk 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

Properly finished walls and ceilings are more easily kept clean and are; therefore, more apt to be kept clean. A light-colored finish aids in the even distribution of light and the detection of un-clean conditions.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be 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 insects 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 insects in the milk plant reduces the likelihood of contamination of the milk. (See Item 7r. - Public Health Reason for information on disease transmission by flies).

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 insects; 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 insects.

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 milk products are handled, processed or stored and/or in which milk containers, utensils and equipment 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 twenty (20) foot-candles of light in all working areas. This shall apply to all rooms where milk or milk products are handled, processed or stored, or where containers, utensils 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 milk products.
2. The cleaning of milk cans, bottles and cases.
3. The fabrication of containers and closures for milk and milk products.
4. Cleaning and sanitizing facilities for milk tank trucks in plants receiving milk in such tanks.
5. Receiving cans of milk and milk products in plants receiving such cans.

Rooms in which milk or milk 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 milk 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 insects therein, as well as to render it too public.

ADMINISTRATIVE PROCEDURES[7]

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 milk 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 Grade "A" 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. 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 milk tank truck cleaning facility. Items relating to facilities for cleaning and sanitizing milk tank trucks are listed at the beginning of this Section.
5. Rooms in which milk or milk products are handled, processed or stored, or in which milk containers, utensils and equipment are washed or stored, do not open directly into any stable or any room used for domestic purposes.
6. All rooms shall be of sufficient size for their intended purposes.

ITEM 6p. TOILET-SEWAGE DISPOSAL FACILITIES

Every milk plant shall be provided with toilet facilities conforming to the regulations of the ... of ...[1] Toilet rooms shall not open directly into any room in which milk and/or milk 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 milk 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 milk plant is provided with toilet facilities conforming to the regulations of the ... of ...[1]
2. Toilet rooms do not open directly into any room in which milk and/or milk 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 State or local 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 milk 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[8]

This Item is deemed to be satisfied when:

1. Water for milk 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 the specification outlined in Appendix D. and the Bacteriological Standards outlined in Appendix G.
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 Item 2. above. Provided, that when approved by the Regulatory Agency, water from sources not complying with Item 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 thirty-five (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 Item 2. above, and water reclaimed from milk or milk products may be reused when all necessary means of protection are afforded and it complies with the procedures outlined in Appendix D., 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 D.) 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 six (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 (6) 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. HANDWASHING FACILITIES

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

PUBLIC HEALTH REASON

Proper use of handwashing facilities is essential to personal cleanliness and reduces the likelihood of contamination of milk and milk products.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. Convenient handwashing facilities are provided, including hot and cold and/or warm running water, soap and individual sanitary towels or other approved hand-drying devices.
2. Handwashing facilities are convenient to all toilets and to all rooms in which milk plant operations are conducted.
3. Handwashing 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 handwashing facilities.

ITEM 9p. MILK PLANT CLEANLINESS

All rooms in which milk and milk products are handled, processed or stored, and/or in which containers, utensils or equipment are washed or stored, 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

Clean floors, free of litter, clean walls, ceilings and all other areas of the dairy plant are conducive to clean milk handling operations. Cleanliness and freedom from insects and rodents reduces the likelihood of contamination of the milk or milk 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 milk products are handled, processed or stored, and/or in which containers, utensils, or equipment are washed or stored, are kept clean, neat and free of evidence of insects and rodents.

ITEM 10p. SANITARY PIPING

All sanitary piping, fittings and connections which are exposed to milk or milk products, or from which liquids may drip, drain or be drawn into milk or milk products, shall consist of smooth, impervious, corrosion-resistant, nontoxic, easily cleanable material which is approved for food contact surfaces. All piping shall be in good repair. Pasteurized milk and milk products shall be conducted from one piece of equipment to another only through sanitary piping.[9]

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 the third sentence 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 milk products, or from which liquids may drip, drain or be drawn into milk 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 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; 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 Item 2. above. If gaskets are used, they shall be self-positioning, of material meeting the specifications outlined in Item 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 inspected as they are made and such 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 or 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 milk 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 that milk or milk products come into contact with 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 that milk or milk products come in contact with 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 cleaned easily, and which is not kept in good repair, it is unlikely that it will 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 that milk or milk products come into contact with 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 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; 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, utensils and equipment are flush and finished as smooth as adjoining surfaces. Where a rotating shaft is inserted through a surface with which milk or milk products come into contact, the joint between the moving and stationary surfaces shall be close fitting. Where a thermometer or temperature-sensing element is inserted through a surface, with which milk or milk products come into contact, a pressure-tight seal shall be provided ahead of all threads and crevices.
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, thermometers, or temperature sensing elements and other equipment extending into a tank, bowl, vat or similar equipment, unless a watertight joint is provided.
5. All surfaces with which milk or milk products come into contact are easily accessible or demountable for manual cleaning or are designed for mechanical cleaning. All product-contact surfaces shall be readily accessible for inspection and shall be self-draining.
6. There are no threads used in contact with milk or milk products except where needed for functional and safety reasons, such as in clarifiers, pumps and separators. Such threads shall be of a sanitary type.
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 milk products, such as buttermilk, whey and dry milk products, woven material may be used where it is impractical to use perforated metal. However, woven material parts shall be mechanically cleaned by such methods that thoroughly clean the woven material and do not contaminate the product.
9. All single-service containers, closures, gaskets and other articles that milk or milk products come in contact are nontoxic.
10. The manufacture, packing, transportation and handling of single-service containers, closures, caps, gaskets and similar articles comply with the requirements of Appendix J., Standards for the Fabrication of Single-Service Containers and Closures for Milk and Milk Products.

Inspections and tests shall be made by the Regulatory Agency or any agency authorized by them.

NOTE: 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 for Food Protection and the Milk Safety Branch, Center for Food Safety and Applied Nutrition, Food and Drug Administration, Public Health Service, Department of Health and Human Services. Equipment manufactured in conformity with 3-A Sanitary Standards complies with the sanitary design and construction standards of this *Ordinance*.

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 milk 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 milk products, beyond the final heat treatment process, shall be sterilized before any aseptically processed milk or milk product is packaged and shall be resterilized whenever any unsterile product has contaminated it.

PUBLIC HEALTH REASON

Milk and milk products cannot be kept clean and safe, if permitted to come into contact with containers, utensils and equipment that 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 FDA and the Regulatory Agency have reviewed and accepted information supporting the cleaning of multi-use containers and utensils at frequencies extending beyond one (1) day or seventy-two (72) hours in the case of storage tanks. Supporting information shall be submitted to and approved by the Regulatory Agency in consultation with FDA prior to initiating the qualification period if required. Finished product produced during an extended run must meet all applicable requirements of Section 7. Any significant equipment or processing changes shall be communicated to the Regulatory Agency. The supporting information may include but is not limited to:

a. Statement of proposal, including desired cleaning frequency;
b. Product and equipment description;
c. Intended use and consumers;
d. Distribution and storage temperatures of product;
e. Diagram of process of interest;
f. Process parameters, including temperature and times;
g. Hazard evaluation and safety assessment;

h. Review of equipment for sanitary design; and

i. When indicated by a hazard evaluation and safety assessment, a plan for initial qualification shall be developed to address identified critical process parameters.

Otherwise, storage tanks shall be cleaned when emptied and shall be emptied at least every seventy-two (72) hours. Records must be available to verify that milk storage in these tanks does not exceed seventy-two (72) hours. These records shall be available for at least the previous three (3) 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 seventy-two (72) hours, the mechanical cleaning records required under Item 2.b. of this Section shall be considered adequate. Storage tanks, which are used to store raw milk or heat-treated milk products longer than twenty-four (24) hours and silo tanks used for the storage of raw milk or heat-treated milk products shall be equipped with a seven (7) day temperature recording device complying with the specifications of Appendix H.

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 fifteen (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 H., or a recording device which provides sufficient information to adequately evaluate the cleaning and sanitizing regimen and which is approved by the 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 H. 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 typical pattern of each circuit cleaned, so that changes in the cleaning regimen may be readily detected.

(3) Electronic storage of required cleaning records, with or without hard copy printouts, may be acceptable, provided, the electronically generated records are readily available. Electronic records must meet the criteria of this Section and those provisions of Appendix H., which are determined to be applicable by the Regulatory Agency and FDA.

c. Cleaning charts and electronically stored records required by this Section shall be identified, dated and retained for three (3) 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 (2)-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. In plants utilizing automatic bottle washers, such washers must provide for bactericidal treatment by means of steam, hot water or chemical treatment. In soaker-type bottle washers, in which bactericidal treatment depends upon the causticity of the washing solution, the caustic strength for a given soaking time and temperature shall be as specified in the following table which lists the combinations of causticity, time and temperature, of equal bactericidal value, for the soaker tank of soaker-type bottle washers:

Table 2. Combinations of Causticity, Time and Temperature, of Equal Bactericidal Value, for the Soaker Tank of Soaker Type Bottle Washers

(Based on NSDA Specifications for beverage bottles)

	Temperature, Degrees						
C	77	71	66	60	54	49	43
F	170	160	150	140	130	120	110
Time in Minutes	**Concentration of NaOH (percent)**						
3	0.57	0.86	1.28	1.91	2.86	4.27	6.39
5	0.43	0.64	0.96	1.43	2.16	3.22	4.80
7	0.36	0.53	0.80	1.19	1.78	2.66	3.98

NOTE: The National Soft Drink Association (NSDA), Washington, D.C. 20036 alkali test, the NSDA caustic test, or other suitable test may be used to determine the strength of the soaker solution. The caustic strength shall be tested monthly by the Regulatory Agency.

When caustic is so used, subsequent final rinsing of the bottles shall be with water, which has been treated with heat or chemicals to assure freedom from viable pathogenic or otherwise harmful organisms, to prevent recontamination of the treated bottle during the rinsing operation.
5. All multi-use containers, utensils and equipment 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 FDA and the Regulatory Agency have reviewed and accepted information supporting the sanitizing of multi-use containers, utensils and equipment at frequencies extending beyond one (1) 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 milk 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.

6. a. The residual bacteria count of multi-use containers and closures shall be conducted as outlined in Appendix J. The residual bacteria count of multi-use containers, used for packaging pasteurized milk and milk products, shall not exceed one (1) organism per milliliter (1/mL) of capacity, when the rinse test is used, or not over fifty (50) colonies per fifty (50) square centimeters (one (1) colony per square centimeter) of product-contact surface, when the swab test is used, in three (3) out of four (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 and closures, used for packaging pasteurized milk and milk products, shall not exceed fifty (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 fifty (50) colonies per eight (8) square inch (one (1) colony per square centimeter) of product-contact surface, when the swab test is used, in three (3) out of four (4) samples taken at random on a given day. All single-service containers shall be free of coliform organisms.

When single-service containers or closures are fabricated in another plant that conforms to the Standards of Appendix J. and the Regulatory Agency has information that they do comply, the Regulatory Agency may accept the containers as being in conformance without additional tests. If there is reason to believe that containers do not conform to the bacteriological standards, additional tests may be required. If containers are fabricated in the dairy plant, the Regulatory Agency shall collect at least four (4) sets of containers, each (6) months, and determine conformance.

7. Plants that utilize multi-use plastic containers, for pasteurized milk and milk products, shall comply with the following criteria:

   a. All containers shall be identified as to plant of manufacture, date of manufacture and type and class of plastic material used. This information may be by code. Provided, that the code is revealed to the Regulatory Agency.

   b. A device shall be installed in the filling line capable of detecting, in each container before it is filled, volatile organic contaminants in amounts that are of public health significance. Such device must be constructed so that it may be sealed by the Regulatory Agency to prevent the changing of its sensitivity functioning level. Models using an air injection system and with a testing device built into the detection equipment do not have to be sealed. To assure proper functioning of the system the operator needs to be able to adjust the sensitivity. However, those models utilizing an external testing device must be sealed. Any container detected by the device, as being unsatisfactory must be automatically made unusable to prevent refilling. In addition, the device must be interconnected so that the system will not operate unless the detecting device is in proper operating condition. Provided, that any other system so designed and operated that will provide equal assurance of freedom from contamination and recognized by FDA to be equally efficient may be accepted by the Regulatory Agency.

   c. A standard must be available for use by the Regulatory Agency for testing the proper sensitivity functioning levels of the detection device.

   d. The containers shall comply with the applicable construction requirements of Item 11p. of this *Ordinance*. The closure for the container shall be single-service. Screw-type closures shall not be used.

e. The container shall not impart, into the product, pesticide residual levels or other chemical contaminants in excess of those considered acceptable under the FFD&CA and regulations issued thereunder.
f. The phrase "Use only for food" shall appear on all containers.

ITEM 13p. STORAGE OF CLEANED CONTAINERS AND EQUIPMENT

After cleaning, all multi-use milk or milk 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:

All multi-use containers, utensils and equipment, after cleaning, are transported and/or stored on racks made of impervious food grade materials, or in clean cases elevated above the floor. Containers shall be stored inverted on racks or in cases constructed of relatively nonabsorbent, impervious, food-grade, 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 milk 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 this *Ordinance*. Packing the caps in tubes, which remain unbroken until they are placed in the bottling 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 milk products are purchased and stored in sanitary tubes, wrappings or cartons; are kept in a clean, dry place until used; and are handled in a sanitary manner.
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

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

PUBLIC HEALTH REASON

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

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

15p.(A)

1. Equipment and operations are so located within the plant as to prevent overcrowding and contamination of cleaned and sanitized containers, utensils and equipment by splash, condensation or manual contact.
2. Packaged milk and milk products which have physically left the premises or the processing plant are not repasteurized for Grade "A" use. The Regulatory Agency may, on a specific individual request, authorize reprocessing of packaged milk and milk 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 milk products shipped in transport milk tank trucks which have been pasteurized at another Grade "A" plant and have been handled in a sanitary manner and maintained at 7ºC (45ºF) or less is permitted. Equipment, designated areas or rooms utilized for handling, processing and storage of returned packaged milk and milk products are maintained, operated, cleaned and sanitized so as to preclude contamination of Grade "A" products and equipment and the Grade "A" operations.

3. All product-contact surfaces of containers, utensils and equipment are covered or otherwise protected to prevent the access of insects, dust, condensation and other contamination. All openings, including valves and piping attached to milk 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 H. The use of steam containing toxic substances is expressly prohibited. Whenever steam is used in contact with milk or milk products, it shall be of culinary quality and shall comply with the applicable standards of Appendix H.

5. Standardization of Grade "A" milk and milk products with other than Grade "A" milk and milk products is prohibited. This *Ordinance* permits standardization as a process of adjusting the milkfat of milk in a milk plant by the addition or removal of cream or non-fat (skim) milk.

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

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

8. Pasteurized milk is not strained or filtered, except through a perforated metal strainer.

9. 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.
10. Those poisonous or toxic materials that are necessary are not stored in any room where milk or milk products are received, processed, pasteurized or stored; or where containers, utensils or equipment, are washed; or where single-service containers, closures or caps are stored.
11. 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 containers, utensils and equipment are washed and sanitized.
12. Only insecticides and rodenticides approved by the Regulatory Agency and/or registered with the EPA shall be used for insect and rodent control. Such insecticides and rodenticides shall be used only in accordance with the manufacturer's label directions and shall be prevented from contaminating milk, containers, utensils and equipment.
13. In the case of separating non-Grade "A" and Grade "A" products, a water rinse after processing non-Grade "A" and prior to Grade "A" is adequate separation, provided both are processed as Grade "A", and raw and pasteurized products are kept physically separated.
14. Grade "A" raw milk or milk products and non-Grade "A" raw products, dairy or non-dairy, shall be separated by one valve.
15. Grade "A" pasteurized milk or milk products and non-Grade "A" pasteurized products, dairy or non-dairy, shall be separated by one valve.
16. 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.

15p.(B)

1. During processing, pipelines and equipment used to contain or conduct milk and milk products shall be effectively separated from tanks or circuits containing cleaning and/or sanitizing solutions. 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 milk 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 that 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 milk 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, milk product, cleaning solutions, or sanitizing solutions into this valve arrangement.

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

2. Except as permitted in Item 16p., there shall be no physical connection between unpasteurized products, dairy, non-dairy, or water, and pasteurized milk or milk products. Pasteurized non-dairy products 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 FDA and the Regulatory Agency.
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 (2) times the diameter of the largest of these pipelines. For purposes of this section an overflow is defined as the flood rim of the constant level 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 (2) times the diameter of the largest of these pipelines.
4. All milk and milk products that have overflowed, leaked, been spilled or improperly handled are discarded. Milk and milk 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 milk products are handled in a sanitary manner and maintained at 7ºC (45ºF) or less. When the handling and/or refrigeration of such milk and milk products are not in compliance with this requirement, they shall be discarded. Milk and milk products from damaged, punctured or otherwise contaminated containers or product from out of code containers shall not be repasteurized for Grade "A" use.
5. Means are provided to prevent contamination of milk containers, utensils and equipment by drippings, spillage and splash from overhead piping, platforms or mezzanines.
6. The processing of foods and/or drinks other than Grade "A" milk and milk products are performed to preclude the contamination of such milk and milk products.

7. In no case shall pasteurized milk or milk products be standardized with unpasteurized milk unless the standardized product is subsequently pasteurized.
8. Reconstituted or recombined milk and milk 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 this *Ordinance*. Aseptic processing shall be performed in accordance with 21 CFR 113, 21 CFR 108 and the Administrative Procedures of Item 16p., C, D and E of this Section. (See Appendix L.)

PUBLIC HEALTH REASON

Health officials unanimously agree upon the public health value of pasteurization. Long experience conclusively shows its value in the prevention of disease that may be transmitted through milk. Pasteurization is the only practical, commercial measure, which, if properly applied to all milk, will destroy all milkborne disease organisms. Examination of lactating animals and milk handlers, while desirable and of great value, can be done only at intervals and; therefore, it is possible for pathogenic bacteria to enter the milk for varying periods before the disease condition is discovered. Disease bacteria may also enter milk accidentally from other sources, such as flies, contaminated water, utensils, etc. It has been demonstrated that the time-temperature combinations specified by this *Ordinance*, if applied to every particle of milk, will devitalize all milkborne pathogens. Compilations of outbreaks of milkborne disease by the PHS/FDA, over many years, indicate that the risk of contracting disease from raw milk is approximately fifty (50) times as great as from milk that has been "pasteurized".
A note of caution is in order. Although pasteurization destroys 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. Aseptic processing has also been conclusively demonstrated to be effective in preventing outbreaks from milkborne pathogens.
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 milk 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 3. Pasteurization Temperature vs. Time	
Temperature	Time
63ºC (145ºF) *	30 minutes
72ºC (161ºF) *	15 seconds
89ºC (191ºF)	1.0 second
90ºC (194ºF)	0.5 seconds
94ºC (201ºF)	0.1 seconds
96ºC (204ºF)	0.05 seconds
100ºC (212ºF)	0.01 seconds

*If the fat content of the milk product is 10 percent (10%) or more, or if it contains added sweeteners, the specified temperature shall be increased by 3ºC (5ºF).

Provided, that eggnog shall be heated to at least the following temperature and time specifications:

69ºC (155ºF)	30 minutes
80ºC (175ºF)	25 seconds
83ºC (180ºF)	15 seconds

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

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

ITEM 16p.(A) BATCH PASTEURIZATION

All indicating and recording thermometers used in connection with the batch pasteurization of milk or milk products shall comply with the applicable specifications set forth in Appendix H. Specifications for test thermometers and other test equipment appear in Appendix I.

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 milk 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 or equivalent, 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 outlet valve and connections to the vats are properly designed and operated, cold pockets of milk may be held in the outlet valve or pipeline 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 pathogenic organisms. Heating the air above the milk, above pasteurization temperature, remedies these conditions. When air heating is not provided, its need may frequently be demonstrated by swabbing milk from the upper vat walls and from the underside of the cover, at the end of the holding period, and running phosphatase tests on the swab samples.

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 contaminants such as dust, insects, drip and splash from entering the milk.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

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 milk product, at the center of the coldest milk or milk product in the vat, will not exceed 0.5ºC (1ºF) at any time during the holding period.

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

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

c. **Assurance of Minimum Holding Periods:** Batch pasteurizers shall be so operated that every particle of milk or milk product will be held at not less than the minimum pasteurization temperature continuously for at least thirty (30) minutes. When milk or milk products are raised to pasteurization temperature in the vat, and cooling is begun in the vat simultaneously with or before the opening of the outlet valve, the recording chart shall show at least thirty (30) minutes, at not less than minimum pasteurization temperature. When milk or milk products are preheated to pasteurization temperature before entering the vat, the recording chart shall show a holding period of at least thirty (30) minutes, at not less than the minimum pasteurization temperature plus the time of filling from the level of the recording thermometer bulb. When cooling is begun in the holder, after opening the outlet valve, or is done entirely outside the holder, the recording chart shall show at least thirty (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 recording time interval on the recording chart at the pasteurization temperature includes filling and/or emptying time, such intervals shall be indicated on the recording 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 recording 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 milk products at a temperature not less than 3ºC (5ºF) higher than the minimum required temperature of pasteurization, during the holding period. (See Appendix H.)

b. Each batch pasteurizer shall be equipped with an airspace thermometer. The surface of the milk or milk 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 at the start of the holding period and at the end of the holding period, at a given time or reference point as indicated on the recording chart.

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 that permits the maximum flow into or out of the pasteurizer.

c. **"The Closed Position"** shall mean any position of the valve seat that 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 inches) 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 so closely coupled that no milk in the valve is more than 0.5ºC (1ºF) 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 so flared that the smallest diameter of the large end of the flare is not less than the diameter of the outlet line, plus the depth of the flare; and

(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 in plug type outlet valves shall be at least 5 millimeters (0.187 inches wide) and at least 2.3 millimeters (0.094 inches) deep at the center. Mating grooves shall provide these dimensions throughout their combined length, whenever the valve is in, or approximately in, the fully closed position. All single leak grooves, and all mating leak grooves when mated, shall extend throughout the entire depth of the seat, so as to divert leakage occurring at all points throughout the depth of the seat and so as to prevent air 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 un-pasteurized 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 so designed as to prevent the accumulation of un-pasteurized 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 leak-protector valves outlet 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.

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

i. 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.

j. All inlet pipelines are disconnected during the holding and emptying periods.

5. **RECORDING CHARTS**

All recording thermometer charts shall comply with all the applicable requirements of Item 16p.(E),1.a.

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

This Item is deemed to be satisfied when:

1. I**NDICATING THERMOMETER AND RECORDER/CONTROLLER INSTRUMENTS**

All indicating thermometers and recorder/controller instruments and devices used in connection with the HTST, continuous-flow pasteurization of milk or milk products shall comply with the applicable specifications set forth in Appendix H.

2. **AUTOMATIC MILK CONTROLLER**

Each HTST, 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 sub-legal temperatures, flow-diversion devices (FDD) 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. **FDD's:** All FDD’s used in continuous pasteurizers shall comply with the following or equally satisfactory specifications:

(1) The forward flow of milk below the minimum pasteurization temperature shall be prevented by requiring the timing pump to be de-energized 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 backpressure 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 FDD shall be so designed and installed that failure of the primary motivating power shall automatically divert the flow of milk.

(6) The FDD 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 FDD.

(7) In the case of higher-heat-shorter-time (HHST) pasteurizing systems utilizing temperatures of 89ºC (191ºF) and above; and holding times of one (1) second or less, the FDD may be located downstream from the regenerator and/or cooler section. Provided, that when the FDD is located downstream from the regenerator and/or cooler section, the FDD shall be automatically prevented from assuming the forward-flow position until all product-contact surfaces between the holding tube and FDD 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 this *Ordinance*.

(8) The pipeline from the diversion port of the FDD 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 FDD shall be self-draining and shall be free of restrictions or valves.

(10) For the timing pump, a one (1) second maximum "off" time delay is allowed to maintain the flow-promoting device in the "on" position through the travel time of the FDD.

(11) If the area between the divert and detect valve seats is not self-draining when the FDD is in the diverted position, a delay of at least one (1) second and not more than five (5) seconds is required between the movement of the divert and detect valves when the FDD assumes the forward flow position. Except that, the delay may be longer than five (5) seconds if: the timing system is a magnetic flow meter based timing system; or if 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 this *Ordinance*; and except that, no time delay is required in pasteurization systems in which the FDD is located down stream from the pasteurized regenerator and in which all forward flow product-contact surfaces of the FDD are sanitized, or sterilized during the normal start-up 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 this *Ordinance* for the milk or

milk product and the process used, nor continue during descending temperatures when the temperature is below the required pasteurization temperature. The seal shall be applied by the 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 that 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 one (1) second or less, with the FDD 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 FDD 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 this *Ordinance*. 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 milk is above the required pasteurization temperature as defined in Definition X of this *Ordinance* for the milk or milk product and the process used, or when the diversion device is in the fully-diverted position.

d. **Holding Tube:**

(1) Holding tubes shall be designed to provide for the holding of every particle of milk or milk product for at least the time required in Definition X of this *Ordinance* for the milk or milk product and the process used.

(2) The holding tube 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 that 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 holding tube to compensate for changes in rate of milk-flow. Holding tubes shall be installed so that sections of pipe cannot be left out, resulting in a shortened holding time.

(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 inches per foot).

(5) Supports for holding 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 holding tube shall be so designed that no portion between the inlet and the recorder-controller temperature sensor is heated.

The following items apply to HHST systems:

(7) The holding time for HHST systems 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 in the injector. This surplus water is evaporated as the pasteurized product is cooled in the vacuum chamber. For example, with a 66ºC (120ºF) increase by steam injection, which is probably the maximum temperature rise that will be used, a volume increase of twelve percent (12%) 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) For those HHST systems capable of operating with less that 518 kPa (75 psig) pressure in the holding tube, a pressure limit indicator/pressure switch must be interwired so that the FDD will move to the divert position if the product pressure falls below a prescribed value. For operating temperatures between 89°C (191ºF) and 100ºC (212ºF) the instrument must be set at 69 kPa (10 psi). To prevent vaporization in the holding tube (which may substantially reduce residence times) HHST systems operating above 100°C (212ºF), the instrument must be set at 69 kPa (10 psi) above the boiling pressure of the product, at its maximum temperature in the holding tube.

(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 FDD 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 thermometers 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),1.a.

f. **Flow-Promoting Devices:**

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

(2) The speed of pumps or other flow-promoting devices, governing the rate of flow through the holding tube, 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 this *Ordinance* for the milk or milk product and the process used. In all cases, the motor shall be connected to the timing 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 also apply to all homogenizers used as timing pumps. Variable speed drives, used in connection with the timing 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 based timing systems as outlined in Appendix H. 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:

(i) 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.

(ii) 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 constant-level tank or to the outlet of the constant-level tank, upstream of any booster pump or other flow-promoting device.

For those systems that 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 that are so designed that both lines cannot be open at the same time. This may be accomplished with three (3)-way plug valves with properly designed and operating pins or other automatic, fail-safe valves that accomplish the same objective.

(3) The holding time shall be taken to mean the flow time of the fastest particle of milk, at or above the required pasteurization temperature as defined in Definition X of this *Ordinance* for the milk or milk product and the process used, throughout the holding tube section; i.e., that portion of the system that is outside of the influence of the heating medium, slopes continuously upward in the downstream direction and is located upstream from the FDD. 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 holding tube, 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 (i) 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 holding tube, the holding time shall be tested with the timing 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:** 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 pasteurization temperature. When culinary steam is injected directly into milk or milk products, as the means of terminal heating to achieve pasteurization temperature, the steam injector shall be designed, installed and operated to comply with the following or equally satisfactory specifications:

(1) The product and steam flows must be isolated from pressure fluctuations inside the injection chamber. One (1) method of isolation is to insert supplementary orifices on the product inlet and the heated product outlet of each injector. The two (2) 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 non-condensable gases that may evolve from the product or be carried in the steam supply. Any two-phase flow caused by the non-condensable gases would displace the product in the holding tube, resulting in reduced residence times. In addition, these gases in the steam supply may also markedly alter the condensation mechanism at the point of injection. Accordingly, the steam boiler shall be supplied with a de-aerator. The de-aerator will aid in keeping the product in the holding tube as free as possible of non-condensable gases.

h. **Prevention of Product Adulteration with Added Water:**

(1) When culinary steam is introduced directly into the milk or milk product downstream from the FDD, means shall be provided to preclude the addition of steam to the product, unless the FDD 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 FDD controls, so that steam cannot flow unless the FDD is in the forward-flow position.

(2) When culinary steam is introduced directly into the milk or milk product, automatic means, i.e., 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.

(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 milk products are being packaged in hermetically sealed containers and stored for long periods of time under non-refrigerated conditions. These conditions are favorable to the growth of many types of bacteria, including pathogenic, toxin producing and spoilage organisms. Because of this, every precaution must be taken to ensure that the chosen heat process, for the particular milk or milk product, destroys all viable organisms and their spores. 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

This Item is deemed to be satisfied when:

The design and operation of aseptic processing systems comply with the applicable specifications and operational procedures of Item 16p. sub-items (C), (D) and (E). Provided, that nothing shall be construed as barring any other aseptic processing system which have been recognized by FDA 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 milk products shall comply with the applicable specifications set forth in Appendix H.

2. **ASEPTIC PROCESSING EQUIPMENT**

a. **Temperature Indicating Device:** Each aseptic processing system shall be equipped with at least one (1) 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 milk 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 FDD 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 milk products.

(3) Manual switches for the control of pumps, homogenizers or other devices that produce flow through the holding tube, 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 FDD is in the fully diverted position.

c. **Timing Pump:**

(1) A timing 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 timing 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 timing 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 based timing systems.

(2) The holding time shall be taken to mean the flow time of the fastest particle of product throughout the holding tube section, i.e., that portion of the system that is outside of the influence of the heating medium; and slopes continuously upward in the downstream direction; and is located upstream from the FDD.

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. In addition, it must be sloped upward at least 2.1 centimeters per meter (0.25 inches per foot). Supports for holding 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 holding tube to compensate for changes in rate of product 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: With the direct addition of steam, 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 aseptically processed product is cooled in the vacuum chamber. For example, with a 66ºC (120ºF) increase by steam injection, which is probably the maximum temperature rise that will be used, a volume increase of twelve percent (12%) 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 (75 psig) 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 that 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 aseptic processing equipment cannot operate in forward flow with less than 518 kPa (75 psig) pressure on the aseptically processed side of the regenerator. (See Appendix I., Test 9). The pressure limit indicator/pressure switch must be interwired so that the FDD, 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 FDD 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, which could lead to some product particles being processed below filed process temperature. When culinary steam is injected directly into milk or milk 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 (1) method of isolation is to insert supplementary orifices on the product inlet and the heated product outlet of each injector. The two (2) 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 non-condensable gases that may evolve from the product or be carried in the steam supply. Any two (2) phase flow, caused by the non-condensable gases, would displace the product in the holding tube, resulting in reduced residence times. In addition, these gases in the steam supply may also markedly alter the condensation mechanism at the point of injection. Accordingly, the steam boiler shall be supplied with a deaerator. The deaerator will aid in keeping the product in the holding tube as free as possible of non-condensable gases.

f. **Prevention of Product Adulteration with Added Water:**

(1) When culinary steam is introduced directly into the milk or milk product, automatic means, i.e., 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 into 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 that is automatically actuated by a control that shuts off the in-flowing water. 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 FDD's used in continuous aseptic process systems shall comply with Item 16p.(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 joints separating the raw and pasteurized milk.

ADMINISTRATIVE PROCEDURES

This Item is deemed satisfied when:

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 30.5 centimeters (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 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 constant-level 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 timing pump is in operation;
   b. The FDD 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 this *Ordinance*.
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 FDD, 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 89ºC (191ºF) and above and holding times of one (1) second or less, with the FDD 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 downstream from the constant-level tank and shall be open to the atmosphere at this or a higher elevation, may be eliminated. Provided, that a differential pressure controller is used to monitor the highest pressure in the raw product side of the regenerator and the lowest pressure in the pasteurized side of the regenerator, and the controller is interlocked with the FDD 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 FDD 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 this *Ordinance*.
In the case of aseptic processing systems used for producing aseptic milk and milk products, there shall be an accurate differential pressure recorder-controller installed on the regenerator. The scale divisions shall not exceed 13.8 kPa (2 psi) on the working scale of not more than 138 kPa (20 psi) per 2.54 centimeters (1 inch). The controller shall be tested for accuracy against a known accurate standard pressure indicator upon installation; at least once every three (3) months of operation thereafter; or more frequently if necessary, to ensure its accuracy. One (1) 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 milk products 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 FDD as described in Paragraph 9 of this Section.
11. When the differential pressure controller is installed and wired to control the FDD as described in Paragraph 9 of this Section, the raw product booster pump may be permitted to run at all times. Provided, that the timing pump is in operation.

MILK-TO-WATER-TO-MILK REGENERATIVE HEATING

Option 1. Milk-to-water-to-milk regenerators, with both the milk and the heat-transfer water in the raw milk section, closed to the atmosphere, shall comply with the following or equally satisfactory specifications:

a. Regenerators of this type shall be so designed, installed and operated that the heat-transfer-medium side of the regenerator, in the raw milk section, will automatically be under greater pressure than the raw milk side at all times.

b. The heat-transfer water shall be a safe water and the heat-transfer water shall be in a covered tank, which is open to the atmosphere at an elevation higher, by at least 30.5 centimeters (12 inches), than any raw milk level downstream from the constant-level tank. The heat-transfer water between its outlet from the regenerator and the nearest point downstream open to the atmosphere shall rise to a vertical elevation of at least 30.5 centimeters (12 inches) above any raw milk in the system and shall be open to the atmosphere at this or a higher elevation.

c. The heat-transfer water circuit shall be full of water at the beginning of the run and all loss of water from the circuit shall be automatically and immediately replenished whenever raw milk is present in the regenerator.

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

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

(1) The heat-transfer water pump is in operation; and

(2) The heat-transfer water pressure exceeds, by at least 6.9 kPa (1 psi), the raw milk pressure in the regenerator. A differential pressure-controller shall be installed at the raw milk inlet and the heat-transfer water outlet of the regenerator. The raw milk booster pump must be wired so that it cannot operate unless the differential pressure is met. The accuracy of the required differential pressure-controller shall be checked by the Regulatory Agency on installation; quarterly thereafter; and following repair or replacement.

Option 2. Milk-to-water-to-milk regenerators may also 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:

a. A differential pressure controller shall be used to monitor pressures of the pasteurized product and the heat-transfer-medium.

b. 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.

c. 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 FDD 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 FDD have been held at or above the required pasteurization or sterilization temperature continuously and simultaneously for at least the pasteurization or sterilization time.

d. The heat-transfer-medium pump shall be wired so that it cannot operate unless the timing pump is in operation.

NOTE: See Appendix H. 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 FDA in place of charts shall be preserved for a period of three (3) months. Provided, that all records and recording charts for aseptic milk and milk product systems shall be retained for a period of three (3) 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 or other records acceptable to FDA in place of charts as applicable:

a. **Batch Pasteurizers:**

(1) Date;
(2) Number or location of recording thermometer 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, at the start of the holding period and at the end of the holding period, at a given time or reference point as indicated on the chart;
(6) Reading of indicating thermometer, at the start of the holding period, at a given time or reference point as indicated on the chart;
(7) Quarterly, the initials of the Regulatory Agency opposite the required readings of the indicating thermometer and airspace thermometer;
(8) Quarterly, the time accuracy of the recording thermometer, as determined by the Regulatory Agency;
(9) Amount and name of pasteurized milk or milk product represented by each batch or run on the chart;
(10) Record of unusual occurrences;
(11) Signature or initials of operator; and
(12) Name of milk plant.

b. **HTST and HHST Pasteurizers:** Recording thermometer charts shall contain all the information specified in Subitem a. above, except (4), (5) and reference to the airspace thermometer in (7), and in addition, shall include the following:

(1) A record of the time during which the FDD 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 (HTST only), and initialed quarterly by the Regulatory Agency.

(3) Number (6) from above shall also be recorded immediately after a chart has been changed.

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

c. **Continuous Flow Pasteurizers or Aseptic Processing Equipment with Magnetic Flow 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 Subitem a. above, except (3), (4), (5), (6), and (7), and in addition, shall include the following:

(1) A continuous record of the time during which the FDD, valve or system is in the forward-flow position.

(2) A continuous record of the flow rate.

d. **Aseptic Processing Systems:** Recording thermometer charts shall contain all the information specified in Subitem a. above, except 4, 5 and reference to the airspace thermometer in item 7. In addition these records shall include Subitem c. above, if applicable, and the following:

(1) A continuous record of the time during which the FDD, valve or system is in the forward-flow position.

(2) A continuous record of applicable regenerator pressures.

(3) Not later than one (1) 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 (6) 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 three (3) 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 (6) 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;

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 eight (8) hours classroom instruction;

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;

d. The individual is in possession of authorization from the Regulatory Agency to perform these tests;

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 results of testing. The individual will provide the identity and volume of products processed during the period that temporary seals were applied to the Regulatory Agency;

f. If regulatory tests reveal that equipment or controls are not in compliance with the provisions of this *Ordinance*, all products that were processed during that period will be recalled;

g. The Regulatory Agency or a properly trained regulatory official, commissioned by the responsible State, of each participating non-U.S. country or political subdivision thereof, will remove the temporary seals, retest the equipment and apply regulatory seals within three (3) working days of notification by industry; and

h. No Grade "A" dairy products will be processed after three (3) working days without the affected equipment being tested and sealed by the Regulatory Agency or a properly trained regulatory official, commissioned by the responsible State, of each participating non-U.S. country or political subdivision thereof.

Table 4. Equipment Tests - Batch, HTST, HHST and Aseptic Processing Systems		
1.	Vat, HTST, HHST, Aseptic indicating and airspace thermometers	Temperature accuracy
2.	Vat, HTST, HHST, Aseptic recording thermometer	Temperature accuracy
3.	Vat, HTST, HHST, Aseptic recording thermometer	Time accuracy
4.	Vat, HTST, HHST, Aseptic indicating and recording thermometer	Recording vs. Indicating thermometer
5.1	HTST, HHST FDD	Leakage pass FDD
5.2	HTST, HHST FDD	FDD freedom of movement
5.3	HTST, HHST FDD	Device assembly (single stem)
5.4	HTST, HHST FDD	Device assembly (dual stem)
5.5	HTST FDD	Manual diversion
5.6	HTST, HHST FDD	Response time
5.7	HTST, HHST FDD	Time delay (inspect)
5.8	HTST, HHST FDD	Time delay (CIP)
5.9	HTST FDD	Time delay (leak-detect flush)
6.	Vat leak protector valve(s)	Leakage
7.	HTST indicating thermometers	Response time
8.	HTST recording thermometers	Response time
9.1	HTST pressure switches	Regenerator pressures
9.2.1	HTST, HHST, Aseptic differential pressure controllers	Calibration
9.2.2	HTST differential pressure controllers	Regenerator pressure
9.2.3	HHST and Aseptic differential pressure controllers	Regenerator pressure
9.3.1	HTST booster pump/FDD	Inter-wiring check
9.3.2	HTST booster pump/metering pump	Inter-wiring check
10.1	HTST FDD	Temperature cut-in/cut-out
10.2	HHST FDD, Aseptic divert system (indirect heat)	Temperature cut-in/cut-out
10.3	HHST FDD, Aseptic divert system (direct heat)	Temperature cut-in/cut-out
11.1	HTST holding tubes/timing pumps (except magnetic flow meter based timing systems)	Holding time
11.2.a	HTST holding tubes/magnetic flow meter based timing systems	Holding time
11.2.b	HTST, HHST, Aseptic magnetic flow meter based timing systems	Flow alarm
11.2.c	HTST, HHST, Aseptic magnetic flow meter based timing systems	Loss of signal/low flow
11.2.d	HTST magnetic flow meter based timing systems	Flow rate cut-in/cut-out
11.2.e	HTST magnetic flow meter based timing systems	Time delay
11.3	HHST holding tubes indirect heat	Holding time
11.4	HHST holding tubes direct injection heat	Holding time
11.5	HHST holding tubes direct infusion heat	Holding time
12.1	HHST, Aseptic systems indirect heating	Sequence logic
12.2	HHST, Aseptic systems direct heating	Sequence logic
13.	HHST, Aseptic systems	Pressure in the holding tube
14.	HHST, Aseptic systems using direct injection heating	Pressure differential across injector
15.	Vat, HTST, HHST, Aseptic (all electronic controls)	Electro-Magnetic Interference

ITEM 17p. COOLING OF MILK

All raw milk and milk products shall be maintained at 7ºC (45ºF) or less until processed. All pasteurized milk and milk products, except those to be cultured, shall be cooled immediately prior to filling or packaging, in approved equipment, to a temperature of 7ºC (45ºF) or less. All pasteurized milk and milk products shall be stored at a temperature of 7ºC (45ºF) or less. On delivery vehicles, the temperature of milk and milk products shall not exceed 7ºC (45ºF). Every room or tank in which milk or milk products are stored shall be equipped with an accurate thermometer. Provided, that aseptically processed milk and milk 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 milk products after pasteurization.

ADMINISTRATIVE PROCEDURES

This Item is deemed to be satisfied when:

1. All raw milk and milk products are maintained at 7ºC (45ºF) or less until processed.
2. All pasteurized milk and milk products, except those to be cultured, are cooled immediately in approved equipment prior to filling and packaging to a temperature of 7ºC (45ºF) or less. All pasteurized milk and milk products shall be stored at a temperature of 7ºC (45ºF) or less. On delivery vehicles, the temperature of milk and milk products shall not exceed 7ºC (45ºF).
3. Each refrigerated room in which milk or milk products are stored, except aseptically processed milk and milk products, is equipped with an indicating thermometer that complies with the applicable specifications of Appendix H. Such thermometer shall be located in the warmest zone of the refrigerated 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 twenty percent (20%) of its calibrated capacity. Such thermometer shall comply with the applicable specifications of Appendix H.
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 inches) between the header sections to permit easy cleaning.
   b. Where header ends are not completely enclosed within the cooler covers, condensation or leakage from the headers shall be prevented from entering the milk or milk products by so shaping the exposed header faces, above and below all gaps, that condensation is directed away from the tubes, and by using deflectors at the bottom of the headers; or by shortening the bottom 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 condensation and leakage from entering the milk or milk products.

d. All open-surface coolers shall be provided with tight-fitting shields that protect the milk and milk products from contamination by insects, dust, drip, splash or manual contact.

5. Recirculated cooling 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 G. Samples shall be taken by the Regulatory Agency and examination shall be conducted in an Official Laboratory. Recirculated cooling water systems, which become contaminated through repair work or otherwise, shall be properly treated and tested before being returned to use. Freezing point depressants and other chemical additives, when used in recirculating systems, shall be nontoxic under conditions of use.

ITEM 18p. BOTTLING AND PACKAGING

Bottling and packaging of milk and milk products shall be done at the place of pasteurization in a sanitary manner by approved mechanical equipment.[10]

PUBLIC-HEALTH REASON

Manual bottling and packaging is very apt to result in the exposure of the milk and milk products to contamination, which would nullify the effect of pasteurization. The transfer of milk from the place of pasteurization to another plant for bottling subjects the pasteurized product to unnecessary risks of contamination.

ADMINISTRATIVE PROCEDURES[11]

This Item is deemed to be satisfied when:

1. All milk and milk products, including concentrated milk and milk products, are bottled and packaged at the plant where final pasteurization is performed. Such bottling and packaging shall be done without undue delay following final pasteurization.
2. All bottling or packaging is done on approved mechanical equipment. The term "approved mechanical equipment" shall not be interpreted to exclude manually operated machinery, but is interpreted to exclude methods in which the bottling and capping devices are not integral within the same system.
3. All pipes, connections, defoaming devices and similar appurtenances shall comply with Items 10p. and 11p. of this Section. Milk and milk products from continuous defoamers are not returned directly to the filler bowl.
4. Bottling or packaging machine supply tanks and bowls are equipped with covers that 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. A drip deflector is installed on each filler valve. Drip deflectors shall be designed and adjusted to divert condensation away from the open container.
6. Container in-feed conveyors to automatic bottling or packaging machines have overhead shields to protect the bottles or packages from contamination. These shields shall extend from the bottle washer discharge to the bottle feed-star, or in the case of single-service packaging machines, from the forming unit discharge to the filling unit and from the filling unit to the

closure unit. Overhead shields shall be required on can in-feed conveyors when the cans are fed to the filler with the covers off.
7. Container coding/dating devices are designed, installed and operated such that the coding/dating operations are performed in a manner that open containers are not subjected to contamination. Shielding shall be properly designed and installed to preclude contamination of open containers.
8. 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.
9. Bottling and packaging machine floats are designed to be adjustable without removing the cover.
10. The filler pipe of all bottling and packaging machines have a diversion apron or other acceptable device, as close to the filler bowl as possible, to prevent condensation from entering the inside of the filler bowl.
11. Filling cylinders on packaging machines are protected from contamination by overhead shields. When lubricants are used on filler pistons, cylinders or other milk-contact surfaces, the lubricant shall be food-grade and applied in a sanitary manner.
12. In the case of aseptic processing systems, the product shall be aseptically filled into sterilized containers and hermetically sealed in conformance with the applicable requirements of 21 CFR 113.

ITEM 19p. CAPPING

Capping or closing of milk and milk product containers shall be done in a sanitary manner by approved mechanical capping and/or closing equipment. The cap or closure shall be designed and applied in such a manner that the pouring lip is protected to at least its largest diameter and, with regard to fluid product containers, removal cannot be made without detection.

PUBLIC HEALTH REASON

Hand capping exposes the milk to contamination. A cover extending over the pouring lip of the container protects it from contamination during subsequent handling, and prevents the sucking back into the bottle, by temperature contraction, of any contaminated liquid on the cap, including milk that has been forced out by temperature expansion and may have become contaminated. Caps or closures that are applied in such a manner that they cannot be removed without detection help to assure the consumer that the milk and milk products have not been contaminated after packaging.

ADMINISTRATIVE PROCEDURES[12]

This Item is deemed to be satisfied when:

1. The capping or closing of milk and milk product containers is done in a sanitary manner on approved mechanical capping/closing equipment. The term "approved mechanical capping and/or closing equipment" shall not exclude manually operated machinery. Hand capping shall be prohibited. Provided, that if suitable mechanical equipment, for the capping or closing of

container(s) of 12.8 liters (3 gallons) or more is not available, other methods which eliminate all possibility of contamination may be approved by the Regulatory Agency.
2. Bottles and packages that have been imperfectly capped or closed are emptied immediately into approved sanitary containers. Such milk or milk products shall be protected from contamination, maintained at 7ºC (45ºF) or less and subsequently repasteurized or discarded.
3. All caps and closures are designed and applied in such a manner that the pouring lip is protected to at least its largest diameter and, with respect to fluid product containers, removal cannot be made without detection. Single-service containers are so constructed that the product and the pouring and opening areas are protected from contamination during handling, storage and when the containers are initially opened.
4. All caps and closures are handled in a sanitary manner. The first cap from each tube, the first lap(s) from each roll of cap or cover stock and the first sheet of parchment or cover paper shall be discarded. The subsequent use of loose caps that are left in the cappers at the end of an operating period, after removal from the cap tubes, shall be a violation of this item, provided, that loose plastic caps and closures supplied by the manufacturer in plastic bags may be returned to storage in a protective wrap if removed from a hopper/descrambler immediately after a production run. Plastic caps and closures remaining in the chute between the hopper and the capping device shall be discarded.

ITEM 20p. PERSONNEL - CLEANLINESS

Hands shall be thoroughly washed before commencing plant functions and as often as may be required to remove soil and contamination. No employee shall resume work after visiting the toilet room without thoroughly washing their hands. All persons, while engaged in the handling, processing, pasteurization, storage or transportation of milk, milk products, containers, utensils and equipment shall wear clean outer garments. All persons, while engaged in the processing of milk or milk 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, milk products, containers, utensils and equipment 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 remove soil and contamination.
2. Each employee washes their hands following a visit to the toilet room and prior to resuming work.
3. All persons while engaged in the handling, processing, pasteurization, storage or transportation of milk, milk products, containers, utensils and equipment wear clean outer garments.
4. The use of tobacco products is prohibited in all rooms in which milk or milk products are handled, processed or stored, or in which milk containers, utensils and equipment 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 wash-up areas. Any person engaged in the processing of milk or milk products wears adequate head coverings.

ITEM 21p. VEHICLES

All vehicles used for the transportation of pasteurized milk and milk products shall be constructed and operated so that the milk and milk products are maintained at 7ºC (45ºF) or less and are protected from contamination.

PUBLIC HEALTH REASON

Milk and milk 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 that is capable of contaminating milk or milk products is not transported with milk or milk products.
3. Vehicles have fully enclosed bodies with well-fitted, solid doors.

ITEM 22p. SURROUNDINGS

Milk plant surroundings shall be kept neat, clean and free from conditions which might attract or harbor flies, other insects and rodents or which otherwise constitute a nuisance.

PUBLIC HEALTH REASON

The surroundings of a dairy plant should be kept neat and clean to prevent attracting rodents, flies and other insects, which may contaminate the milk or milk 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 milk products 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 milk plant. Waste material stored in suitable covered containers shall be considered in compliance.
2. Driveways, lanes and areas serving milk plant vehicular traffic are graded, drained and free from pools of standing water.

3. Outdoor areas for milk tank truck unloading are constructed of smooth concrete or equally impervious material, properly sloped to drain and equipped with trapped drains of sufficient size.
4. Only insecticides and rodenticides that are approved for use by the Regulatory Agency and/or registered with EPA shall be used for insect and rodent control.

NOTE: Appendix M. provides a source for milk plants receiving stations and transfer station inspection forms, which summarize the applicable sanitation requirements of this section.

SECTION 8. ANIMAL HEALTH

1. All milk for pasteurization shall be from herds in Areas which have a Modified Accredited Advanced Tuberculosis status or greater as determined by the U.S. Department of Agriculture (USDA). Provided, that in an Area which fails to maintain such status, any herd shall have been accredited by said Department as tuberculosis free, or shall have passed an annual tuberculosis test, or the Area shall have established a tuberculosis testing protocol for livestock that assures tuberculosis protection and surveillance of the dairy industry within the Area and that it is approved by FDA, USDA and the Regulatory Agency.
2. All milk for pasteurization shall be from herds under a brucellosis eradication program, which meets one (1) of the following conditions:
   a. Located in a Certified Brucellosis-Free Area as defined by USDA and enrolled in the testing program for such areas; or
   b. Meet USDA requirements for an individually certified herd; or
   c. Participating in a milk ring testing program at least two (2) times per year at approximately one hundred eighty (180) day intervals and all herds with positive milk ring results shall have the entire herd blood tested within thirty (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 (2) months.
3. Goat milk and sheep milk for pasteurization or ultra-pasteurization or aseptic processing shall be from a herd or flock which:
   a. Has passed an annual whole herd or flock brucellosis test as recommended by the State Veterinarian or USDA Area Veterinarian in Charge (AVIC); or
   b. Has passed an initial whole herd brucellosis test, followed only by testing replacement animals or any animals entering the milking group or sold as dairy animals; or
   c. Has passed an annual random blood-testing program sufficient to provide a confidence level of 99% with a P value of 0.05. Any herd or flock with one (1) or more confirmed positive animals shall go to 100% testing until the whole herd tests show no positive animals are found; or
   d. Has passed a USDA approved bulk milk test, at USDA recommended frequency, with an implementation date based on availability of the test.

The following table[13] will provide the random sampling size needed to achieve 99% confidence with a P value of 0.05.

Herd/Flock Size	Sampling Size	Herd/Flock Size	Sampling Size
20	20	500	82
50	41	600	83
100	59	700	84
150	67	800	85
200	72	1000	86
250	75	1400	87
300	77	1800	88
350	79	4000	89
400	80	10000	89
450	81	100000	90

4. 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 and accredited[14] veterinarian or an accredited 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.
5. Records supporting the tests required in this Section shall be available to the Regulatory Agency and be validated with the signature of a licensed and accredited veterinarian or an accredited veterinarian in the employ of an official agency.

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.
The great reduction in the incidence of bovine tuberculosis in man indicates that the practice of good sanitation in animal husbandry, the testing of dairy animals and removal of the reactors from the herds and the pasteurization of milk, have been effective in the control of this disease. The reservoir of bovine tuberculosis still exists; however, constant vigilance against this disease must be continued by industry and Regulatory Agencies.

ADMINISTRATIVE PROCEDURES

BOVINE TUBERCULOSIS: All tuberculin tests and retests shall be made, and any reactors disposed of, in accordance with the current edition of *Uniform Methods and Rules; Bovine Tuberculosis Eradication, Uniform Methods and Rules for Establishment and Maintenance of Tuberculosis-Free Accredited Herds of Cattle, Modified Accredited Areas and Areas Accredited Free of Bovine Tuberculosis in the Domestic Bovine*, as published by USDA. For tuberculosis test purposes, the herd is defined as all adult cattle twenty-four (24) months of age and over,

including any commingled beef animals. Dairy cattle less than two (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 USDA accredited veterinarian, shall be evidence of compliance with the above requirements and shall be filed with the Regulatory Agency. (See Appendix A.)

BOVINE BRUCELLOSIS: All brucellosis tests, retests, disposal of reactors, vaccination of calves and certification of herds and areas shall be in accordance with the current edition of *Brucellosis Eradication, Recommended Uniform Methods and Rules,* as published by USDA. 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 thirty (30) days following the expiration of an official milk ring testing program, or in the case of a herd subject to annual blood tests, thirteen (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 thirty (30) days of written notice shall result in immediate suspension of the permit. (See Appendix A.)

SECTION 9. MILK AND MILK PRODUCTS WHICH MAY BE SOLD

From and after twelve (12) months from the date on which this *Ordinance* is adopted, only Grade "A" pasteurized, ultra-pasteurized, or aseptically processed milk and milk products shall be sold to the final consumer, to restaurants, soda fountains, grocery stores or similar establishments. Provided, that in an emergency, the sale of pasteurized milk and milk products, which have not been graded, or the grade of which is unknown, may be authorized by the Regulatory Agency, in which case, such milk and milk products shall be labeled "ungraded".

SECTION 10. TRANSFERRING; DELIVERY CONTAINERS; COOLING

Except as permitted in this Section, no milk producer, bulk milk hauler/sampler or distributor shall transfer milk or milk products from one (1) container or milk tank truck to another on the street, in any vehicle, store or in any place except a milk plant, receiving station, transfer station or milkhouse especially used for that purpose. The dipping or ladling of milk or fluid milk products is prohibited.
It shall be unlawful to sell or offer for sale any pasteurized milk or milk product that has not been maintained at the temperature set forth in Section 7 of this *Ordinance*. If containers of pasteurized milk or milk products are stored in ice, the storage container shall be properly drained.

ADMINISTRATIVE PROCEDURES

TRANSFERRING: The dipping or ladling of milk and fluid milk products is expressly prohibited, except for immediate cooking purposes. Milk and milk product containers, which have been filled and sealed at a milk plant, shall be used for the delivery of milk or milk products. Caps, closures or labels shall not be removed or replaced during transportation.

BULK DISPENSERS: Bulk dispensers, approved by the Regulatory Agency, shall satisfy the following sanitary design, construction and operation requirements:

1. All dispensers shall comply with the applicable requirements of Section 7 of this *Ordinance*.
2. Product-contact surfaces shall be inaccessible to manual contact, droplet infection, dust or insects, but the delivery orifice may be exempted from this requirement.
3. All parts of the dispensing device with which milk or milk products come into contact, including any measuring device, shall be thoroughly cleaned and sanitized at the milk plant. Provided, that dispensing valves, which are applied to the dispenser subsequent to its delivery to the retail vendor may be cleaned and sanitized at such establishments.
4. The dispensing container shall be filled at the milk plant and shall be sealed so that it is impossible to withdraw any part of its contents, or to introduce any substance without breaking the seal(s).
5. The milk or milk products shall be thoroughly and automatically mixed with each dispensing operation, except for milk or milk products that remain homogeneous.
6. All cans shall be thoroughly cleaned and sanitized. Milk and milk products shall be kept at or below 7ºC (45ºF) at all times. The dispenser tube shall be integral with the dispensing container, shall be protected and shall be under adequate refrigeration during transportation and storage.

SECTION 11. MILK AND MILK PRODUCTS FROM POINTS BEYOND THE LIMITS OF ROUTINE INSPECTION

Milk and milk products from points beyond the limits of routine inspection of the ... of... or its jurisdiction, shall be sold in…, [1] or its jurisdiction, provided they are produced and pasteurized, ultra-pasteurized or aseptically processed under regulations which are substantially equivalent to this *Ordinance* and have been awarded acceptable Milk Sanitation Compliance and Enforcement Ratings.

ADMINISTRATIVE PROCEDURES

The Regulatory Agency should accept, without their actual physical inspection, supplies of milk and milk products from an area or an individual shipper not under their routine inspection. Provided, that:

1. Milk and milk 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 (1) 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, ultra-pasteurized, or aseptically processed milk and milk products shall comply with Sections 2, 4 and 10;

NOTE: Raw and pasteurized milk and milk products beyond the limits of routine inspection shall be sampled, as the Regulatory Agency requires.

3. The milk or milk products are produced and processed under regulations substantially equivalent to those of this *Ordinance*;
4. The supplies are under routine official supervision;
5. The supplies have been awarded, by a State Milk Sanitation Rating Officer (SRO) certified by FDA, Milk Sanitation Compliance and Enforcement Ratings equal to that of the local supply or equal to ninety percent (90%) or higher; and
6. All ratings are made on the basis of procedures outlined in the *Methods of Making Sanitation Ratings of Milk Supplies* (MMSR).

NOTE: Names of interstate milk shippers and their ratings, as reported by State Milk Rating Agencies, are contained in the *Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers* (IMS List), issued semi-annually by FDA. Copies of this list may be obtained from the State Milk Rating or Regulatory Agency or from the Food and Drug Administration, HFS-626, 5100 Paint Branch Parkway, College Park, MD 20740-3835.

7. The supplies have been awarded, a satisfactory listing, by a State Listing Officer, standardized by FDA, under the NCIMS HACCP Pilot Program Phase II Expansion. This provision will expire on December 31, 2003 unless extended by future Conference action.

SECTION 12. PLANS FOR CONSTRUCTION AND RE-CONSTRUCTION

Properly prepared plans for all milkhouses, milking barns, stables and parlors, milk tank truck cleaning facilities, milk plants, receiving stations and transfer stations regulated under this *Ordinance*, which are hereafter constructed, reconstructed or extensively altered shall be submitted to the Regulatory Agency for written approval before work is begun.

SECTION 13. PERSONNEL HEALTH

No persons affected with any disease capable of being transmitted to others through the contamination of food shall work at a milk plant in any capacity which brings them into direct contact with finished products, such as pasteurized or aseptically processed milk or milk products, or which brings them into direct contact with associated pasteurized or aseptically processed milk product-contact surfaces.

ADMINISTRATIVE PROCEDURES

Milk plant operators who have received reports, under this Section, from employees who have handled pasteurized milk, pasteurized milk products or associated product-contact surfaces shall

immediately report these facts to the appropriate milk 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 or applicants to whom a conditional offer of employment has been made is responsible to report to the dairy plant management, in a manner that allows the dairy plant to prevent the likelihood of the transmission of diseases that are transmissible through foods, if the employee or applicant to whom a conditional offer of employment has been made:

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, enterotoxigenic Escherichia coli, Campylobacter jejuni, Entamoeba histolytica, Giardia lamblia,* Non-typhoidal *Salmonella, Rotovirus, Taenia solium, Yersinia enterocolitica, Vibrio cholerae O1* or other infectious or communicable disease that has been declared by the Secretary of Health and Human Services (HHS) to be transmissible to others through the handling of food, or has been clearly shown to be so based upon verifiable epidemiological data; or
2. Is exposed to, or suspected of causing, a confirmed foodborne disease outbreak of one (1) of the diseases specified in Item 1 above, including an outbreak at an event such as a family meal, church supper or ethnic festival because the employee or applicant to whom a conditional offer of employment has been made:
   a. Prepared food implicated in the outbreak; or
   b. Consumed food implicated in the outbreak; or
   c. Consumed food at the event prepared by a person who is infected or ill.
3. Lives in the same household as a person who attends or works in a day care center or school, similar institution experiencing a confirmed outbreak of one (1) of the diseases specified in Item 1 above.

Similarly, dairy plant employees shall be instructed by the dairy plant management to report to the dairy plant management if the employee, or applicant to whom a conditional offer of employment has been made.

4. Has a symptom associated with acute gastrointestinal illness such as: abdominal cramps or discomfort, diarrhea, fever, loss of appetite for three (3) or more days, vomiting, jaundice; or
5. Has a pustular lesion such as a boil or infected wound that is:
   a. On the hands, wrists or exposed portions of the arms, unless the lesion is covered by a durable, moisture proof, tight-fitting barrier, or
   b. On other parts of the body if the lesion is open or draining, unless the lesion is covered by a durable, moisture proof, tight-fitting barrier.

SECTION 14. PROCEDURE WHEN INFECTION OR HIGH RISK OF INFECTION IS DISCOVERED

When a person who may have handled pasteurized or aseptically processed milk or milk products or pasteurized or aseptically processed milk product-contact surfaces meets one (1) or more of the conditions specified in the Administrative Procedures of Section 13, the Regulatory Agency is authorized to require any or all of the following measures:

1. The immediate restricting of that person from duties that require handling finished product, such as pasteurized milk or milk 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 Table:

Table 5. 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, Yersinia enterocolitica, Vibrio cholerae* O1 or other infectious or communicable disease that has been declared by the Secretary of HHS to be transmissible to others through the handling of food or has been clearly shown to be so based upon verifiable epidemiological data.	Restrictions lifted by medical clearance.
b. Meeting a high-risk scenario as specified in Section 13 (2 or 3) and/or experiencing symptoms in Section 13 (4 or 5).	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.

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 finished products, such as pasteurized, ultra-pasteurized or aseptically processed milk or pasteurized or aseptically processed milk products and associated product-contact surfaces.

SECTION 15. ENFORCEMENT

This *Ordinance* shall be enforced by the Regulatory Agency in accordance with the *Grade "A" Pasteurized Milk Ordinance with Administrative Procedures*, 2001 Revision. A certified copy[15] of which shall be on file at the appropriate Regulatory Agency's office. Where the mandatory compliance with provisions of the Appendixes is specified, such provisions shall be deemed a requirement of this *Ordinance*.

SECTION 16. PENALTY

Any person who shall violate any of the provisions of this *Ordinance* shall be guilty of a misdemeanor and upon conviction thereof shall be punished by a fine of not more than $ ... and/or such persons may be enjoined from continuing such violation(s). Each day upon which such a violation(s) occurs shall constitute a separate violation.

SECTION 17. REPEAL AND DATE OF EFFECT

All ordinances and parts of ordinances in conflict with this *Ordinance* shall be repealed twelve (12) months after the adoption of this *Ordinance*, at which time this *Ordinance* shall be in full force and effect, as provided by law.

SECTION 18. SEPARABILITY CLAUSE

Should any Section, paragraph, sentence, clause or phrase of this *Ordinance* be declared unconstitutional or invalid for any reason, the remainder of this *Ordinance* shall not be affected thereby.

FOOTNOTES

1. Substitute proper legal jurisdiction here and in all similar places throughout this *Ordinance*.
2. Regulatory Agencies desiring to regulate cottage cheese and dry curd cottage cheese under the terms of this *Ordinance* should insert the following definitions:

   Cottage cheese is the product defined in 21 CFR 133.128.
   Dry curd cottage cheese is the product defined in 21 CFR 133.129.

3. Whey, caseinates, lactalbumin and other milk derived ingredients are required to be derived from a Grade "A" raw milk source.
4. Where State law does not permit the sale of reconstituted or recombined milk and/or milk products, Definition AA and other corresponding references should be omitted.
5. The permit for a milk tank truck may be issued to the responsible person for the milk tank truck(s).
6. Regulatory Agencies desiring to inspect dairy farms under a performance-based inspection system should substitute the following language in 5:

   "5. Inspect each dairy farm as provided in Appendix P, Performance-Based Dairy Farm Inspection System."

7. Regulatory Agencies desiring to regulate cottage cheese, dry curd cottage cheese and reduced fat or low fat cottage cheese under the terms of this Ordinance should include the following in the Administrative Procedures of Item 5p:

   "Cottage cheese vats shall be located in a separate room, maintained free from insects and other vermin and kept in a clean condition. Provided, that in existing installations, cottage cheese vats may be located in the processing room when there is no evidence of overcrowding, excessive traffic, condensation or splash. Cottage cheese vats located in processing rooms shall be equipped with multi-service or single-service covers which shall be kept in place at all times during the setting operation."

8. Regulatory Agencies desiring to regulate cottage cheese, dry curd cottage cheese and reduced fat or lowfat cottage cheese under the terms of this Ordinance should include the following in the Administrative Procedures of Item 7p:

   "Water supply outlets are provided immediately available to the cottage cheese vats. The hose for transport of water, for washing cottage cheese curd, shall be arranged in such a way as to preclude the possibility of the hose touching the floor or the product."

9. Regulatory Agencies desiring to regulate cottage cheese, dry curd cottage cheese and reduced fat or lowfat cottage cheese under the terms of this *Ordinance* should add the following:

   "Provided, that cottage cheese, cheese dressings or cheese ingredients may be transported by other methods which protect the product from contamination."

10. Regulatory Agencies desiring to regulate the sale of cottage cheese, dry curd cottage cheese and reduced fat or lowfat cottage cheese under the terms of this *Ordinance* should add the following:

    "Provided, that cottage cheese, dry curd cottage cheese and reduced fat or lowfat cottage cheese may be transported in sealed containers in a protected, sanitary manner from one (1) plant to another for creaming and/or packaging. If suitable equipment is not available for the packaging dry curd cottage cheese, other methods of packaging which eliminate possible chances of contamination may be approved by the Regulatory Agency."

11. Regulatory Agencies desiring to regulate the sale of cottage cheese, dry curd cottage cheese and reduced fat or lowfat cottage cheese under the terms of this *Ordinance* should add the following to the Administrative Procedures of Item 18p:

    "If cottage cheese, and dry curd cottage cheese are protected in a sanitary manner, they may be transported in sealed containers from one (1) plant to another for creaming and/or packaging."

12. Regulatory Agencies desiring to regulate the sale of cottage cheese, dry curd cottage cheese, and reduced fat or lowfat cottage cheese under the terms of this *Ordinance* should add the following to the indicated Administrative Procedures of Item 19p:

    1. "Provided further, that if suitable equipment is not available for capping cottage cheese, dry curd cottage cheese and reduced fat or lowfat cottage cheese, other methods of capping which eliminate possible chances of contamination may be approved by the Regulatory Agency.
    4. Closures for cottage cheese, dry curd cottage cheese and reduced fat or lowfat cottage cheese containers shall extend over the top edges of the container so as to protect the product from contamination during subsequent handling.
    5. Provided, that this requirement shall not apply to cottage cheese, dry curd cottage cheese and reduced fat or lowfat cottage cheese container closures, when such closures are supplied in a totally enclosed package, or wrapped so as to protect the closures."

13. From Table 1, Regulatory Statistics, 5th Edition (June 1975) by Victor C. Beal, Jr., Programs Development and Application. Veterinary Services, APHIS: Animal Health Programs
14. The term "accredited" in this Section means accredited by the USDA APHIS Veterinary Services.
15. A certified copy may be secured from the Food and Drug Administration, HFS-626, 5100 Paint Branch Parkway, College Park, MD 20740-3835

APPENDIX A. ANIMAL DISEASE CONTROL

Copies of the *Uniform Methods and Rules; Bovine Tuberculosis Eradication, Uniform Methods and Rules for Establishment and Maintenance of Tuberculosis-Free Accredited Herds of Cattle, Modified Accredited Areas and Areas Accredited Free of Bovine Tuberculosis in the Domestic Bovine* and recommended *Brucellosis Eradication, Recommended Uniform Methods and Rules,* current at the time of adoption of this *Ordinance* may be obtained from your State Veterinarian or:

Veterinary Services
Animal and Plant Health Inspection Service
U. S. Department of Agriculture
Federal Center Building
Hyattsville, MD 20782

Or

Federal Area Veterinarian in Charge
VS, APHIS, USDA
Your State Capitol

It is recommended that Regulatory Agencies initiate and/or promote a mastitis control program. A well-planned and extended educational phase will encourage the support of producers and reduce the problems of enforcement.

The National Mastitis Council, Inc., 2820 Walton Commons West, Suite 131, Madison, WI 53718-6797, has studied a large number of existing control programs and has outlined a suggested flexible control program. In addition, review of the current knowledge of mastitis may be found in their publications: *Current Concepts of Bovine Mastitis* and the *Laboratory Handbook Of Bovine Mastitis.*

Sanitarians may find the screening test a useful device for detecting abnormal milk. Sample screening methods, as well as somatic cell diagnosis and reduction programs are discussed in the references above as well as the Dairy Practices Council, 51 East Front Street, Suite 2, Keyport NJ 07735 publication: *The Field Person's Guide to Troubleshooting High Somatic Cell Counts.*

Regulatory action should not be based on the use of mastitis screening tests alone. Screening tests should be used as an adjunct to a complete program of mastitis control and milking-time inspections.

APPENDIX B. MILK SAMPLING, HAULING AND TRANSPORTATION

Milk sampling, hauling, and transport are integral parts of a modern dairy industry. Hauling, sampling and transport can be categorized into three (3) separate functions: Dairy Plant Samplers, Bulk Milk Hauling and Sampling and Milk Transport from one (1) milk handing facility to another.

I. MILK SAMPLING AND HAULING PROCEDURES

The dairy plant sampler is a person responsible for the collection of official samples for regulatory purposes outlined in Section 6 of this *Ordinance.* These persons are employees of the Regulatory Agency and are evaluated at least once each two (2) year period by a State Sampling Surveillance Officer (SSO). These individuals are evaluated using Form FDA 2399 - MILK SAMPLE COLLECTOR EVALUATION FORM, which is derived from the most current edition of SMEDP. (See Appendix M.)

The bulk milk hauler/sampler is any person who collects official samples and may transport raw milk from a farm and/or raw milk products to or from a milk plant, receiving station or transfer station and has in their possession a permit from any State to sample such products. The bulk milk hauler/sampler occupies a unique position making this individual a critical factor in the current structure of milk marketing. As a weigher and sampler, they stand as the official, and frequently the only judge of milk volumes bought and sold. As a milk receiver, the operating habits directly affect the quality and safety of milk committed to their care. When the obligations include the collection and delivery of samples for laboratory analysis, the bulk milk hauler/sampler becomes a vital part of the quality control and regulatory programs affecting producer dairies. Section 3 of this *Ordinance* requires that Regulatory Agencies establish criteria for issuing permits to bulk milk hauler/samplers. These individuals are evaluated at least once each two (2) year period using Form FDA 2399a - MILK TANK TRUCK, HAULER REPORT AND SAMPLER EVALUATION FORM. (See Appendix M.)

The milk tank truck driver is any person who transports raw or pasteurized milk products to or from a milk 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.

The criteria for permitting these individuals should embrace at least the following:

TRAINING: To understand the importance of bulk milk collection and the techniques of sampling, all bulk milk hauler/samplers must be told why, and instructed how, in the proper procedures of picking up milk and the collection of samples. The Regulatory Agency, dairy field person, route supervisors or any appropriate person whose techniques and practices are known to meet requirements can conduct this training. If the Regulatory Agency does not conduct the training, the training must be approved by or conducted under the supervision of the Regulatory Agency.

Training also frequently takes the form of classroom sessions in which the trainer describes pickup practices, demonstrates sampling and care of samples and affords the candidate the opportunity for guided practice in these techniques. Basic considerations of sanitation and personal cleanliness, which are important to the protection of milk quality, are discussed here.

Officials administering weights and measures may participate in these programs and provide instruction in the measuring of milk and the keeping of required records.
An examination, approved by the Regulatory Agency, shall be administered at the conclusion of this program. Candidates failing the exam, a score of less than seventy percent (70%), shall be denied permits or licenses until indicated deficiencies are corrected. The examination should be adequate enough to determine if a bulk milk hauler/sampler is competent. The exam shall be composed of a minimum of twenty (20) total questions broken down into the following areas:

1. Six (6) questions relating to sanitation and personal cleanliness;
2. Six (6) questions relating to sampling and weighing procedures;
3. Four (4) questions relating to equipment, including the proper use, care, cleaning, etc.; and
4. Four (4) questions relating to proper record keeping requirements.

Regularly scheduled refresher short courses by the regulatory agents and officials administering weights and measures would assist in maintaining and increasing the efficiency of the bulk milk hauler/sampler.

QUALIFICATIONS:
1. **Experience:** Experience may include a required period of observation during which the candidate accompanies a bulk milk hauler/sampler in the performance of their duties.
2. **Personal References:** Permit applications should be supported by suitable references testifying to the character and integrity of the candidate.

EVALUATION OF BULK MILK HAULER/SAMPLER PROCEDURES: The routine inspection of bulk milk hauling/sampling procedures provides the Regulatory Agency with an opportunity to check both the condition of the bulk milk hauler/sampler's equipment and the degree of conformance with required practices.
The bulk milk hauler/sampler's technique is best determined when the regulatory agent is able to observe the bulk milk hauler/sampler at one (1) or more farms. Each bulk milk hauler/ sampler must be inspected by the Regulatory Agency prior to the issuance of a permit and at least once every twenty-four (24) months thereafter as referenced in Section 5 of this *Ordinance*. The bulk milk hauler/sampler must hold a valid permit prior to the collection of official samples. States may use inspections from any Regulatory Agency as a means of maintaining record requirements and enforcement.
The procedures for sampling and the care of samples should be in compliance with the current edition of SMEDP.
Specific Items to be evaluated in determining compliance include:

1. **Personal Appearance:** Bulk milk hauler/samplers shall practice good hygiene; shall maintain a neat and clean appearance; and not use tobacco in the milkhouse.
2. **Equipment Requirements:**
   a. Sample rack and compartment to hold all samples collected.
   b. Refrigerant to hold temperature of milk samples between 0º- 4.4ºC (32º- 40°F).
   c. Sample dipper or other sampling devices of sanitary design approved by the Regulatory Agency, clean and in good repair.
   d. Sterile sample bags, tubes or bottles; properly stored.

e. Calibrated pocket thermometer; certified for accuracy every six (6) months; accuracy ± 1°C (2°F).

f. Approved sanitizing agent and sample dipper container.

g. Watch for timing milk agitation.

h. Applicable sanitizer test kit.

3. **Milk Quality Checks:**

a. Examine the milk by sight and smell for any off odor or any other abnormalities that would class the milk as not being acceptable. Reject if necessary.

b. Wash hands thoroughly and dry with a clean single-service towel or acceptable air dryer immediately prior to measuring and/or sampling the milk.

c. Record milk temperature, time, date of pick-up and bulk milk hauler/sampler identification on the farm weight ticket; monthly the hauler/sampler shall check the accuracy of the thermometer on each bulk tank and record results. Pocket thermometer must be sanitized before use.

4. **Milk Measurements:**

a. The measurement of the milk shall be taken before agitation. If the agitator is running upon arrival at the milkhouse, the measurement can be taken only after the surface of the milk has been quiescent.

b. Carefully insert the measuring rod, after it has been wiped dry with a single-service towel, into the tank. Repeat this procedure until two identical measurements are taken. Record measurements on the farm weight ticket.

c. Do not contaminate the milk during measurement.

5. **Universal Sampling System:** When bulk milk hauler/samplers collect raw milk samples, the "universal sampling system" shall be employed, whereby samples are collected every time milk is picked up at the farm. This system permits the Regulatory Agency, at its discretion, at any given time and without notification to the industry, to analyze samples collected by the bulk milk hauler/sampler. The use of the "universal sample" puts more validity and faith in samples collected by industry personnel. The following are sampling procedures:

a. Pick-up and handling practices are conducted to prevent contamination of milk contact surfaces.

b. The milk must be agitated a sufficient time to obtain a homogeneous blend. Follow State and/or manufacturer's guidelines.

c. While the tank is being agitated, bring the sample container, dipper, dipper container and sanitizing agent for the outlet valve, or single-service sampling tubes into the milkhouse aseptically. Remove the cap from the tank outlet valve and examine for milk deposits or foreign matter and then sanitize if necessary. Protect the hose cap from contamination when removing it from the transfer hose and during storage.

d. The sample may only be collected after the milk has been properly agitated. Remove the dipper or sampling device from the sanitizing solution or sterile container and rinse at least twice in the milk.

e. Collect a representative sample or samples from the bulk tank. When transferring milk from the sampling equipment, caution should be used to assure that no milk is spilled back into the tank. Do not fill the sampling container more than ¾ full. Close the cover on the sample container.

f. The sample dipper shall be rinsed free of milk and placed in its carrying container.

g. Close the cover or lid of the bulk tank.

h. The sample must be identified with the producer's number at the point of collection.

i. A temperature control sample must be taken at the first stop of each load. This sample must be labeled with time, date, temperature and producer and bulk milk hauler/sampler identification.

j. Place the sample or samples immediately into the sample storage case.

6. **Pump Out Procedures:**

a. Once the measurement and sampling procedures are completed, with the agitator still running, open the outlet valve and start the pump. Turn off the agitator when the level of milk is below the level that will cause over-agitation.

b. When the milk has been removed from the tank, disconnect the hose from the outlet valve and cap the hose.

c. Observe the inside surfaces of the bulk tank for foreign matter or extraneous material and record any objectionable observations on the farm weight ticket.

d. With the outlet valve open, thoroughly rinse the entire inside surface of the tank with warm water.

7. S**ampling Responsibilities:**

a. All sample containers and single-service sampling tubes used for sampling shall comply with all the requirements that are in the current edition of SMEDP. Samples shall be cooled to and held between 0°C (32°F) and 4.4°C (40°F) during transit to the laboratory.

b. Means shall be provided to properly protect the samples in the sample case. Keep refrigerant at an acceptable level.

c. Racks must be provided so that the samples are properly cooled in an ice bath.

d. Adequate insulation of the sample container box or ice chest shall be provided to maintain the proper temperature of the samples throughout the year.

The SSO's conduct periodic evaluations of sampling procedures. This program will promote uniformity and compliance of sample collection procedures.

II. MILK TANK TRUCK PERMITTING AND INSPECTION

Milk tank trucks shall be evaluated annually using the requirements established in Sections 3. and 5. of this *Ordinance* using Form FDA 2399b - MILK TANK TRUCK INSPECTION FORM. (See Appendix M.)

PERMITTING: Each milk tank truck shall bear a permit for the purpose of transporting milk and milk products. (See Section 3. of this *Ordinance.*) The permit shall be issued to the owner of each milk tank truck by an authorized Regulatory Agency. The permit identification and State issuing the permit shall be displayed on the milk tank truck. It is recommended that this permit be renewed each year pending satisfactory completion of an inspection as outlined in the following **Inspection** Section.

RECIPROCITY: Each permit shall be recognized by other Regulatory Agencies under the reciprocal agreements of the NCIMS and supporting documents of this *Ordinance.* A milk tank truck need only bear one (1) permit from an appropriate Regulatory Agency. A milk tank truck may be inspected at any time when deemed appropriate by the Regulatory Agency. Absent proof of a current permit and current inspection, when the milk tank truck is inspected by a

Regulatory Agency other than the permitting agency, an inspection fee may be charged to the owner of the milk tank truck. This is necessary to allow a milk tank truck to pickup and deliver in several jurisdictions without the need for more than one (1) permit. A Regulatory Agency may have the option of inspecting any milk tank truck at any time when milk and milk products are transported in or out of a particular jurisdiction. It is the responsibility of the milk tank truck owner or operator to maintain a current proof of inspection to avoid a re-inspection fee. Disputes concerning reciprocal agreements on milk tank truck inspection between Regulatory Agencies may be tendered to the Chair of the NCIMS or the Chair's designee for resolution.

INSPECTION: Each milk tank truck shall be inspected at least once each year by a Regulatory Agency. (See Section 5. of this *Ordinance.*) A copy of the current inspection report shall accompany the milk tank truck at all times, or the tank shall bear an affixed label, which identifies the Regulatory Agency with the month and year of inspection. The affixed label shall be located near the tank outlet valve.

When significant defects or violations are encountered by a Regulatory Agency, a copy of the report shall be forwarded to the permitting agency and also carried on the milk tank truck until the violations are corrected.

Milk tank truck inspections shall be conducted in a suitable location, i.e., a dairy plant, receiving or transfer station or milk tank truck-cleaning facility. Inspections may not require entry of confined spaces as defined by the Occupational Safety and Health Administration (OSHA) standards. When significant cleaning, construction or repair defects are noted the milk tank truck shall be removed from service until proper confined entry safety requirements can be satisfied to determine cleaning or repairs needed. Cleaning or repairs may be verified by a qualified individual to the satisfaction of the Regulatory Agency.

Inspection reports completed by Regulatory Agencies other than the permitting agency shall be forwarded to the permitting agency for verification of annual inspection as required in the **Permitting** Section of this Appendix. The permitting agency may use these reports to satisfy permit requirements.

MILK TANK TRUCK STANDARDS: All Items of the Milk Tank Truck Inspection Form fall into the categories of 'Compliance', 'Non-Compliance' or 'Not Applicable' (NA) as determined during the inspection. The following Items relate to Form FDA 2399b (See Appendix M.):

1. **Samples and Sampling Equipment:** (When provided.)
   a. Sample containers shall be stored to preclude contamination.
   b. The sample box shall be in good repair and kept clean.
   c. Sample transfer instrument shall be cleaned and sanitized to insure that proper samples are collected.
   d. The sample transfer instrument container is provided and adequate means for maintaining sanitizer solutions is on hand.
   e. The samples are properly stored to preclude contamination.
   f. The sample storage compartment shall be clean.
   g. Samples are maintained at an acceptable temperature (32ºF to 40ºF) and a temperature control sample is provided.

h. An approved thermometer is available for use by the sampler. The accuracy of the thermometer is checked each six (6) months with the results and date recorded on the carrying case.

2. **Product Temperature 4.4º C (45ºF) or Less:**

a. The product temperature must meet all the requirements of Section 7, Items 18r. and 17p., Cooling of Milk, of this *Ordinance.*

b. Product that remains in external transfer systems that exceeds 4.4ºC (45ºF) is discarded. This includes pumps, hoses, air elimination equipment or metering systems.

3. **Equipment Construction, Cleaning, Sanitizing and Repair:** Items A through K on Form FDA 2359b shall be evaluated according to the following criteria:

a. Construction and Repair Requirements.

(1) The milk tank truck and all appurtenances shall meet applicable requirements of Section 7, Item 10p. - Sanitary Piping and Item 11p. - Construction and Repair of Containers and Equipment, of this *Ordinance*. Equipment manufactured in conformity with 3-A Sanitary Standards, complies with sanitary design and construction requirements of this *Ordinance.*

(2) The interior of the milk tank trucks shall be constructed of smooth, non-absorbent, corrosion-resistant, non-toxic material; and it shall be maintained in good repair.

(3) The appurtenances of the milk tank truck includes hoses, pumps and fittings, shall be constructed of smooth, non-toxic cleanable material; and shall be maintained in good repair. Where flexibility is required, the fluid transfer system shall be free draining and so supported to maintain uniform slope and alignment. They shall be easily disassembled and accessible for inspection.

(4) The cabinet portion(s) of the tank, used for the storage of appurtenances and sampling equipment, where applicable, shall be constructed to preclude contamination by dust, dirt; be clean; and in good repair.

(5) The milk tank truck dome lid assembly, vent and dust cover shall be designed to protect the tank and milk from contamination.

b. Cleaning and Sanitizing Requirements:

(1) The milk tank truck and all of its appurtenances shall be cleaned and sanitized in accordance with applicable requirements of Section 7, Item 12p. -Cleaning and Sanitizing of Containers and Equipment, of this *Ordinance.*

(2) The milk tank truck shall be cleaned and sanitized prior to its first use. When the time elapsed after cleaning and sanitizing, and before its first use, exceeds seventy-two (72) hours the tank must be re-sanitized.

(3) It is allowable to pickup multiple loads continuously within a twenty-four (24) hour period, provided the milk tank truck is washed after each day's used.

4. **Exterior Condition of Tank:** The exterior of the milk tank truck is properly constructed and in good repair. Defects and damage that would adversely affect products contained in the milk tank truck are pointed out on the Milk Tank Truck Inspection Form and corrective actions are prescribed. Cleanliness of the milk tank truck exterior is evaluated with consideration for existing weather and environmental conditions.

5. **Wash and Sanitize Record:**

a. The bulk milk hauler/sampler shall be responsible for assuring that the milk tank truck has been properly cleaned and sanitized. A milk tank truck without proper cleaning and

sanitizing documentation shall not be loaded or unloaded until the proper cleaning and sanitization can be verified.

b. A cleaning and sanitizing tag shall be affixed to the outlet valve of the milk tank truck until the milk tank truck is next washed and sanitized. When the milk tank truck is washed and sanitized, the previous cleaning and sanitizing tag shall be removed and stored at the location where the milk tank truck was washed for a period of not less than fifteen (15) days.

c. The following information shall be recorded on the cleaning and sanitization tag:

(1) Identification of the milk tank truck.

(2) Date and time of day the milk tank truck was cleaned and sanitized.

(3) Location where the milk tank truck was cleaned and sanitized.

(4) Signature or initials of the person who cleaned and sanitized the milk tank truck.

d. The maintenance of all information on the cleaning and sanitizing tag shall be the responsibility of the bulk milk hauler/sampler or the milk tank truck operator.

6. **Location of Last Cleaning/Sanitizing:**

The location of the last cleaning and sanitizing shall be verified by the Regulatory Agency during any milk tank truck inspection and recorded on the Milk Tank Truck Inspection Form.

7. **Labeling:** The maintenance of all pertinent information on all shipping documents, shipping invoices, bills of lading or weight tickets is the responsibility of the bulk milk hauler/sampler. A milk tank truck transporting raw, heat-treated or pasteurized milk and milk products to a milk plant from another milk plant, receiving station or transfer station is required to be marked with the name and address of the milk plant or hauler and the milk tank truck shall be under a proper seal. All shipping documents must contain the following information as outlined in Section 4 - Labeling of this *Ordinance*:

a. Shipper's name, address and permit number. Each milk tank truck load of milk shall include the IMS Bulk Tank Unit (BTU) identification number(s) or the IMS listed Plant Number, for farm groups listed with a plant, on the farm weight ticket or manifest.

b. Permit identification of the hauler, if not an employee of the shipper.

c. Point of origin of shipment.

d. Milk tank truck identification number.

e. Name of product.

f. Weight of product.

g. Temperature of product when loaded.

h. Date of shipment.

i. Name of supervising Regulatory Agency at the point of origin of shipment.

j. Whether the contents are raw, pasteurized, or in the case of cream, lowfat or skim milk, whether it has been heat-treated.

k. Seal number on inlet, outlet, wash connections and vents.

l. Grade of product.

All information contained on the above described documents shall be verified by the Regulatory Agency and recorded on the appropriate inspection sheet for any bulk milk tank trucks under inspection.

8. **Vehicle and Milk Tank Truck Properly Identified:** It shall be the responsibility of the milk tank truck owner or operator to insure the proper and legible identification of the milk tank truck(s) in their possession.

9. **Previous Inspection Sheet or Affixed Label Available:** When a milk tank truck transports milk and milk products from one (1) regulatory jurisdiction to another it is not necessary to

inspect each milk tank truck upon each arrival. Milk tank truck owners and operators shall carry proof of annual inspection from a recognized Regulatory Agency. A milk tank truck may be inspected at any time or at the discretion of any Regulatory Agency responsible for the milk supply.

10. **Sample Chain-of-Custody:** When samples for official laboratory analysis are transported by any individual where the sample chain-of-custody must be established, the driver may be required to carry a valid permit or shall be evaluated biennially for the collection of samples for official laboratory analysis. The criteria from Section I - Evaluation of Bulk Milk Hauler/ Sampler Procedures, Item 7 - Sampling Responsibilities of this Appendix will be used as the basis for the evaluation. As an alternative, a sample case sealed as required by the Regulatory Agency may be accepted.

APPENDIX C. DAIRY FARM CONSTRUCTION STANDARDS AND MILK PRODUCTION

I. TOILET AND SEWAGE DISPOSAL FACILITIES

FLUSH TOILETS

Flush toilets are preferable to pit privies, earth closets or chemical toilets at both dairy farms and milk plants. Their installation shall conform to the Local or State plumbing regulations. Toilets shall be located in a well-lighted and well-ventilated room. Fixtures shall be protected against freezing. The following shall be considered defects in flush-toilet installations:

1. Insufficient water pressure or volume;
2. Leaky plumbing;
3. Clogged sewers, as evidenced by overflowing toilet bowl;
4. Broken tile lines or clogged disposal field;
5. Access of dairy lactating animals to the effluent below the sewer or disposal-field discharge;
6. Effluent coming to the surface of the ground in the absorption field;
7. Toilet room floor soaked with urine or other discharges;
8. Offensive odors or other evidence of lack of cleanliness; or
9. Location of soil lines, septic tank, absorption field or leaching pit closer to the source of water supply than the limits indicated in Appendix D.

SEPTIC TANKS

Disposal of the wastes from toilets should preferably be into a sanitary-sewer system. Where such systems are not available to a dairy farm or milk plant, the minimum satisfactory method should include treatment in a septic tank, with the effluent discharged into the soil. Where soil of satisfactory permeability is not available, the effluent shall be disposed of in accordance with the rules of the Local or State Health Authority. It is preferable to treat floor drainage, wastes from washing of utensils, etc., in separate systems. When such wastes are combined with toilet wastes in the septic tank system, careful consideration must be given to the expected flow in the design of both the septic tank and the leaching system.

The septic tank shall be located a safe distance from water sources as determined by consideration of the criteria indicated in Appendix D. The Regulatory Agency shall review and approve proposed installations prior to the initiation of construction. The location should permit easy access for inspection and cleaning. The site should be chosen to make the largest possible area available for the disposal field.

The size of the septic tank should be based on the average daily flow of sewage, a retention period of approximately twenty-four (24) hours and adequate sludge storage. The minimum liquid capacity of a septic tank should be 3,000 liters (750 gallons). The outlet should be baffled to prevent scum from passing out with the overflow. The septic tank cover or slab should be watertight, designed to be insect and rodent proof and to withstand any load likely to be placed upon it. Each tank should have a manhole for each compartment, when it is provided with a solid-slab cover. The manhole covering should be made watertight. Septic tanks should be constructed of materials that are not subject to excessive corrosion or deterioration.

DISPOSAL FIELDS FOR SEPTIC TANKS

A distribution box is considered desirable in every field system. The design of the field should be based on the expected sewage flow, the actual absorptive quality of the soil and the total bottom area of the trenches. Tile or perforated pipe designed for this use, of not less than 10 millimeters (4 inches) diameter, is recommended for field laterals. Laterals should be separated by at least three (3) times the width of the trenches, with a minimum of 2 meters (6 feet).

Trenches should be filled with broken stone or screened gravel, from a depth of at least 15 centimeters (6 inches) below the distributing pipes, to a level at least 5 centimeters (2 inches) above the top of the lines. When drain tile is used, joints should be open about 5 millimeters (¼-inch), and the openings protected by tarpaper strips over the top and sides. The aggregate should be protected from loose backfill by means of a separating strip of untreated building paper or similar material. Under no condition should a field with less than 13.9 square meters (150 square feet) of effective absorption area (30 meters of 46 centimeters (100 linear feet of 18-inch) trench be provided for any individual unit. The maximum length of individual lines should not exceed 30 meters (100 feet). The slope of the field's lateral lines may vary from 5 centimeters (2 inches) to 10 centimeters (4 inches) per 30 meters (100 feet), but should never exceed 15 centimeters (6 inches) per 30 meters (100 feet). It is desirable to have the tile lines within 46 centimeters (18 inches) of the finished grade; however, the total depth of the lateral trenches should never average more than 91 centimeters (36 inches).

In some instances seepage pits may provide a more satisfactory means of disposal of effluent. Walls should be permeable and the liquid capacity should be not less than that of the septic tank. Total wall area should be proportionate to absorptive quality of the soil and to expected sewage flow.

Information as to methods of making percolation tests to determine absorptive quality of the soil may be obtained from Local and/or State Health Departments. From the same sources, advice may be obtained as to trench areas needed for various numbers of users, in relation to observed percolation rates. In view of their close knowledge of local conditions, it is recommended that such assistance be requested before an absorption system is constructed.

EARTH-PIT PRIVY

The earth-pit privy offers the most suitable type of excreta disposal unit for the dairy farm where water carriage systems of disposal cannot be provided. While there are many different designs in use, the basic elements are the same in all cases.

1. **General:** The earth pit should be of such capacity that it may be used for several years without requiring the privy to be moved. Excreta and toilet paper are deposited directly into the pit. Aerobic bacteria break down the complex organic material into more or less inert material. Insects, animals and surface water must be prevented from entering the pit. It is essential that the privy be designed and constructed so that the pit can be kept fly tight.

2. **Location:** The location of the privy shall take into account the need to prevent the contamination of water supplies. The criteria of Appendix D. shall be applied. On sloping ground, it shall be located at a lower elevation than the water supply. On level ground, the area around both the privy and water supply should be mounded with earth. If the installation of an

earth-pit privy will endanger the safety of the water supply, other methods of disposal must be used.

The site should be accessible to all potential users. Consideration should be given to the direction of prevailing winds to reduce fly and odor nuisances. The privy pit should not encroach within 2 meters (6 feet) of any building line or fence, in order to allow proper construction and maintenance.

3. **Pit, Sill, and Mound:** A minimum pit capacity of 4.6 cubic meters (50 cubic feet) is recommended. The pit should be tightly sheathed for a meter or several feet below the earth surface, but openings in the sheathing are desirable below this depth. The sheathing should extend from 25-50 millimeters (1-2 inches) above the natural ground surface, to provide space between the sill and the upper portion of the sheathing, so that the floor and building will not rest on the sheathing. A reinforced concrete sill should be provided for support of the floor and superstructure. The sill should be placed on firm, undisturbed earth.

An earth mound, at least equal in thickness to the concrete sill, should be constructed with a level area 46 millimeters (18 inches) away from the sill in all directions.

4. **Floor and Riser:** Impervious materials, such as concrete, are believed to be most suitable for the floor and riser. Because privy units are commonly used as urinals, the use of impervious materials for risers is desirable in the interest of cleanliness. In cold climates, wood treated with a preservative, such as creosote, has been found to be durable and to reduce the problem of condensation. Therefore, in some sections of the country, wood may be used if approved by the Local or State Health Authority.

5. **Seat and Lid:** Both seat and lid should be hinged to permit raising. Material used in construction should be light in weight, but durable. Seats should be comfortable. Lids shall be self-closing. Two (2) objections to self-closing seat lids are: discomfort from the lid resting on the upper portion of the user's back and contact of the oftentimes soiled or frost-covered bottom surface of the lid with the user's clothing. A seat lid has been devised which overcomes these objections. This lid is raised to a vertical position by lifting it from the rear, so that the top surface of the lid is against the user, rather than the bottom surface that is normally exposed to the pit.

6. **Vent:** Venting practices differ in many parts of the United States, because of differences in climatic conditions. In some States, particularly those in the South, vents have been omitted entirely and results from this practice appear to be satisfactory. Vents may pass vertically from either the pit or the riser, through the roof or directly through the wall near the floor. The vertical vent from pit or riser may lead to a horizontal vent passing through both walls or diagonally across a corner of the building.

In all cases, vents are screened. Galvanized, steel-wire screens dipped in paint, copper screens and bronze screens are used. Nearly all designs employ a screen with 6 (six) meshes to the centimeter (sixteen (16) meshes to the inch). Hardware cloth is used to cover the outside entrance to vents to prevent entrance of large objects that would clog the vent.

It is stated by some authorities that venting serves no useful purpose and that vents should be eliminated from earth-pit privies. Satisfactory recommendations with respect to vents can be made only after certain technical problems have been solved. The most important of these is the moisture condensation problem due to the temperature difference between the pit and the superstructure. The use of a cold wall, to condense moisture within the pit, has been suggested. In view of the uncertain value of venting, no recommendations are offered.

7. **Superstructure:** Privy structures are standardized to some extent. The majority are 1.2 meters by 1.2 meters (4 x 4 feet) in plan, with a height of 2 meters (6.5 feet) in front, and 1.8 meters (5.5 feet) at the rear. A roof with a 1-to-4 slope is commonly used. The building should be constructed of substantial material, painted for resistance to weather and fastened solidly to the floor slab. Proper roof overhang should be provided to dispatch rainwater from the roof away from the mound.

The roof should be constructed of watertight materials, such as wood, composition shingles or metal. Achieving ventilation of the building by omitting siding beneath the roof is common, except in cold climates, where the siding is usually perforated. Windows are sometimes used in the northern latitudes. Provision of coat hooks is desirable.

8. **Defects in Earth-Pit Privies:** The following shall be considered defects in pit-toilet installations:

a. Evidence of caving around the edges of the pit;
b. Signs of overflow, or other evidence that the pit is full;
c. Seat covers broken open or not self-closing;
d. Broken, perforated or unscreened vent pipe;
e. Uncleanliness of any kind in the toilet building;
f. Toilet room opening directly into milkhouse; and
g. Evidence of light entering the pit, except through the seat when the seat cover is raised.

MASONRY-VAULT PRIVY

A masonry-vault privy is essentially a pit privy in which the pit is lined with impervious materials and in which provision is made for the removal of excreta.

1. **Function:** Masonry vaults are used chiefly where the ground water table is close to the ground surface, or where it is necessary to prevent contamination of nearby water courses, wells and springs. They are also recommended for use in limestone formations to prevent contamination of water streams in the solution channels of the limestone. This type of disposal unit is satisfactory only where adequate maintenance and servicing are assured.

2. **Construction:** Masonry vaults may be constructed of brick, stone or concrete, with the latter preferred. The vault must be watertight to keep out ground water and to prevent leakage of the vault's contents. A readily accessible cleanout door is necessary. It shall be constructed to prevent access of insects, animals and surface water to the vault's contents. The floor of the superstructure, which forms a partial covering for the vault, must be impervious. Concrete is recommended.

CHEMICAL TOILET

In some areas where pit toilets might menace water supplies, where a sufficient volume of water for the operation of flush toilets is not available and where there is no prohibitive statute or ordinance, the chemical toilet may be accepted. Provided that it:

1. Has a receiving tank of acid resisting material with an opening easily accessible for cleaning;
2. Has a bowl, of nonabsorbent materials, sufficiently elevated above the receiving basin to prevent splashing the user;

3. Has the tank and bowl vented with at least a 7.6 centimeters (3 inches) screened pipe, preferably of cast iron, extending at least 60 centimeters (2 feet) above the roof line;
4. Has the tank charged, at proper intervals, with chemicals of a bactericidal nature and concentration;
5. Is placed in a well-lighted and well-ventilated room which does not open directly into the milkhouse; and
6. Has an effective method of final disposal, including burial, or a leaching vat or a cesspool where it will not endanger any water supply.

1. **Type:** Chemical toilets differ from privies, in that they are commonly placed inside the dwelling, whereas privies are generally located apart from the dwelling. There are, in general, two (2) types of chemical toilets:

a. The commode type, in which a pail containing a chemical solution is placed immediately below the seat; and

b. The tank type, in which a metal tank holding the chemical solution is placed in the ground directly beneath the seat. A pipe or conduit connects the riser with the tank. Tanks are usually cleaned by draining to a subsurface seepage pit.

2. **Function:** Toilets of this type are predominant in cold climates, where it is found desirable to have toilet facilities in or near the home, and where running water is not available for flush toilets.
3. **Chemicals:** Sodium hydroxide is commonly used to prepare the caustic solution for either commode or tank type chemical toilets. The chemical is dissolved in water and placed in the receptacle. The purpose of the chemical solution is to emulsify the fecal matter and paper and to liquefy the contents. In order to accomplish this action, the chemical solution must be maintained at proper strength and the mixture must be agitated each time the toilet is used. Odors are produced chiefly by the liberation of ammonia, when the caustic solution is weak, or when mixing by agitation is not carried out.
Difficulties are encountered when the caustic solution becomes diluted and fails to emulsify the fecal matter. When this occurs, the chemical solution breaks down, due to absorption of carbon dioxide from the air, and the solution ceases to be caustic. The decomposition of fecal matter produces foul odors.
4. **Sludge Disposal:** Disposal of the resultant mixture is a disagreeable task. In the case of small commode types, the usual method of disposal is burial in the earth. Tank units are usually so constructed that the tank is emptied into a seepage pit. When emulsification is not complete, particles of paper clog the seepage pit requiring corrective measures. Because of fundamental differences in design, chemical toilets resemble other types of privies only in the seat construction and manner of venting. Usually, risers or stools manufactured commercially are used.
Chemical toilets shall be used only where there is assurance of constant maintenance and where safe disposal of the contents is assured. Neither sludge nor liquid effluent from chemical toilet tanks shall be discharged to a sewage system in which treatment processes are involved. Otherwise, the chemical constituents of the sludge or liquid effluent may seriously interfere with the biological action upon which such treatment processes depend.
5. **Defects:** The following shall be considered defects in a chemical toilet installation:

a. Violation of any of the above requirements;

b. Disagreeable odors indicating to-infrequent charging with chemicals or inadequate concentration of chemicals in the charge;

c. Evidence of improper disposal of the tank contents; and
d. Lack of cleanliness in the toilet compartment and room.

CONSTRUCTION PLANS

Detailed construction drawings for septic tanks, pit privies, masonry-vault privies and chemical toilets complying with State regulations may be secured from the Local and State Health Authority.

II. GUIDELINE #45 - GRAVITY FLOW GUTTERS FOR MANURE REMOVAL IN MILKING BARNS

Published by the Dairy Practices Council

The gravity flow gutter concept for manure removal comes from Europe. Manure falls into a deep gutter in the barn floor and then flows by gravity to a cross channel or outlet pipe to storage. A low (8-20 centimeters) (3"-8") dam retains a lubricating liquid layer over which the manure flows (Fig. 1). After one (1) to three (3) weeks in a newly started gutter, the manure surface forms an incline of 1-3% above the dam. Then the manure moves continuously over the lip. The gutter must be deep enough to contain manure sloped at this shallow angle.

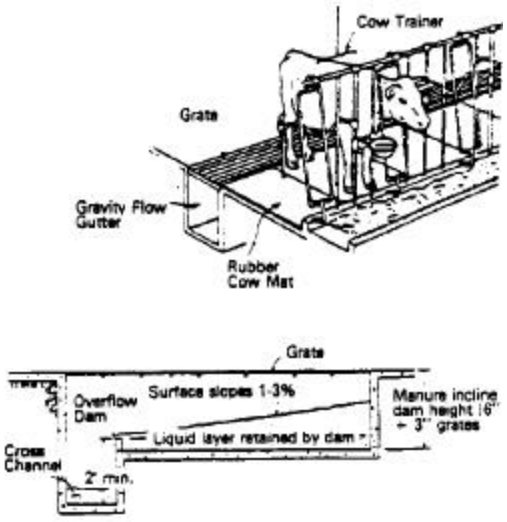

Figure 1. Side Cross Section of a Gravity Flow Gutter

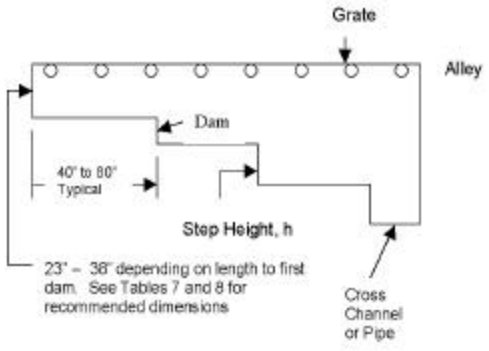

Figure 2. Stepped Gravity Flow Gutter

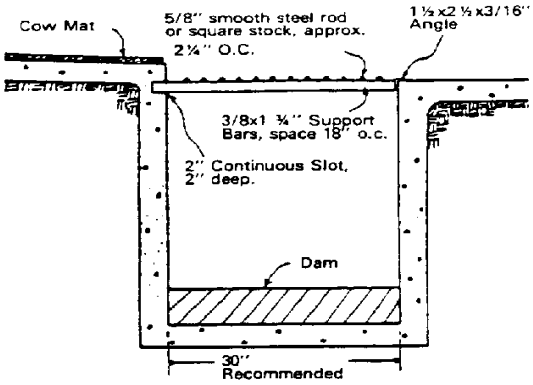

Figure 3. Cross Section of a Typical Gutter and Grate

Because manure moves by its own weight, no mechanical equipment is required to remove it from the barn. Generally the cost of the gutter and cover grates is less than the cost of installing, operating and maintaining a mechanical cleaner.

This system is neither a flush gutter, where 115-225 liters (30-60 gallons) of water per cow is needed to remove manure from the gutter, nor is it an under-barn storage that is open to the barn. Rather, it is a conveying channel that carries the manure from behind the cow to the outside storage. The top surface of the slurry has been recorded to move 3 meters (10 feet) per hour.

CONSTRUCTION

1. **Gutter Depth:** Gutter depth depends on the length of the gutter and the angle of incline of the manure surface. Design in this guideline assumes the manure surface forms a 3% slope. Most diets form wetter manure, and with no bedding the slope may be 1% less. The bottom should be level so the dam will hold a uniform liquid layer. The maximum depth of the gutter at

the end opposite the discharge shall not exceed 138 centimeters (54 inches). In addition, the outlet shall be clear of obstructions.
The depth includes an allowance for a 15 centimeter (6 inch) dam and a 8 centimeter (3 inch) deep grates.
Adding steps may decrease the maximum manure depth. The depth from the bottom of each dam to the bottom of the next level varies depending on the distance between steps. (See Figure 2)

Table 6. Slot Size vs. Cattle Age

Age (Months)	1-6	6-12	12-24	Over 24
Slot Size (in.)	1 – 1 ⅛	1⅛ – 1⅜	1⅜ – 1⅝	1 ½ - 1⅝

2. **Width of Gutters:** The bottom of the gutter shall not exceed 91 centimeters (36 inches) in width. A 76 centimeters (30 inches) wide gutter is recommended. The gutter opening may be narrowed to 50-60 centimeters (20-24 inches) in order to reduce the size and costs of grates.
3. **Overflow Dam:** The dam retains a lubricating liquid layer over the channel, which is essential to maintain flow. Typical heights range between 8 and 20 centimeters (3 and 8 inches). Dams, if removable, would facilitate total cleanout, when and if necessary. Concrete, a steel plate, or a plank may be used to construct the dam. Caulking may be needed to seal the dam.

Table 7. Gravity Flow Gutter Depth vs. Length for Manure from Lactating Animals

Length		Depth	
Meters	Feet	Cm.	Inches
12	40	58	12
18	60	78	18
24	80	96	24
30	100	114	30
36	120	132	36

4. **Length**: A 70 meters (226 feet) long gutter has worked, but typical distances between dams range from 12 to 24 meters (40 to 80 feet). Longer channels must be deeper; hence, they may cost more because they require more concrete and stronger forms.

Table 8. Step Height vs. Length for Stepped Gravity Flow Gutters		
	Step Height	
Length Between Dams	For 1.5% Manure Incline	For 3% Manure Incline
40’	7”	14”
50’	9”	18”
60’	11”	22”
70’	13”	25”
80’	15”	29”

5. **Grates:** Commercial steel grates for stall barns and concrete slats for freestall barns are generally available. Table 7 suggests slot widths. Grates for stall barns are made from round or flat steel stock.

6. **Cross Channel:** The cross channel may be constructed like the gutter. At least a 60 centimeters (2 feet) drop from the top of the dam to the bottom of the cross channel is suggested to prevent backup of manure into it. The channel may be extended directly to storage. The slurry should enter the bottom; to prevent storage gases and cold air from returning up the channel. Channel depth, below grade, should be sufficient to prevent freezing.

Gravity flow via a concrete, steel or plastic pipe may also be used to transfer manure to the bottom of the outside storage. Pipe as small as 38 centimeters (15inches) diameter has been used successfully. However, 60 centimeters (24inches) diameter pipe is recommended.

Do not empty channels into large sumps or pits within, or having direct openings into the barn. These storages will produce gas and odors that will be drawn into the barn through the ventilation systems.

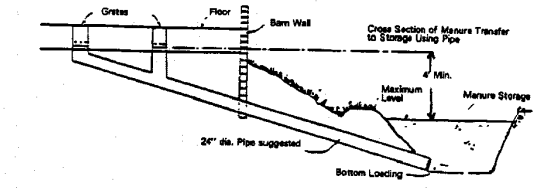

Figure 4. Manure Transfer to Storage

MANAGEMENT

1. **Flooding of Gutters:** Prior to stocking the building, fill the gutters with 8-15centimeters (3-6 inches) of water to start the lubrication layer.

2. **Bedding Usage**: The type and amount of bedding used is important to successful operation. Up to .5 kilograms (1 pound) per lactating animal per day of sawdust, fine cut shavings or peanut hulls still allows the system to work. Some have worked with long straw bedding, but it is not recommended. More bedding or long straw increases manure stiffness and may clog the gutter.

Lactating animal mats allow minimum bedding use. Sometimes water may need to be added, depending upon the feed ration and amount of bedding used.

3. **Wastage and Deposits:** Keep feed and hay out of the gutter. Barn lime and soil brought in from outside may settle to the bottom. For this reason, the overflow dam, on some gutters, is removable for clean out. Buildup of solids has not been a problem under normal management, although the gutter will need cleaning if it has not been used for some time. Watch for islands of solids, especially where excess bedding or feed builds up. Cut these islands free of the walls to keep them flowing.

4. **Cleaning Grates:** Grates need cleaning at least weekly and, preferably, daily. A broom connected to a hose makes the job easy.

5. **Flies and Odors**: Flies have caused little or no problems. Biodegradable oil such as mineral oil may be sprayed on the manure surface to control them. Little or no odors have been observed in barns with good ventilation. There is no need to install fans to ventilate the gutters.

III. CONVALESCENT (MATERNITY) PENS IN MILKING BARNS AND STABLES

While the requirement for concrete floors in milking barns and stables is necessary for good sanitation, climatic conditions in some areas of the country has created a need for convalescent (maternity) pens to be located in milking barns and stables.

Therefore, convalescent pens may be allowed in the milk barn or stable. Provided that the following requirements are met:

1. All floors in the production milking facility, with the exception of the convalescent pens, must be of an impervious surface, with slopes for drainage as currently listed in the regulations.
2. Milk from animals milked in convalescent pens with non-impervious floors must not enter the distribution system or be sold.
3. Routine milking in pens shall not be allowed.
4. Pens must be located in a location so as not to contaminate milk holding transfer facilities or water supplies. Convalescent pens cannot be within 15 meters (50 feet) of a well.
5. A curb of at least 15 centimeters (6 in.) shall be provided on all exposed sides of the pen(s).
6. Convalescent pens shall be well bedded, clean and dry at all times.
7. No water faucet or drinking fountain shall be located within the curbed area.
8. State sanitarians, at their discretion, may require cleaning and/or reconstruction of such pens, based at intervals as necessary when the pens present a sanitation problem.
9. It is recommended that the number of pens be limited to one (1) per fifty (50) lactating animals.

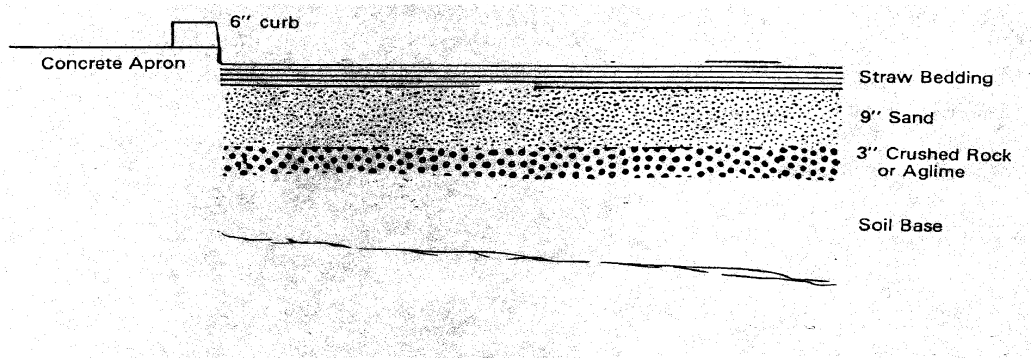

Figure 5. Side Cross Section of a Convalescent Pen

IV. GUIDELINES FOR CONVENTIONAL STALL BARN WITH GUTTER GRATES OVER LIQUID MANURE STORAGE

INTRODUCTION

The use of liquid manure storage under milking barns can be a cost, labor and energy efficient method for handling dairy animal wastes. This type of system can aid in pollution control and will provide a safe and healthy environment for cattle and humans under the following guidelines:

1. Plans for the construction of a conventional stall barn, with gutter grates over liquid manure storage, shall be submitted to the Regulatory Agency for approval before work is begun. Upon completion of the work, the builder shall furnish the purchaser with a signed written statement certifying that the system is constructed so as to be in full compliance with these guidelines.
2. The storage capacity of the liquid manure tank shall be for a minimum of nine months.
3. A negative pressure mechanical ventilation system must be installed to meet the following requirements (See Figures 6 and 7):

a. Provide a maximum exhaust capacity of forty (40) air changes per hour from the occupied area. Of this total, about one-half, twenty (20) air changes per hour shall be considered the cold weather part of the system and shall be exhausted through the manure storage area. The remaining twenty (20) air changes per hour shall be considered the warm weather part of the system and shall be exhausted through the barn walls.

b. Of the twenty (20) air changes exhausted through the manure storage area there shall be a minimum continuous exhaust of four (4) air changes per hour. The additional cold weather capacity of about sixteen (16) air changes per hour shall be thermostatically controlled. All fans exhausting from the manure storage area shall be installed in permanent fan houses built on the exterior wall of the barn and connected directly to the manure storage area. These fans must be single-speed with a certified delivery rating against 6 millimeters (¼ inch) water gauge static pressure. One pit fan must operate continuously. Airflow must be from the occupied area through the gutters. The use of variable-speed fans is prohibited.

c. Fans supplying the additional summer capacity shall be mounted to discharge directly through the barn walls. They may be mounted on the outside of the building and the openings closed with insulated panels in cold weather, or when mounted in the walls be protected with an inside insulated cover to eliminate condensation and frost formation on the shutters and mountings. Warm weather fans are to be located on the same side of the barn as the pit fans. They must have a certified delivery rating against 3 millimeters (?-inch) water gauge static pressure and should be single speed.

d. All fans, except those providing the minimum continuous exhaust rate are to be controlled by thermostats located away from the barn walls. All pit fans are to be in operation before any of the wall fans are started. An electrical thermal overload device of the proper size shall protect each fan.

e. Calculation Method: To calculate the fan capacity in cubic feet per minute (cfm) for a particular barn, multiply the length times the width times the average ceiling height, all in feet, to obtain the volume. Divide the volume by 15 to obtain the minimum continuous capacity of 4 air changes per hour in cfm (4 x 15 = 60 minutes).

$$\frac{\mathbf{W \times L \times H}}{\mathbf{15}} = \mathbf{cfm}$$

For Example: Barn width 36', length 160' and average ceiling height 8' 6". This would be a reasonable size for sixty (60) stalls and two (2) pens. The calculation of the minimum continuous exhaust for this example would be:

$$\frac{36 \times 160 \times 8.5}{15} = 3{,}264 \text{ cfm}$$

Total cold weather capacity of twenty (20) air changes per hour equals five (5) times the minimum capacity: 3,264 x 5 = 16,320 cfm.

Use two (2) fans of 3,264 each and two (2) fans of 4,896 cfm each to make up the total. Build two (2) fan houses. Mount one 3,264 cfm and one 4,896 cfm fan in each. Operate one 3,264 cfm fan continuously. Thermostatically control the second 3,264 cfm fan at 4.4ºC (40°F). Control the two (2) larger fans with thermostats set at 6°C (43°F) and 8°C (46°F). Divide the summer capacity of an additional twenty (20) air changes per hour among three (3) fans of 5,440 cfm each. Locate these fans in the walls. Control them with thermostats set to 10°C–13°C (50°F–56°F). (See Figure 6 for the approximate locations for all fans) Fans of the exact calculated capacity are usually unavailable. Always select those having a slightly higher rather than lower capacity.

f. Adequate incoming fresh air, to enable the fan exhaust system to function as designed, must be provided. A continuous slot inlet with manual adjustment on one (1) side is recommended to provide uniform fresh air distribution throughout the barn. (See Figure 7) Adjustment of the slot opening opposite the fans is to be done manually for cold and warm weather conditions. Careful construction of the fresh air intake system is essential to the satisfactory performance of the ventilation system.

4. A stand-by generator to supply electric current to the ventilation system, in the event of a power failure, shall be provided.

5. Construction Requirements:

a. The floor system over the pit shall be designed to safely support all animal weight, plus the possibility of a tractor that may be needed to remove a sick or dead animal. Agitating and pumping of the stored manure shall be done through annexes built outside the barn. (See Figures 6 and 7) Service alley floor and lactating animal stall platforms shall be constructed to drain to the grated gutter tank opening, located between the lactating animal stall and the service alley.

b. Waste water from the milkhouse can be discharged into the pit. Sanitary (toilet) waste shall not be disposed of in the manure storage tank. When wastewater from the milkhouse is discharged into the pit, a drop pipe must be connected to the discharge line so that the liquid waste will be deposited beneath the surface of the tank contents to prevent turbulence and possible odor production.

c. Grates over the gutters, tank slot openings, shall be of sufficient strength to support all applied loads. A suitable grate design is one using 16 millimeters (? inches) smooth steel bars running the length of the open gutter. The distance between the center of the first bar and the vertical face of the stall platform should be 57 millimeters (2¼ inches). The

remaining bars should be spaced 63 millimeters (2½ inches) center-to-center. Support bars crossing the gutters should be 19 millimeters (¾ inch) diameter and spaced 40 centimeters (16 inches) center-to-center.

6. Little or no bedding can be used with this system, rubber mats or equivalent, and lactating animal trainers shall be installed at the time the barn is constructed. Daily cleaning of grates with a stiff broom or scraper is recommended.

7. Other construction criteria and management practices recommended for stall dairy barns should be followed.

8. Requirements for emptying holding tanks:

a. Remove all animals and post signs on all doors that no one is to enter the milking barn during the time the tank is being agitated.

b. All pit fans must be operating during agitation and emptying.

c. All milkhouse and feed storage area openings, doors, windows, etc., must be closed.

d. The milking barn must remain evacuated by animals and people for at least one (1) hour, after agitation of the holding tank is completed.

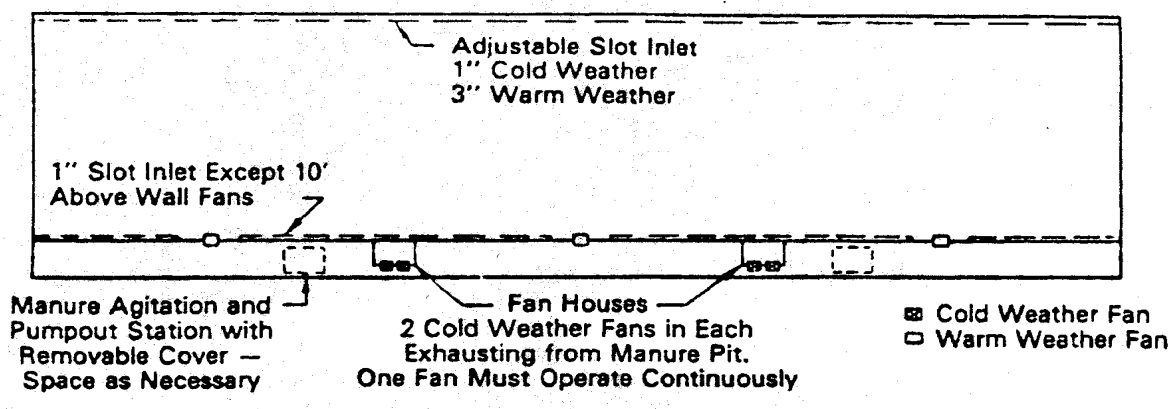

Figure 6. Schematic Diagram Showing Suggested Exhaust Fan Locations for a Typical Stall Dairy Barn with Gutter Grates Over Liquid Manure Storage

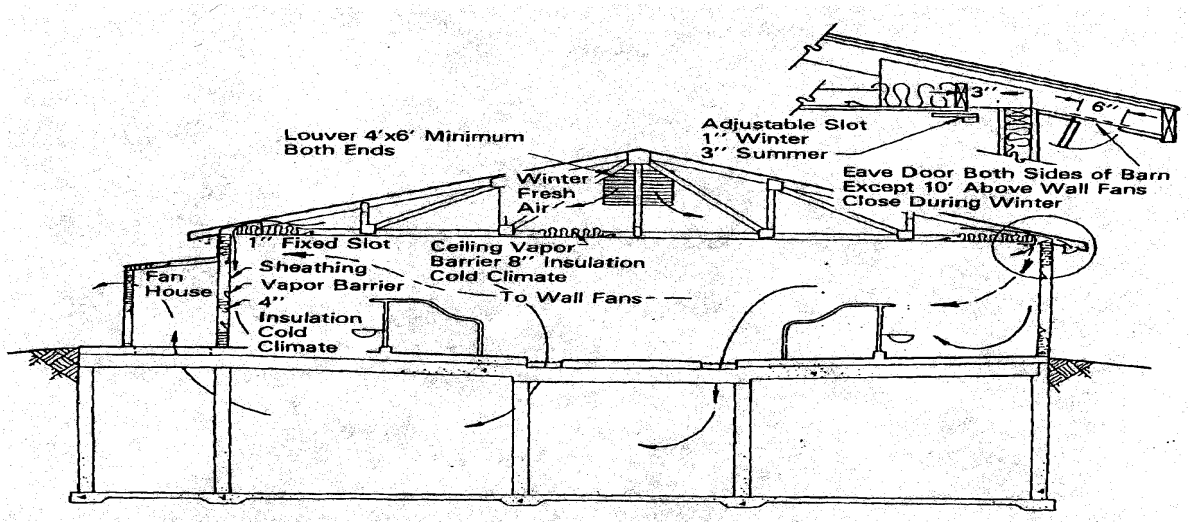

Figure 7. Schematic Diagram Showing General Pattern of Ventilation Air Movement, Slot Inlet Design and Fan House for Pit Fans

V. DAIRY - CONSTRUCTION AND OPERATION

MILKING BARN, STABLE OR PARLOR

Numerous factors, including the size and topography of the farm, the availability of utilities, the condition and disposition of existing buildings, the dairy operator's ultimate goals for the enterprise, and the operator's construction budget serve to make each milk producer's herd housing problems individual and unique.

While there has been a tendency for workers to develop strong convictions about the practicability of given housing or milking systems, there is little doubt that the success or failure of most dairy farm operations may be traced to good or poor planning. When the unique problems of each system in its individual applications are given proper consideration, the job of producing clean milk is made easier and compliance with regulations is simplified. For example, operators of barns in which lactating animals are housed and milked will find that efficient ventilation not only reduces condensation but also relieves the problem of dust and mold on walls, ceilings and windows. When window sills are sloped or windows set flush with interior walls in stanchion barns, the accumulation of dust and unwanted miscellaneous items is similarly lessened. Covered recessed light fixtures remain clean longer and are less subject to damage than those projecting from the ceiling.

Operators of milking parlor loose-housing systems, on the other hand, will value design features such as mechanically operated doors, which speed up animal traffic, and glazed wall finishes, which cut down the time required for proper post-milking wash-up of the parlor. Cleaner lactating animals result from proper planning and management of exercise yards and bedded areas. At least 9 square meters (100 square feet) of surfaced yard and not less than 5 square meters (50 square feet) of bedded space are recommended for each animal to be accommodated. Provisions must also be made for the removal at least daily of manure from exercise yards and traffic lanes. Operators utilizing loose housing have shown considerable interest in free-stall housing. Many workers have concluded that it provides the solution to the problems of unclean lactating animals and excessive bedding demands that have plagued loose housing in past years. Milk producers planning new construction or large-scale changes in existing housing should carefully study its features.

Adequate light must be available in all work areas in the milking barn, stable or parlor. Because many dairy functions are frequently performed after dark, it is important that the required minimum of ten (10) foot-candles of illumination be available from artificial sources. While absolute certainty of compliance with this requirement can only be confirmed by the use of a light meter, experience has shown that milking barns which otherwise meet the standards of this *Ordinance* will be properly lighted when equipped with one (1) 100-watt bulb (or its fluorescent equal) for each three (3) stanchions or per 3 meters (10 linear feet) of walkway behind each row of lactating animals in face-in barns or between rows of lactating animals in face-out barns. In addition, a smaller number of bulbs, equally spaced, are recommended for feed alleys in front of the lactating animals. When natural light is utilized, a minimum of .37 square meter (4 square feet) of window space for each 5.6 square meter (60 square feet) of floor space is recommended.

Construction plans and suggestions for the various systems of animal management are available to the sanitarian and the dairyman from numerous sources, including the USDA, the county extension agent, farm periodicals and the trade associations serving the building supply industry.

MILKHOUSE

Milkhouses should be large enough to provide adequate space to meet present needs and should take into account the prospect of future expansion. Installed milkhouse equipment should be readily accessible to the operator. Aisles should be at least 76 centimeters (30 inches) wide, with added allowance at the outlets of bulk milk tanks, adjacent to wash-and-rinse vats and where operational conditions warrant. It is especially important that the space available to bulk milk tanks and mechanical cleaning systems be adequate to permit their disassembly, inspection and servicing.

Floor drains should not be located under bulk milk tanks unless there is sufficient room for servicing. Floor drains should not be located directly under the outlet of a bulk milk tank. Drains and waste disposal systems should be adequate to drain the volume of water used in rinsing and cleaning.

Milkhouses should be well ventilated. Proper ventilation not only avoids the obvious disadvantages of condensation on equipment and walls, it also lengthens the useful life of the building and its equipment. The constant need for renewal of painted surfaces, the repair of wooden fixtures and frames and the removal of algae and mold from walls and ceilings of poorly ventilated milkhouses can represent a continuing expense to the operator.

Where possible, windows should be placed to provide cross ventilation. In addition, one (1) or more ceiling vents should be located to receive water vaporizing from wash-and-rinse vats and other sources of evaporative moisture.

Glass brick is sometimes substituted for windows in milkhouse construction. In these instances, mechanical ventilation must be provided. A system affording filtered positive air pressure is recommended over exhaust ventilation, as the latter frequently draws dust, insects, and odors into the milkhouse.

The great demand for water under pressure in milkhouse operations has emphasized the importance of protecting plumbing from freezing. Devices that have proved effective include, the insulation of water lines, the use of wrap-around heat tape, infrared lamps, and thermostatically controlled space heaters.

Insulated milkhouses make protection against freezing easier and more economical, and offer the additional advantage of greater comfort for the operator. The factor of personal convenience frequently results in better performance by the operator, with subsequent benefits to milk quality.

Automated milking and mechanical cleaning systems of milking equipment has increased the use of hot water in the milkhouse. The following Table indicates the volumes of water required to fill 30 meters (100 feet) of pipeline of varying diameters:

Table 9. Work Water Volume of Various Sized Pipelines

Pipe Diameter (Inches)	Gallons
1	4.7
1.5	9.2
2	16.3

Since most cleaning installations employ a pre-rinse, followed by wash-and-rinse cycles, this Table actually represents only one-third (?) the usual milking-time demand for heated water. Also, it does not include the "take up" of collecting jars, pumps, rubber parts, etc.

Udder washing, bulk milk tank cleaning and similar milkhouse tasks offer additional uses for hot water.

Sanitarians should compute the hot water demand of the individual milking systems under their supervision and require that not less than the minimum amount be available at all times. Milk producers should be made aware of the fact that effective cleaning of mechanically cleaned installations is impossible without adequate hot water and should be encouraged to provide a supply which exceeds their expected need. Such planning avoids emergency shortages and allows for normal expansion of the herd and facilities.

Detailed plans for milkhouses, as well as recommendations on hot water needs, insulation, lighting and ventilation are available from power companies, building supply associations, County Agricultural Extension Agents and State Universities.

Refrigeration, electrical or mechanical systems powered by gasoline or diesel engines, have no place in a milkhouse, milking barn, or in any communicating passageway between the milkhouse and milking barn. Such equipment is characteristically given to oil leakage and the discharge of fumes. The space occupied by it is difficult to keep clean and frequently becomes a gathering place for trash and flammable materials. With effective planning, these engines and their accessory equipment can be located, without detriment to their performance, in a separate room or building adjacent to the barn or milkhouse.

MILKING METHODS

Milking methods must be geared to permit the efficient withdrawal of milk without introducing undue numbers of bacteria or causing injury to the udder.

In addition to assessing the nation's milk producers a cost, which has been estimated to approach $500 million annually, mastitis has been found to pose serious public health hazards. The most widespread of these is a gastrointestinal disorder caused by toxins produced by certain strains of staphylococci.

It has been known for many years that a relationship exists between mastitis and milking practices. While not all the facts are known about mastitis, it is abundantly clear that its control is enhanced by use of mechanically sound milking equipment and good milking practices. The National Mastitis Council (NMC) has described a satisfactory milking system as one which:

1. Maintains a stable vacuum in the teat cup and at a level adequate for completely milking most udders in three (3) to five (5) minutes;
2. Does not stress the tissues of the teat by excessive stretching and ballooning;
3. Produces massage without harsh action; and
4. Is designed so that the entire system can be sanitized efficiently and satisfactorily.

The NMC considers proper milking procedure to include the following:

1. Before the milking unit is applied to the udder, the operator takes thirty (30) seconds to prepare the lactating animal in the recommended manner to obtain milk letdown, and the milking machine should be applied immediately thereafter;

2. The teat cups are attached in a manner to limit the volume of air drawn into the system;
3. The teat cups are positioned as low on the teats as practicable;
4. The operator stays near the machine and, at the end point of milk removal, the claw is briefly pulled down to open the teat cavity and remove the strippings. Stripping by machine should not extend over a period of more than fifteen to twenty (15-20) seconds. Prolonging stripping can be injurious to the udder;
5. Before removing the machine, the vacuum to the teat cups is broken and the cups removed in a gentle manner; and
6. To avoid over-milking, the operator should limit the number of machines in use. Two (2) bucket-type units, two (2) movable pipeline units or three (3) fixed units, in a walk-through barn, usually represent maximum workloads with conventional milking systems.

Hooded, or small-mouthed pails may be used for carrying only that milk which has been drawn into them by hand-milking. Their extended use as carrying pails is considered hazardous in view of their inability to be covered or otherwise protected from flies, dust, splash, etc.

DRUG RESIDUE AVOIDANCE CONTROL MEASURES

Animal identification and record keeping are critical for avoiding milk drug residues. Producers should establish systems to ensure that animal drugs are used properly and be able to provide evidence that adequate control over the administration of drugs to prevent residues in milk and/or meat has been implemented. These control systems should accomplish the following objectives:

1. Identification and tracking the location of treated animals.
2. Maintenance of a system of medication/treatment records that, at a minimum, records the identity of the animals(s) being treated, the date(s) of treatment, the drugs(s) or other chemicals administered, who administered the treatment, the dosage, and the prescribed withdrawal time for milk and slaughter.
3. Quarantine/segregation of treated animals or other means to preclude the sale of milk or offering of treated animals for sale for slaughter prior to the end of the prescribed withdrawal time.
4. Education of all farm personnel involved in treating animals on proper drug use and methods to avoid marketing adulterated milk or meat for human food.

INSECT AND RODENT CONTROL

The complete elimination of flies from the farm premises is practically unattainable. However, a major reduction of fly infestation is obtainable by the dairy farm operator who conscientiously follows a sustained program of sanitation, screening and the proper use of insecticides.
The milk producer or plant operator must be continually aware of the potential hazard to people and animals which is inherent in most pesticides, including insecticides and rodenticides. It is important that they employ only those insecticides and rodenticides that are recommended by competent authority for the insect and rodent problems they seek to overcome, and that they follow implicitly the manufacturer's label directions for their use. Questions on the use of

pesticides should be referred to the appropriate Regulatory Agency and/or County Agricultural Extension Agent.

Effective rodent control, like insect control, is dependent on sanitation for much of its success. The careful elimination of trash and woodpiles; the rodent-proofing of feed bins, corn cribs and similar structures; the prompt removal of spilled feed and manure to places of ultimate disposition; and the deliberate elimination of protected harborage areas in farm buildings, all tend to discourage rodents near the dairy farm. Such a program, also pays excellent dividends in feed savings, lowered maintenance costs for farm buildings, reduced fire hazards and lessened risk of disease outbreaks among farm animals.

Anticoagulant poisons, Warfarin, Fumarin, etc. have offered improved means of controlling rodents on the farm. Used according to directions, and with due precaution against their consumption by domestic animals, these chemicals should keep the rodent population in check while additional preventive programs are instituted.

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APPENDIX D. 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 following 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. A person with sufficient training and experience to evaluate all of the factors involved should inspect each installation.

Since the 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 Local or State Agency Officials, has determined 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 Local or State 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 Local or State Health Agency.

The following Table is offered as a guide in determining acceptable distances of a well from sources of contamination:

Table 10. Distance of a Well from Sources of Contamination	
Formation	**Minimum Acceptable Distance of a Well from Sources of Contamination**
Favorable (Unconsolidated)	15 meters (50 feet) – Lesser distances only on Health Department approval following a comprehensive sanitary survey of the proposed site and immediate surroundings.
Unknown	15 meters (50 feet) – Only after a comprehensive geological survey of the site and its surroundings has established, to the satisfaction of the Health Department, 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 that should be investigated or considered in a sanitary survey. Not all of the Items are pertinent to any one (1) supply and, in some cases; Items not in the list would be important additions to the survey list.

Ground Water Supplies:

1. Character of local geology and slope of ground surface.
2. 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; and depth to water table and location; and log and construction details of local wells in use and abandoned.
3. Slope of water table, preferably determined from observational wells or as indicated, presumptively, but not certainly, by the slope of ground surface.
4. Extent of drainage area likely to contribute water to the supply.
5. Nature, distance and direction of local sources of pollution.
6. Possibility of surface-drainage water entering the supply and of wells becoming flooded and methods of protection.
7. Methods used for protecting the supply against pollution by means of sewage treatment, waste disposal and the like.
8. Well Construction:
    a. Total depth of well.
    b. Casing: Diameter; wall thickness; material; and lengths from surface.
    c. Screen or Perforations: Diameter; material; construction; locations; and lengths.
    d. Formation Seal: Material, cement, sand, bentonite, etc.; depth intervals; annular thickness; and method of placement.
    9. 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.
10. Pump-house Construction: Floors, drains, etc.; capacity of pumps; and draw-down when pumps are in operation.
11. Availability of an Unsafe Supply: Usable in place of normal supply, hence involving danger to the public health.
12. Disinfection Equipment: Supervision; test kits or other types of laboratory control.

Surface Water Supplies:

1. Nature of Surface Geology: Character of soils and rocks.

2. Character of Vegetation: Forests; cultivated and irrigated land; including salinity, effect on irrigation water, etc.
3. Population and sewered population per square mile of catchment area.
4. Methods of sewage disposal, whether by diversion from watershed or by treatment.
5. Character and efficiency of sewage-treatment works on watershed.
6. Proximity of sources of fecal pollution to intake of water supply.
7. Proximity, sources and character of industrial wastes, oil field brines, acid mine waters, etc.
8. Adequacy of supply as to quantity.
9. For Lake or Reservoir Supplies: Wind direction and velocity data; drift of pollution; sunshine data; and algae.
10. Character and Quality of Raw Water: Coliform organisms (MPN); algae; turbidity; color; and objectionable mineral constituents.
11. Nominal period of detention in reservoirs or storage basin.
12. Probable minimum time required for water to flow from sources of pollution to reservoir and through reservoir intake.
13. Shape of reservoir, with reference to possible currents of water, induced by wind or reservoir discharge, from inlet to water supply intake.
14. 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.
15. Efficiency and constancy of policing.
16. 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.
17. Pumping Facilities: Pump-house; pump capacity; 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 .6 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, as with 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 (2) 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 pit-less 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 wastewater cannot stand near the well. The minimum thickness of such a slab or floor shall be 10 centimeters (4 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 meter (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. And 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 centimeters (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 15 centimeters (6 inches) from a roof, roof drain, floor, and 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 0.6 centimeters (¼ inch) hardware cloth, or shall terminate in a horizontal angle seat check valve.

DEVELOPMENT OF SPRINGS

There are two (2) 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. (See Figure 12)

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 down-hill 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 drainpipe 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 centimeters (6 inches) above the drain outlet and properly screened. Care shall be taken in casting pipes into the walls of the tank to insure a good bond with the concrete and freedom from honeycombs 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 sinkholes 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 judgment. 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 a 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, fire-fighting 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 that is free from bacterial contamination and certain chemical elements.

Where the final 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 milk plant operator, who is considering surface sources of water for milking, milkhouse and milk plant, receiving station or transfer station 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.

NOTE: The EPA publishes a document entitled *Manual of Individual Water Supply Systems* that is an excellent source of detailed information on the development, construction and operation of individual water systems and also contains a suggested well-drilling code.

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 seventy percent (70%) 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 1 gram (0.03 ounce) of dry chemical per 13.5 liters (3.56 gallons) of water to be disinfected. A stock solution of disinfectant may be prepared by mixing 30 grams (1 ounce) of high-test hypochlorite with 1.9 liters (2 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 ten (10) to fifteen (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 liters (2 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 rubber lined 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 (½ ounce).

When calcium hypochlorite is not available, other sources of available chlorine such as sodium hypochlorite (12-15% of volume) can be used. Sodium hypochlorite, which is also commonly available as liquid household bleach with 5.25% available chlorine, can be diluted with two (2) parts of water to produce the stock solution. 1.9 liters (2 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 latest edition of *Standard Methods for the Examination of Water and Wastewater* (SMEWW), published by the American Public Health Association.

DUG WELLS

After the casing or lining has been completed, follow the procedure outlined below:

1. Remove all equipment and materials that will not form a permanent part of the completed structure.
2. Using a stiff broom or brush, wash the interior walls of the casing or lining with a strong solution (100 mg/l of chlorine) to insure thorough cleaning and sanitizing.
3. Place the cover over the well and pour the required amount of chlorine solution into the well through the manhole or pipe opening just before inserting the pump cylinder and drop-pipe assembly. The chlorine solution should be distributed over as much of the surface of the water as possible to obtain proper diffusion of the chemical through the water hose or pipeline, as the line is being alternately raised and lowered. This method should be followed whenever possible.
4. Wash the exterior surface of the pump cylinder and drop pipe, with the chlorine solution, as the assembly is being lowered into the well.
5. After the pump has been set in position, pump water from the well and through the entire water distribution system to the milkhouse until a strong odor of chlorine is noted.
6. Allow the chlorine solution to remain in the well for at least twenty-four (24) hours.
7. After twenty-four (24) hours or more have lapsed, flush the well to remove all traces of chlorine.

DRILLED, DRIVEN, AND BORED WELLS

After the casing or lining has been completed, follow the procedure outlined below:

1. Remove all equipment and materials that 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 the water, discharged through the entire distribution system to waste, has a distinct odor of chlorine. Repeat this procedure a few times, at one (1) 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 twenty-four (24) hours.
7. After twenty-four (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 (1) 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. Therefore, it is 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 twenty-four (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 that 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 that 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% 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/1 of available chlorine.
The disinfectant should be retained in the system, tank or standpipe, if included, for not less than twenty-four (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 that 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 that may be present in the water. If an excessive amount of chlorine is used, free chlorine residual will be present. When the quantity of chlorine is increased, disinfection is faster and the amount of contact time required insuring safe water is decreased.

Dechlorination: The de-chlorination process may be described as the partial or complete reduction of any chlorine present in the water. When de-chlorination is provided in conjunction with proper superchlorination, the water will be both properly disinfected and acceptable to the consumer for domestic or culinary uses.
De-chlorination can be accomplished in individual water systems by the use of activated carbon, de-chlorinating filters. Chemical de-chlorination by reducing agents such as sulphur dioxide or sodium thiosulfate can be used for batch de-chlorination. Sodium thiosulfate is also used to de-chlorinate 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, hypo-chlorinators provide a reliable method for applying chlorine to disinfect water.
Types of hypo-chlorinators include positive displacement feeders, aspirator feeders, suction feeders and tablet hypo-chlorinators.
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 hypo-chlorinator is one (1) that 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 hypo-chlorinator can be

synchronized with the pumping unit. A hypo-chlorinator 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 (1) 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 hypo-chlorinators inject water into a bed of concentrated calcium hypochlorite tablets. The result is metered into the pump suction line.

V. WATER RECLAIMED FROM MILK AND MILK PRODUCTS

Condensing water from milk evaporators and water reclaimed from milk and milk products may be reused in a milk processing plant. The three (3) general categories for reclaimed water use are:

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.

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 G., and, in addition, shall not exceed a total plate count of 500 per milliliter.

2. Samples shall be collected daily for two (2) weeks following initial approval of the installation and semi-annually thereafter. Provided, that daily tests shall be conducted for one (1) 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 that 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 latest edition of SMEWW.

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 Items 3-11 of this Section are satisfied and:

1. There is no carry-over of water from one (1) day to the next, and any water collected is used promptly; or
   a. The temperature of all water in the storage and distribution system is maintained at 63ºC (145ºF) or higher by automatic means; or
   b. 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,
2. Distribution lines and hose stations are clearly identified as "limited use reclaimed water"; and
3. Water handling practices and guidelines are clearly described and prominently displayed at appropriate locations within the plant; and
4. 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 feed-water 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 Grade "A" 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 G.
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.

VII. DRAWINGS OF CONSTRUCTION DETAILS FOR WATER SOURCES

NOTE: The following Figures 8-25 are taken from *The Manual of Individual Water Supply Systems*, Environmental Protection Agency (EPA) publication number EPA-430-9-73-003.

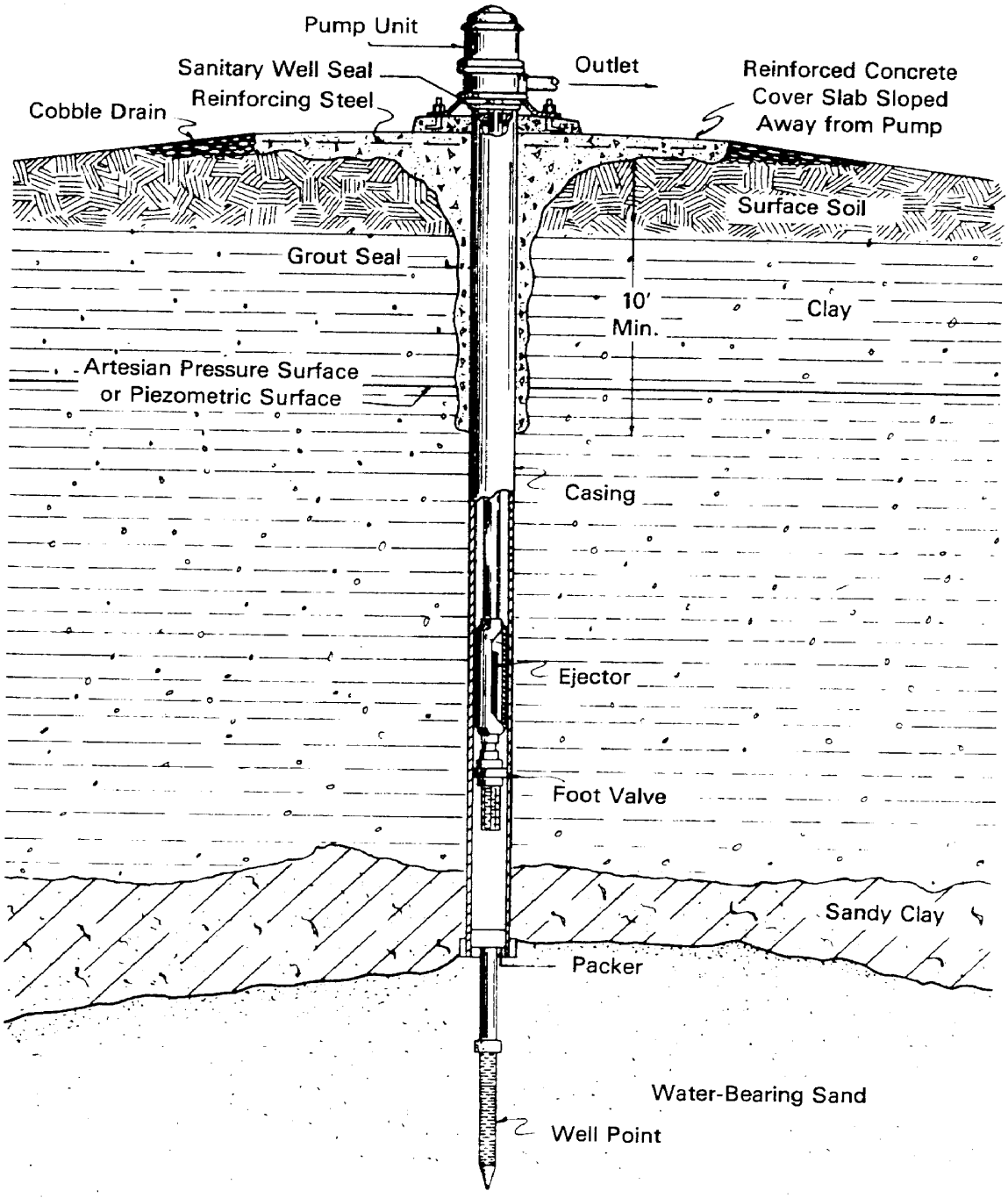

Figure 8. Bored Well with Driven Well Point

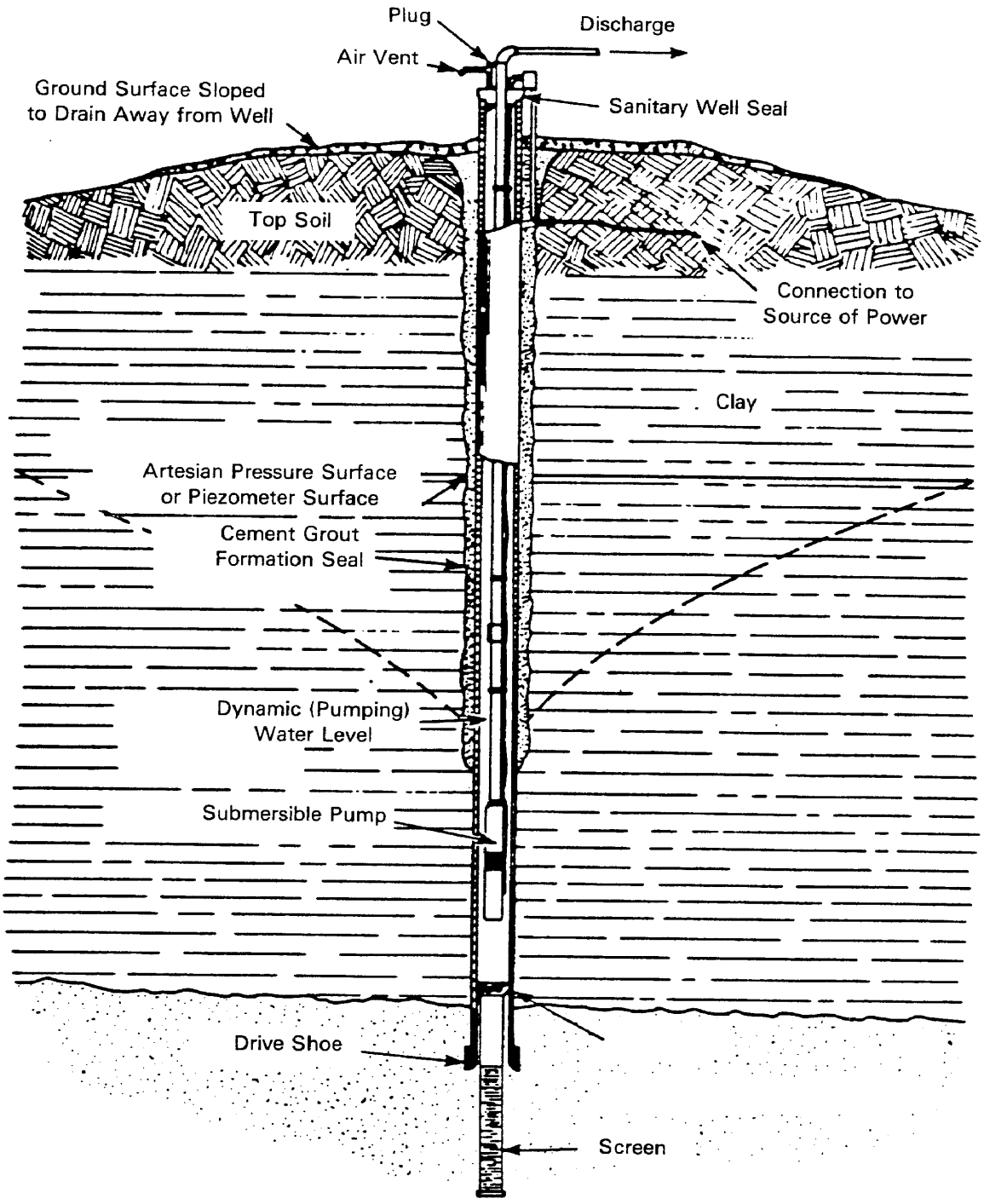

Figure 9. Drilled Well with Submersible Pump

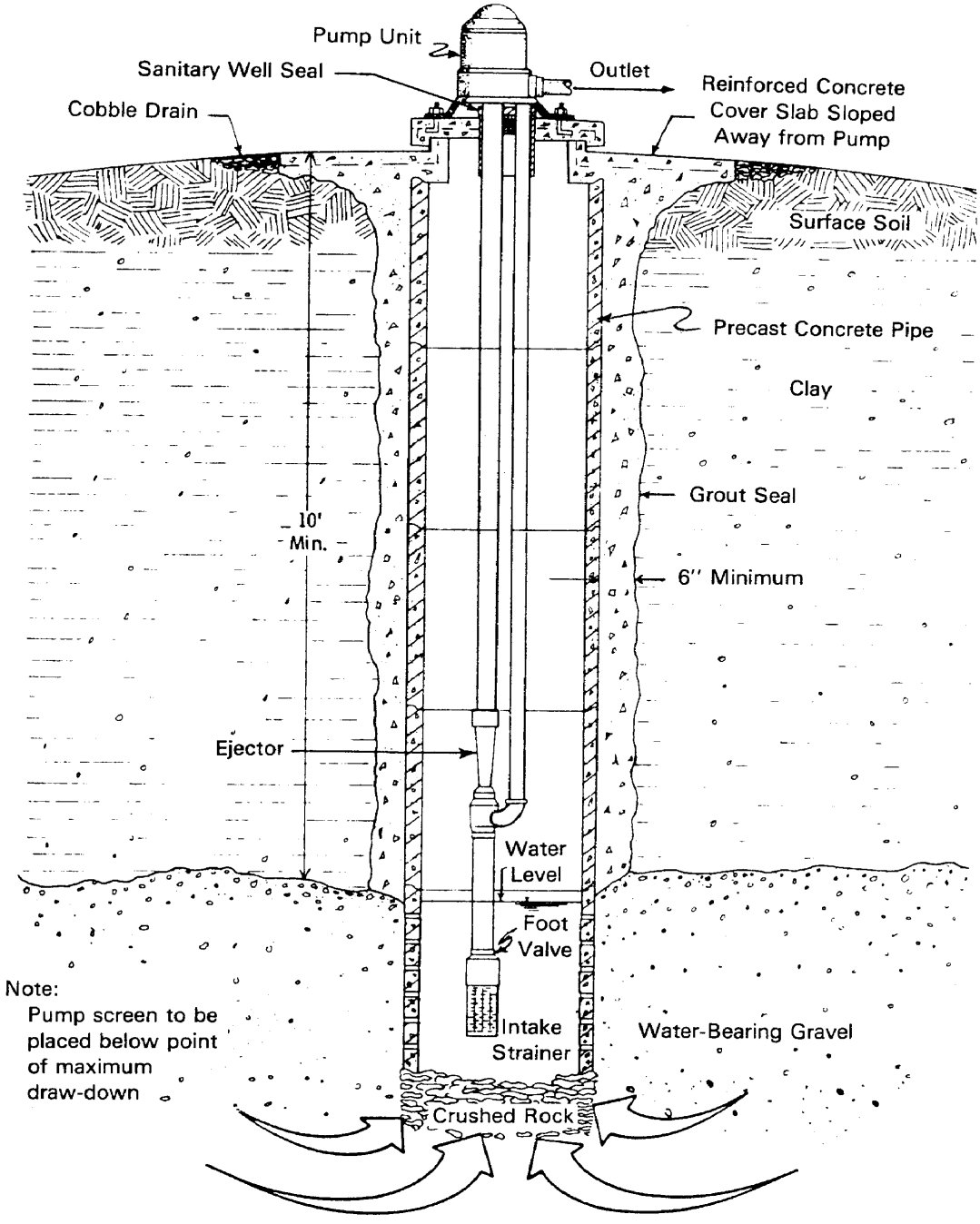

Figure 10. Dug Well with Two-Pipe Jet Pump Installation

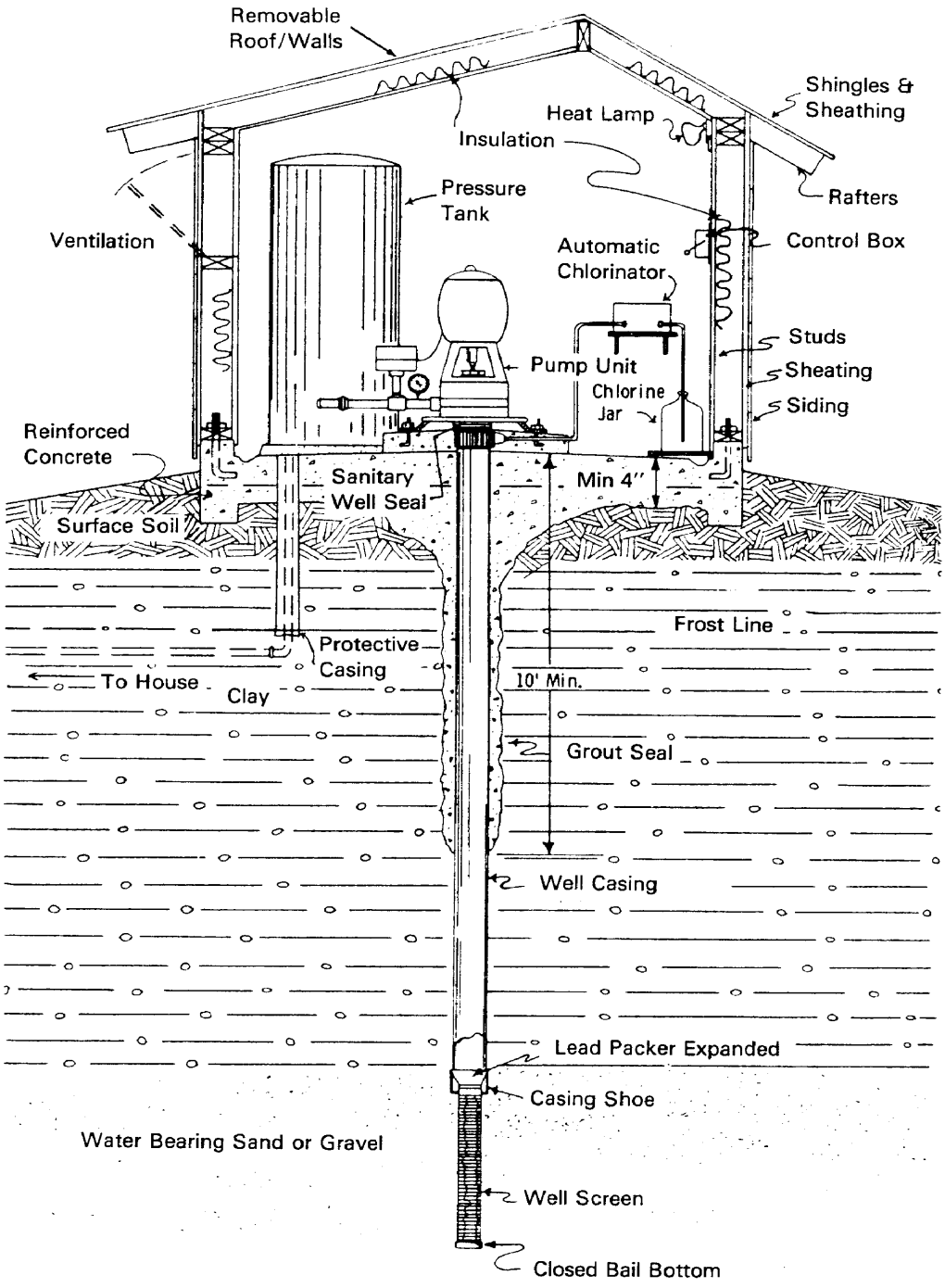

Figure 11. Pumphouse

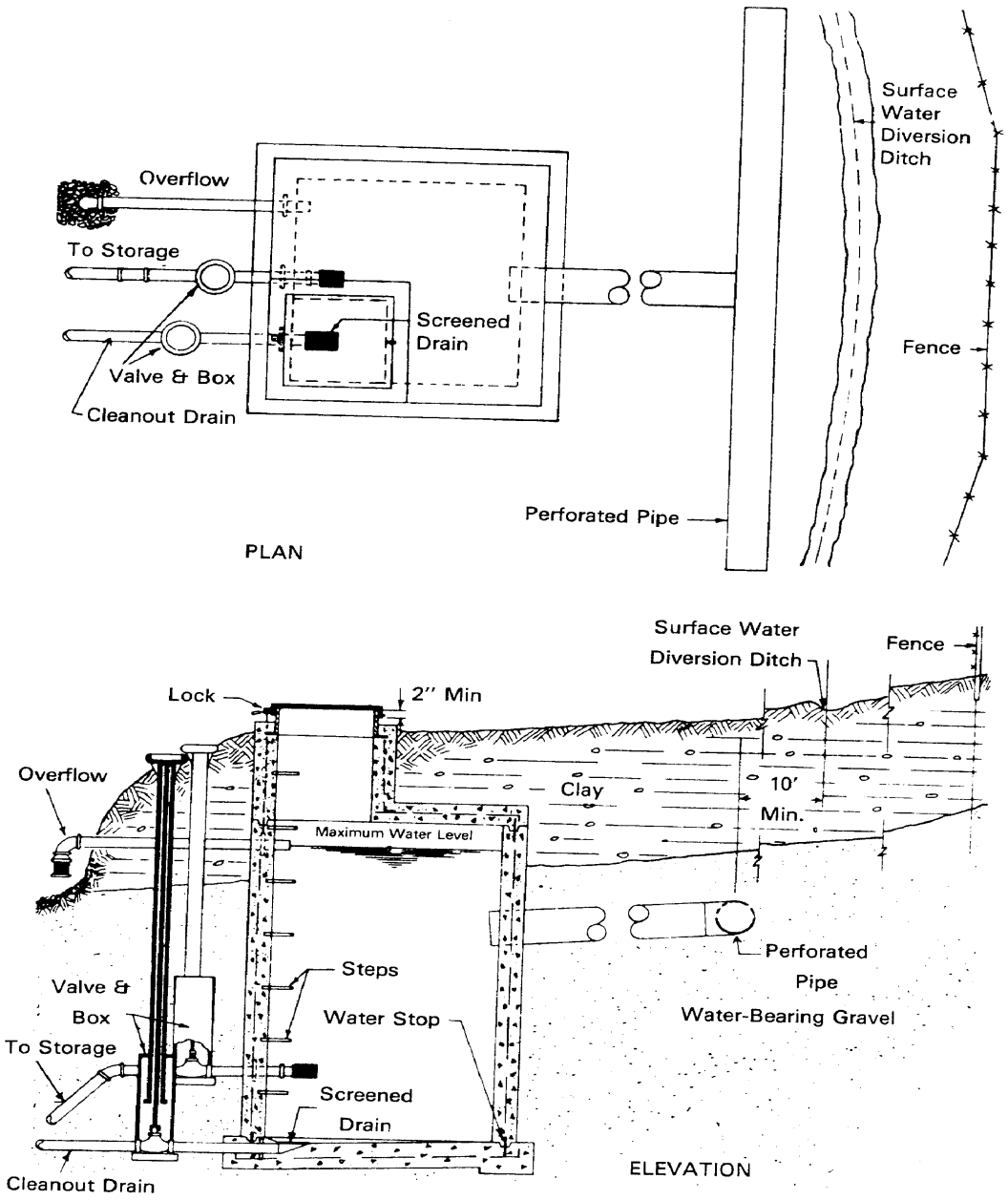

Figure 12. Spring Protection

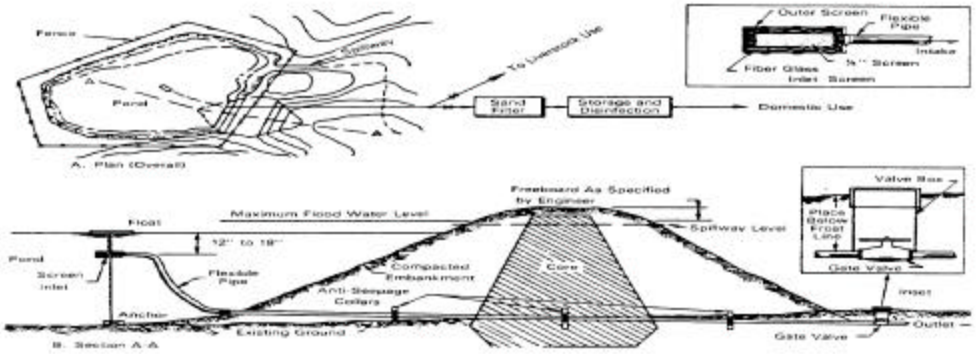

Figure 13. Pond

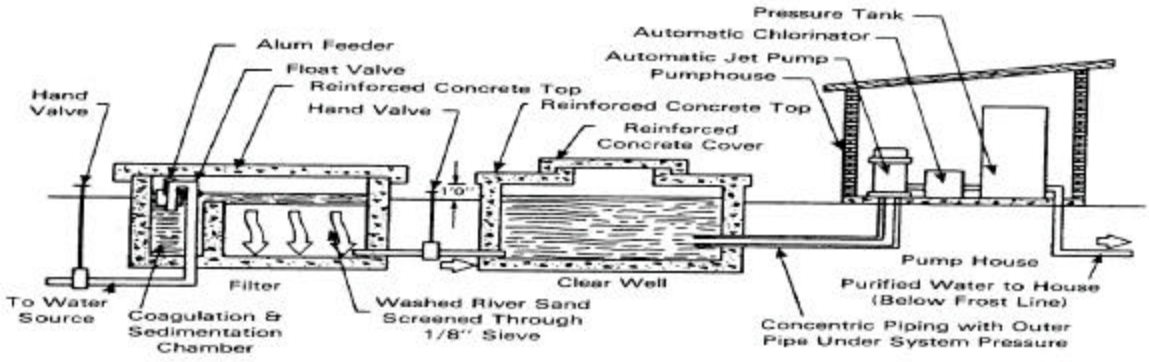

Figure 14. Schematic Diagram of a Pond Water-Treatment System

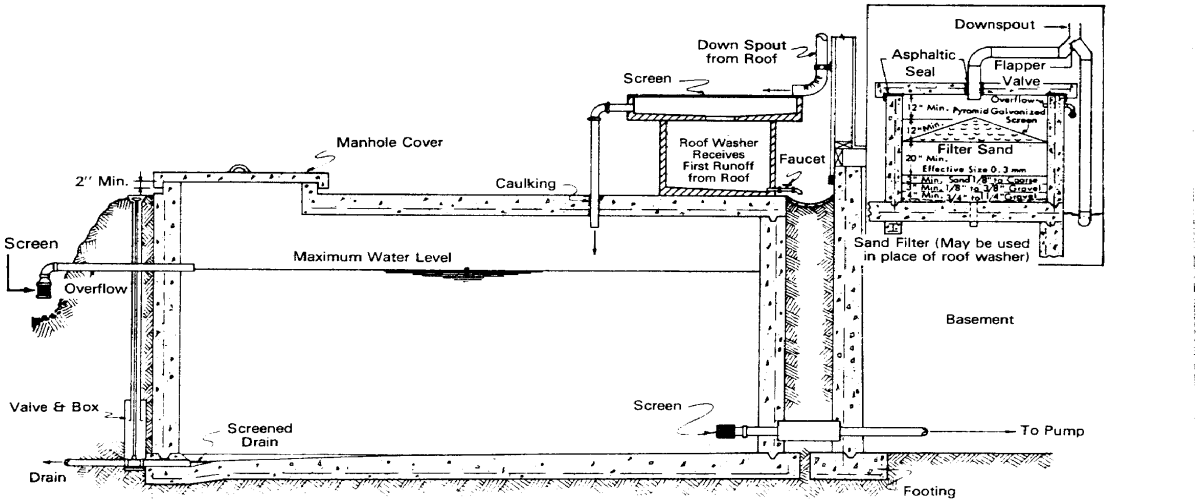

Figure 15. Cistern

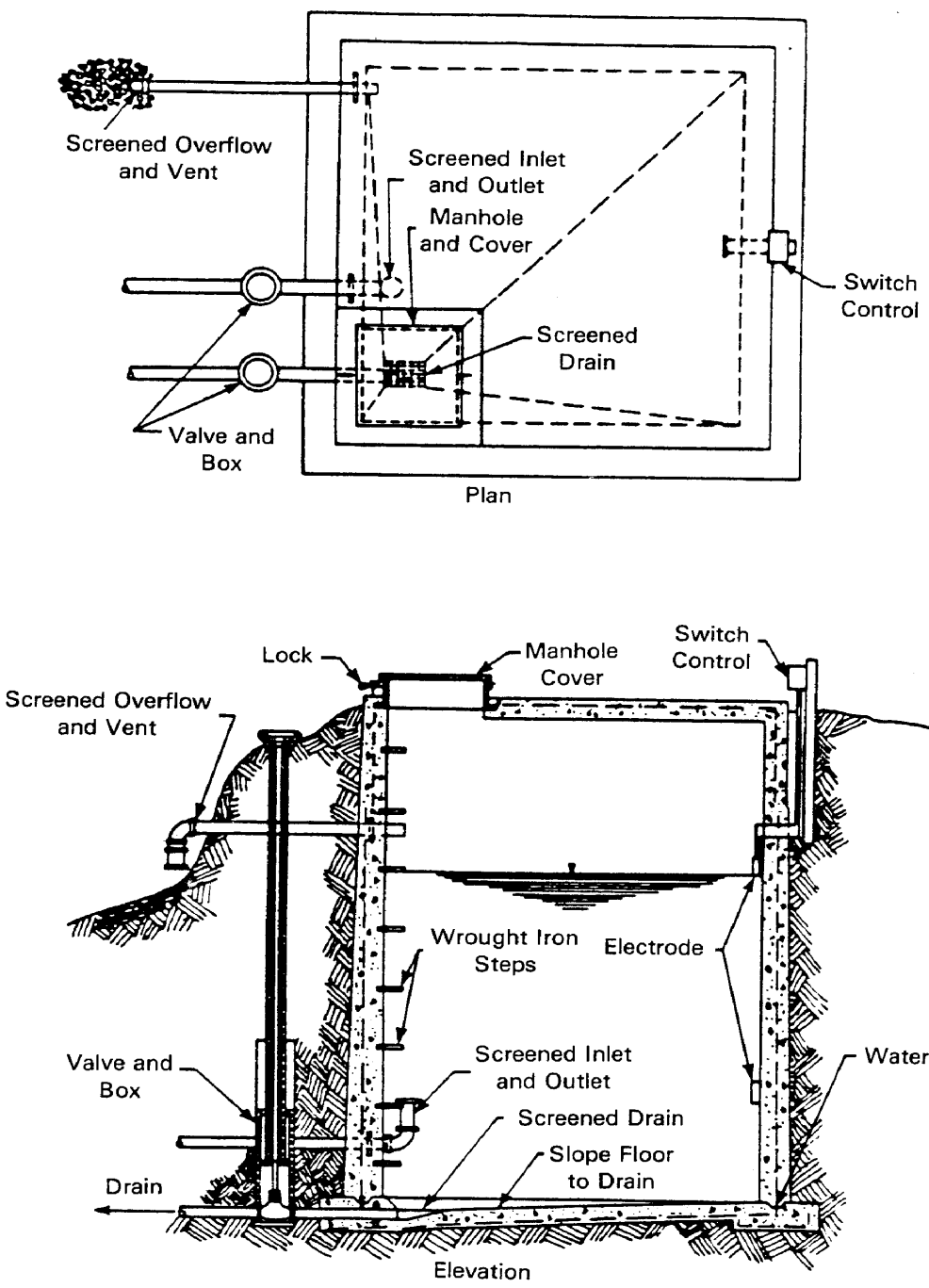

Figure 16. Typical Concrete Reservoir

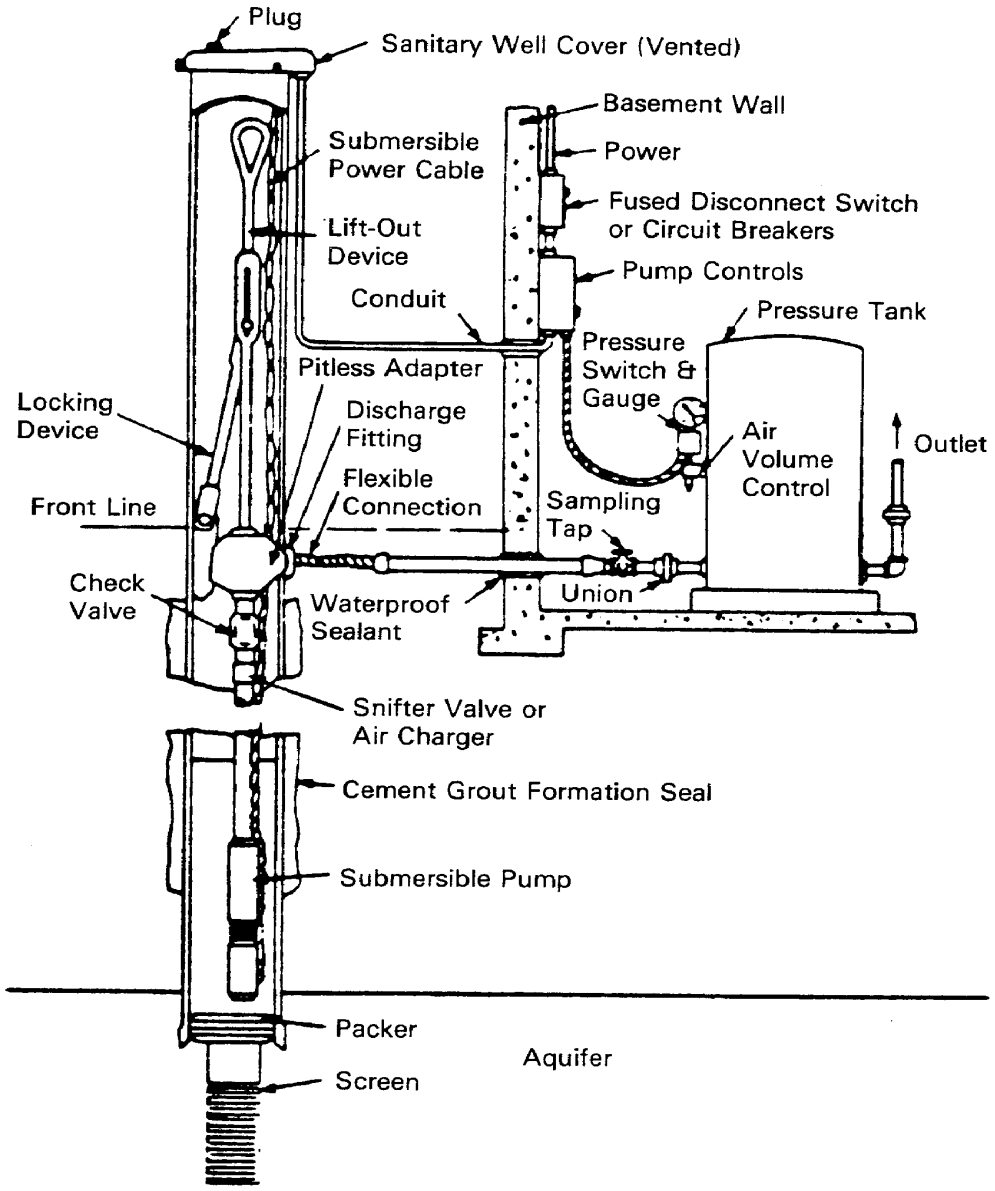

Figure 17. Pit-less Adapter with Submersible Pump Installation for Basement Storage

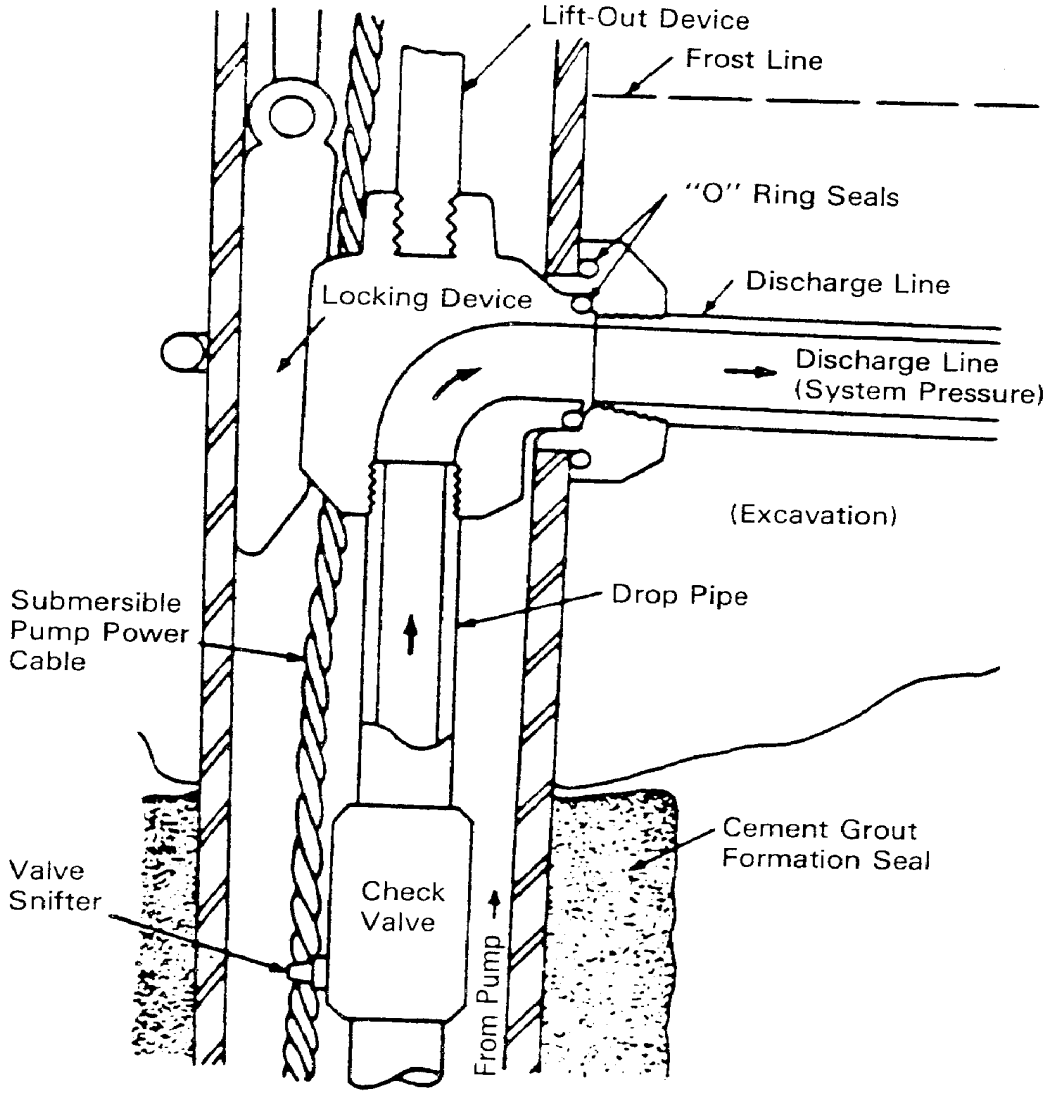

Figure 18. Clamp-on Pit-less Adapter with Concentric External Piping for "Shallow Well" Pump Installation

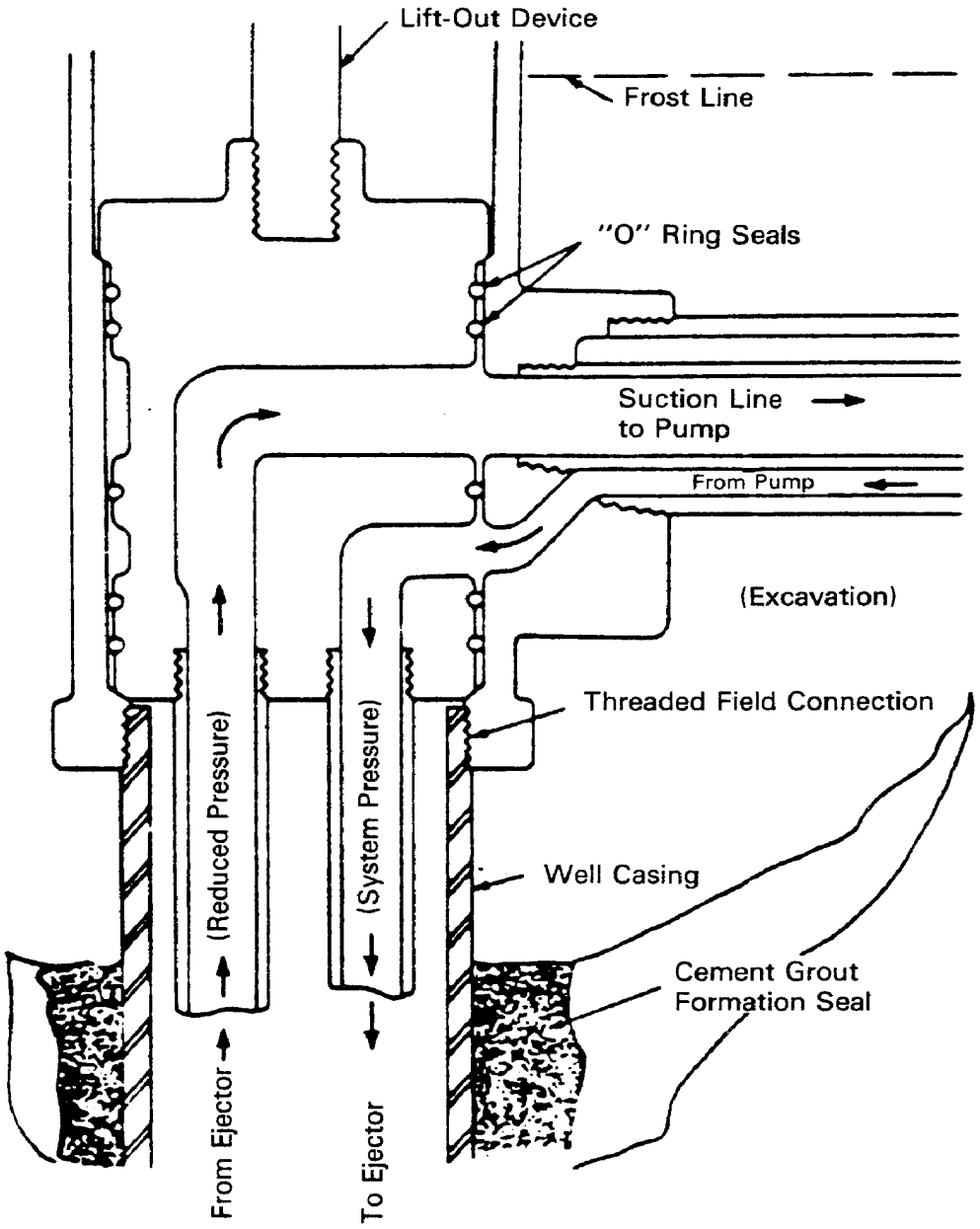

Figure 19. Pit-less Unit with Concentric External Piping for Jet Pump Installation

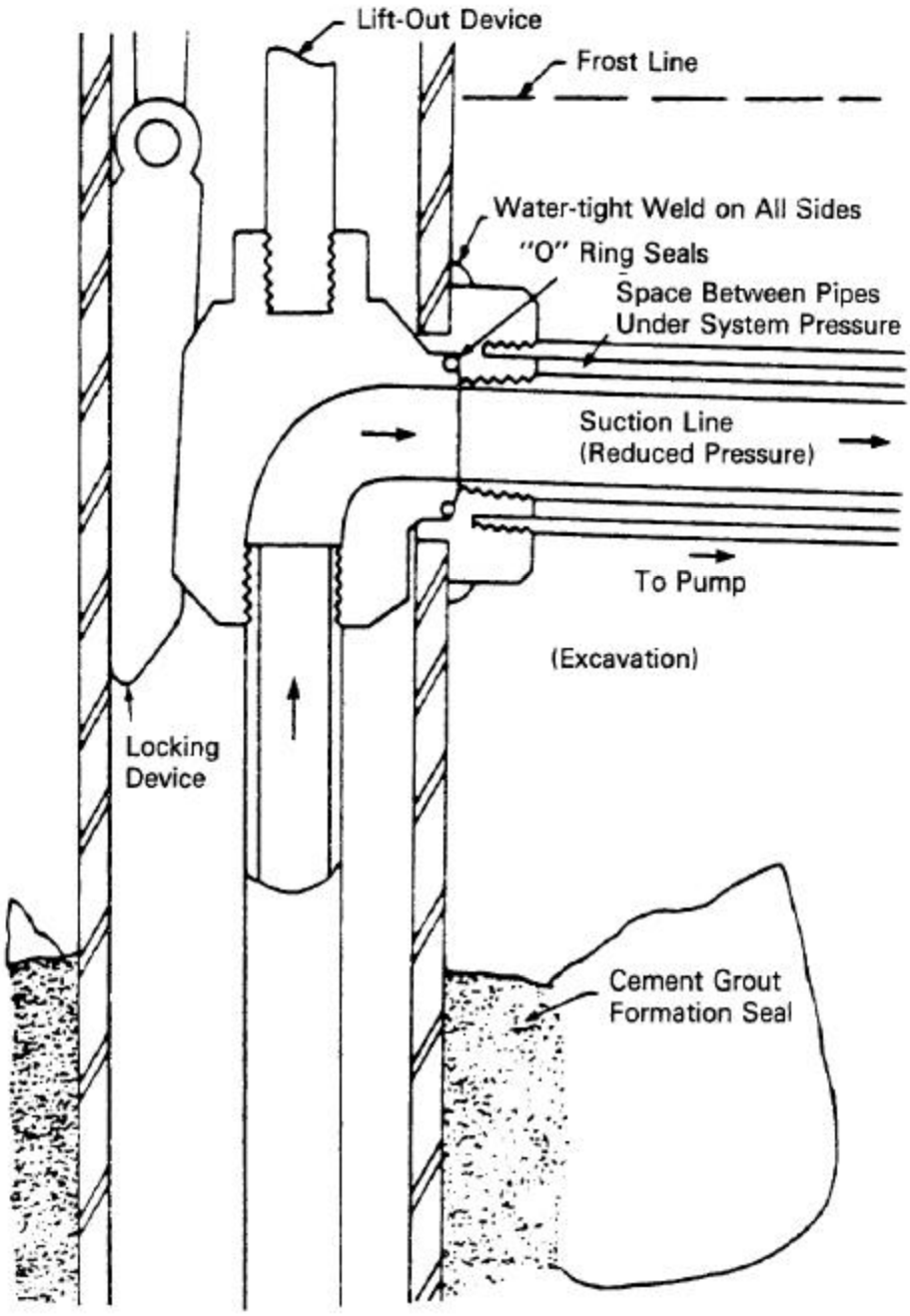

Figure 20. Weld-on Pit-less Adapter with Concentric External Piping for "Shallow Well" Pump Installation

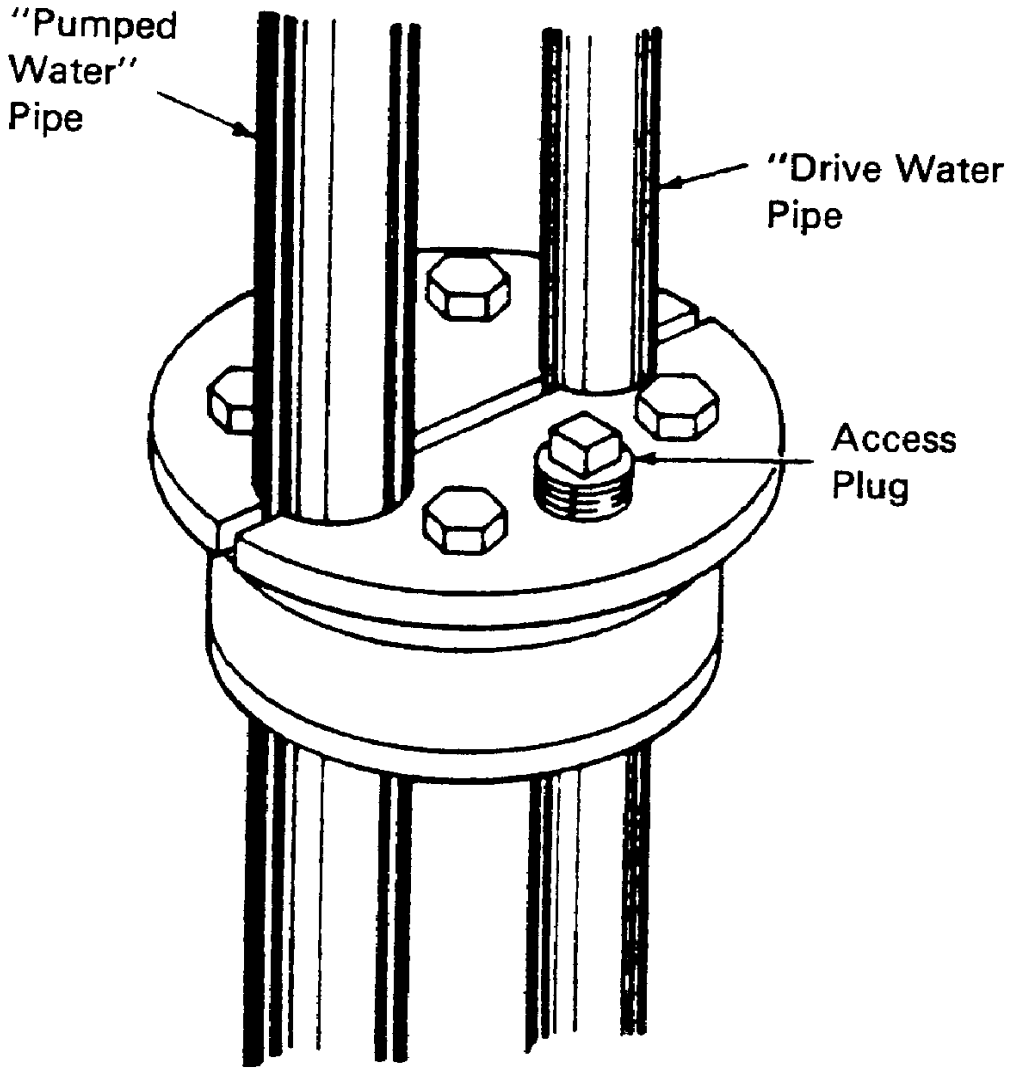

Figure 21. Well Seal for Jet Pump Installation

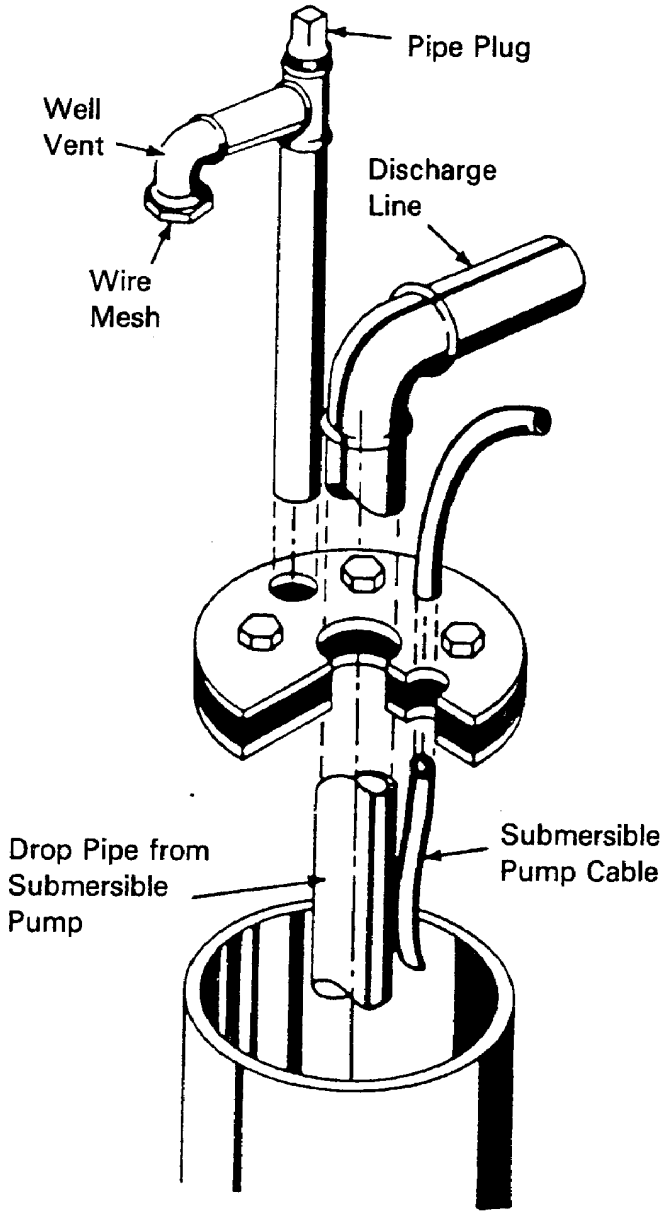

Figure 22. Well Seal for Submersible Pump Installation

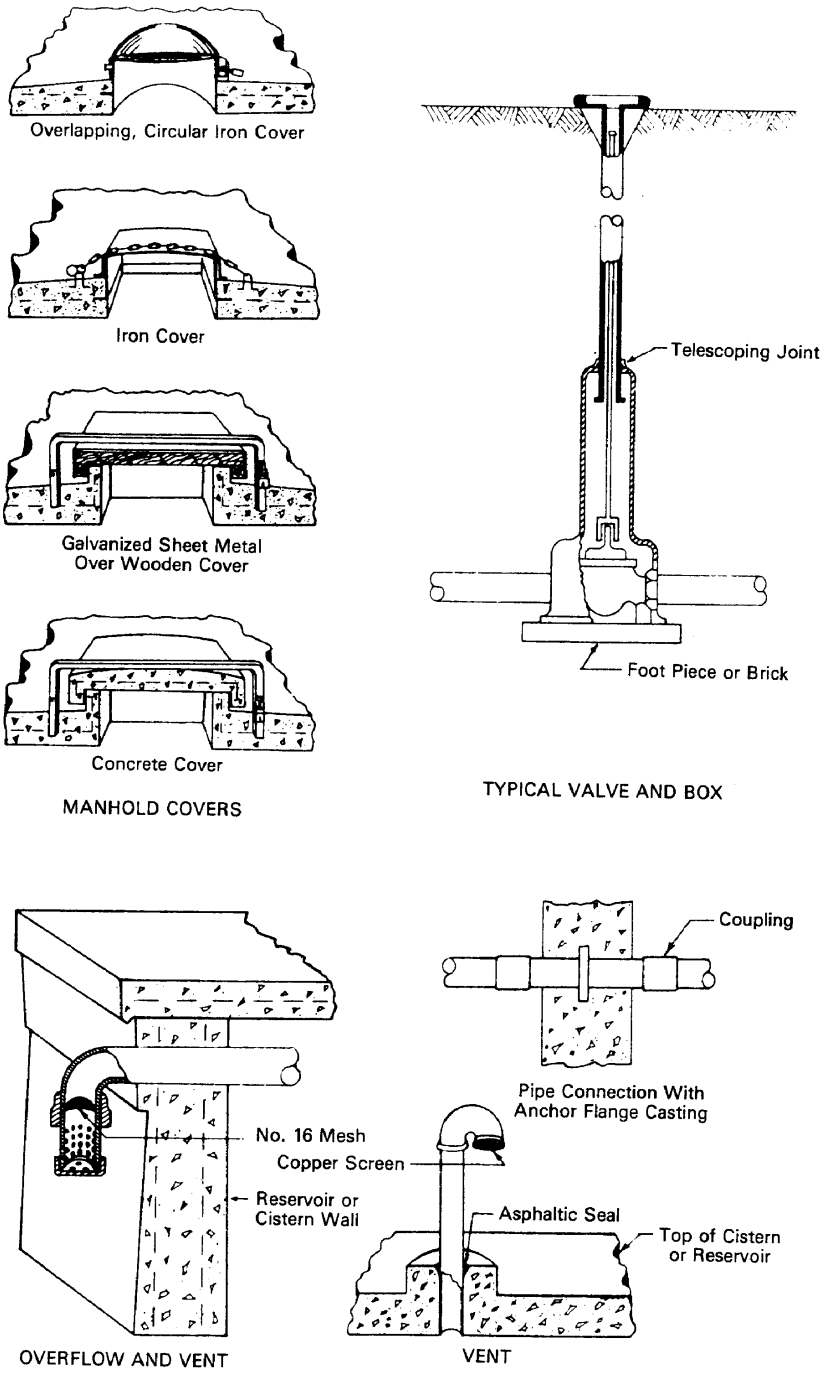

Figure 23. Typical Valve and Box, Manhole Covers, and Piping Installation

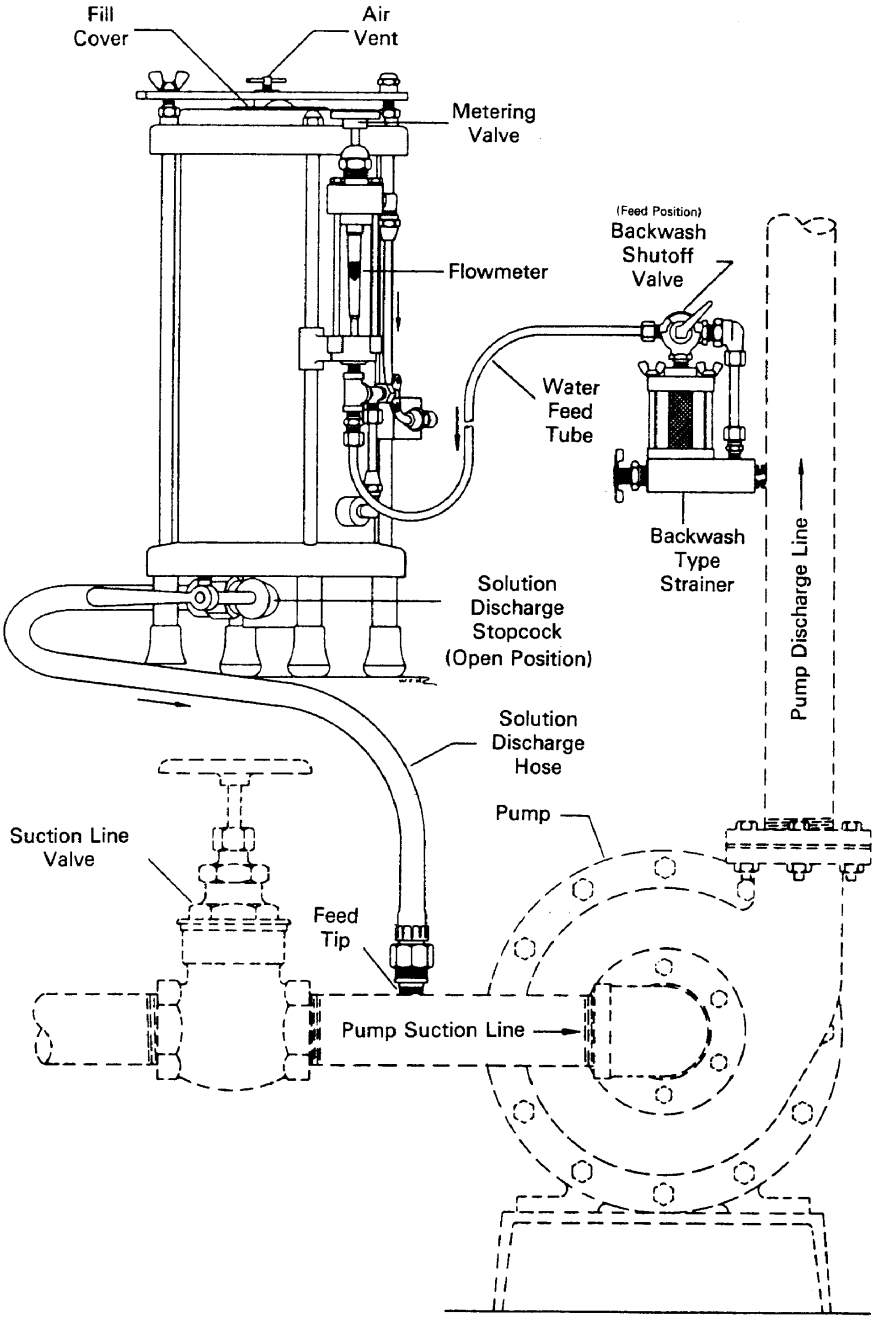

Figure 24. Suction Feeder

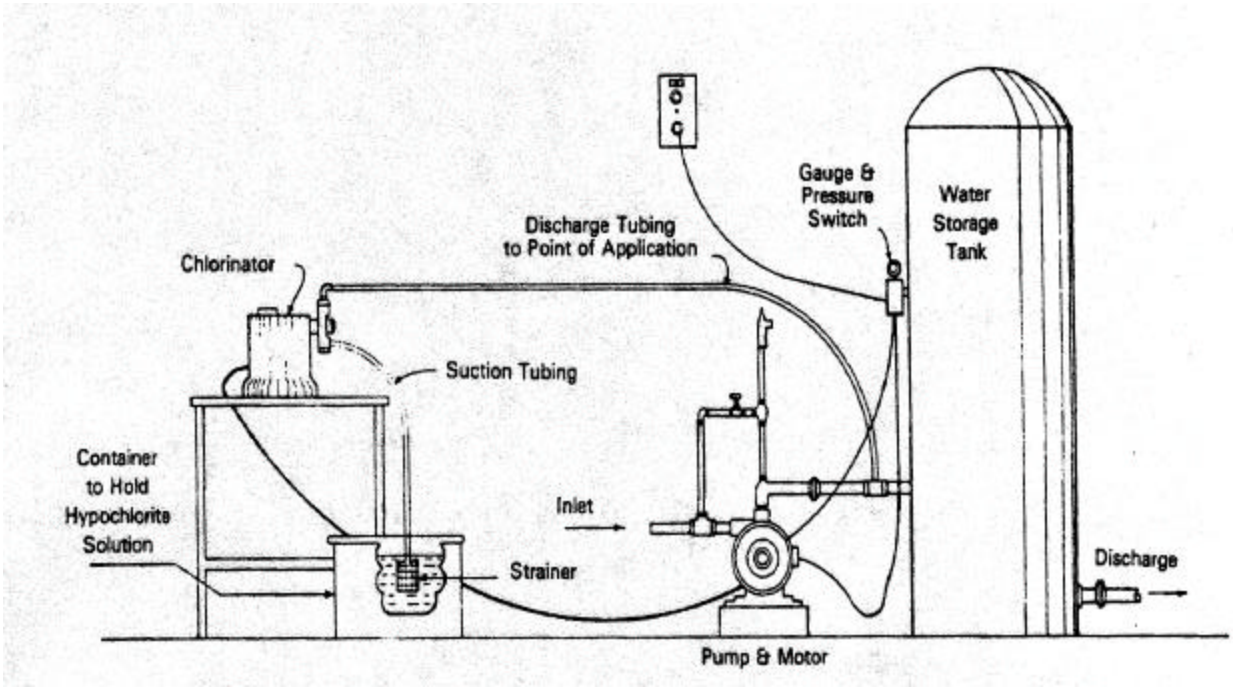

Figure 25. Positive Displacement Chlorinator

APPENDIX E. EXAMPLES OF 3-OUT-OF-5 COMPLIANCE ENFORCEMENT PROCEDURES

The following Tables provide several useful examples in the application of the enforcement system described in Section 6. While the illustrations given, relate only to pasteurized milk bacterial counts and somatic cell counts of raw milk, the method is applied, in like fashion, to the enforcement of established standards for cooling temperature, coliform limits, etc. Pasteurized milk that shows a positive phosphatase reaction and milk, in which the presence of drug residue, pesticides and other adulterants is found, shall be dealt with as indicated in Sections 6 and 2, respectively.

Table 11. Example of Enforcement Procedures for Pasteurized Milk Laboratory Examinations

Date	Bacterial Count per mL	Enforcement Action as Applied to a Standard of 20,000/mL
1/05/01	6,000	No Action Required
1/28/01	11,000	No Action Required
2/11/01	12,000	No Action Required
3/15/01	22,000	Violative; No Action Required
3/25/01	23,000	Violative; Written notice to plant, 2 of last 4 counts exceed the standard. (This notice shall be in effect as long as 2 of the last 4 consecutive samples exceed the standard). Additional sample required within 21 days from the date of the notice, but not before the lapse of three (3) days.
4/02/01	9,000	No Action Required
4/19/01	51,000	Violative (3 of last 5 counts exceed the standard); Required Regulatory Actions: (1) Suspend plant permit; or (2) Forego permit suspension, provided the product(s) in violation are not sold as Grade "A" product(s); or (3) Impose monetary penalty in lieu of permit suspension, provided the product(s) in violation are not sold as Grade "A" product(s).
4/23/01		Issue temporary permit (if applicable) after plant inspection. Begin accelerated sampling schedule.
4/25/01	11,000	No Action Required
4/29/01	3,000	No Action Required
5/4/01	22,000	Violative; No Action Required NOTE: Samples collected prior to 4/23/01 are not used for subsequent bacterial count enforcement purposes.
5/9/01	5,000	Permit Fully Reinstated

Table 12. Example of Enforcement Procedures for Raw Milk Laboratory Examinations

Date	Confirmed Somatic Cell Counts per mL	Enforcement Action as Applied to a Standard of 750,000 per mL
7/10/01	500,000	No Action Required
8/15/01	600,000	No Action Required
10/1/01	800,000	Violative; No Action Required
11/7/01	900,000	Violative; Written notice to producer, 2 of last 4 counts exceed the standard. (This notice shall be in effect as long as 2 of the last 4 consecutive samples exceed the standard). Additional sample required within 21 days from the date of the notice, but not before the lapse of three (3) days.
11/14/01	1,200,000	Violative (3 of last 5 counts exceed the standard); Required Regulatory Actions: (1) Suspend producer permit; or (2) Forego permit suspension, provided the milk in violation is not sold as Grade "A"; or (3) Impose monetary penalty in lieu of permit suspension, provided the milk in violation is not sold as Grade "A".
11/18/01	700,000	Issue temporary permit (if applicable) after sampling indicates the milk is within the standards prescribed in Section 7. Begin accelerated sampling schedule.
11/20/01	800,000	Violative; No Action Required NOTE: Samples collected prior to 11/18/01 are not used for subsequent somatic cell count enforcement purposes.
11/24/01	700,000	No Action Required
11/29/01	550,000	Permit Fully Reinstated

APPENDIX F. SANITIZATION

METHODS OF SANITIZATION

CHEMICAL

Certain chemical compounds are effective for the sanitization of milk containers, utensils and equipment. These are contained in 21 CFR 178.1010 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 five (5) minutes after the temperature of the drainage at the outlet has reached 94ºC (200ºF). 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 the outlet end of the assembly is maintained to at least 77ºC (170ºF) for at least five (5) minutes.

APPENDIX G. CHEMICAL AND BACTERIOLOGICAL TESTS

I. PRIVATE WATER SUPPLIES AND RECIRCULATED WATER - BACTERIOLOGICAL

Reference: Section 7, Items 8r., 19r., 7p. and 17p.

Application: To private water supplies, used by dairy farms, milk plants, receiving stations, transfer stations and milk tank truck cleaning facilities, and to recirculated cooling water, used in milk plants, receiving stations and dairy farms.

Frequency: Initially; after repair, modification or disinfection of the private water supplies of dairy farms, milk plants, receiving stations, transfer stations and milk tank truck cleaning facilities, and thereafter; semiannually for all milk plants, receiving stations, transfer stations and milk tank truck cleaning facilities water supplies and at least every three (3) years on dairy farms. Recirculated cooling water in milk plants, receiving stations and on dairy farms shall be tested semiannually.

Criteria: A Most Probable Number (MPN) of coliform organisms of less than 1.1 per 100 mL, when ten (10) replicate tubes containing 10 mL, or when five (5) replicate tubes containing 20 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 Too Numerous To Count (TNTC) - greater than two hundred (200) total bacteriological colonies per 100 mL by the membrane filter technique; or confluent growth by the multiple tube fermentation, MPN technique, without coliform present, shall have a subsequent heterotrophic plate count of less than five hundred (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 current edition of SMEWW 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 requirements of Item 16p.

Criteria: Less than one (1) microgram per milliliter by Scharer Rapid Method or equivalent by other means. (See SMEDP)

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 thirty (30) minutes or 72°C (161°F) for fifteen (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 dichloro-quinonechlorimide to form an indophenol blue color.

Procedure: See SMEDP 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 milk 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 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 PESTICIDES IN MILK

Any Regulatory Agency that has adopted this *Ordinance* should operate under a control program that will insure that milk supplies are free from pesticide contamination, in conformance with

Section 2.
Pesticide compounds gain access to milk by various routes. Insecticide contamination may result from any of the following:

1. Application to the lactating animals;
2. Inhalation of toxic vapors, by the animals, following application of insecticides to their environment;
3. Ingestion of residues in feed and water; and
4. Accidental contamination of milk, feed and utensils. Herbicide contamination may result from residues on the lactating animals feed and in their water supply and/or rodenticides may be present in milk as a result of accidental contamination.

At the present time, chlorinated hydrocarbon pesticides are the chief concern. While there are other pest control compounds that are more toxic than the chlorinated hydrocarbons, many of the agents in this latter group tend to accumulate in the body fat of both lactating animals and human beings, and are secreted in the milk of contaminated lactating animals. The accumulation of these toxic agents in persons continually consuming contaminated milk may reach hazardous concentrations.
Advances in residue analysis have resulted in a radical decrease in the use of paper chromatographic screening procedures for milk, because of its rather limited sensitivity. Regulatory Agencies can now routinely detect residues as low as 0.01 ppm of many of the chlorinated organic pesticides. Satisfactory screening procedures should, therefore, attain this level of sensitivity, which usually necessitates the use of gas chromatography or thin layer chromatography.
General screening procedures of the latter two (2) types are described and discussed in Volume 1 of the *Pesticide Analytical Manual* (PAM) published by FDA.
The need for closer scrutiny of milk supplies for pesticide residues has stimulated considerable research in detection technology. The Regulatory Agency entering upon a surveillance program should carefully check the available equipment in relation to its adaptability to the indicated need.
While a schedule of testing comparable to that for microorganisms, four (4) tests of individual producers milk during any consecutive six (6) months, would be desirable, broad-spectrum procedures are too time consuming to render such a schedule feasible. As a more practical approach, the following procedure is suggested:

1. Test one (1) load of milk from each tank truck route, every six (6) months, by a broad spectrum method and trace positive samples; or
2. Test each producer's milk four (4) times every six (6) months for the most common chlorinated hydrocarbon pesticides, by available instrumental methodology.

NOTE: The above testing disciplines may be applied conveniently to can milk supplies. Where procedure 1. is used, samples of commingled milk from known sources are drawn from receiving station storage tanks. Sampling for procedure 2. may be done directly from the weigh tank.

V. 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 (2) reasons:

1. It comes from an unhealthy lactating animal; and
2. 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 of this *Ordinance*. These tests are specified in informational memoranda from the FDA. (See M-a-85, M-a-86, and the 2400 series forms for each specific test method).

NOTE: *Bacillus stearothermopilus* disk assay analysis performed to fulfill the provisions of Section 7 of this *Ordinance* must be capable of detecting at least four (4) of six (6) Beta lactam drugs at or below FDA reference levels. A zone equal to or greater than 16mm will be considered positive when the *Bacillus stearothermophilus* disk assay is used, provided the 5ppb Beta lactam control zone is 16-20mm. (See the most recent FDA 2400 series form(s) for details related to this analysis).

VI. ANALYSIS OF MILK AND MILK PRODUCTS FOR VITAMIN A AND D_3 CONTENT

Reference: Section 6.

Frequency: Annually for each product type, or when any doubt arises as to the adequacy of vitamin fortification. (See Appendix O.)

Methods: Vitamin testing shall be performed using test methods acceptable to FDA and other official methodologies that give statistically equivalent results to the FDA methods.

REFERENCES

Official Methods of Analysis of AOAC INTERNATIONAL, 17th Edition, 2000.

Pesticide Analytical Manual, (PAM) available from the U. S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, HFS-335, 5100 Paint Branch Parkway, College Park, MD 20740-3835.

APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES

I. HTST PASTEURIZATION

OPERATION OF HTST SYSTEMS

HTST pasteurization is important to the dairy industry because of the operating efficiencies that 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 that 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 FDD, 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 77ºC (170ºF). 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 that 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 $72^{O}C$ ($161^{O}F$).
5. The milk, at pasteurization temperature, and under pressure, flows through the holding tube where it is held for at least fifteen (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 the indicating thermometer and recorder/controller, the milk passes into the FDD, which automatically assumes a forward-flow position, if the milk passes the recorder/controller bulb at the preset cut-in temperature, i.e., $72^{O}C$ ($161^{O}F$).
7. Improperly heated milk flows through the diverted-flow line back to the raw milk constant-level 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 16p.(D), 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 30.5 centimeters (12 inches) 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 16p.(D)2.

During a shutdown, i.e., when the timing pump stops, the raw milk in the regenerator will be retained under suction, except 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 constant-level 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 FDD would lower the pasteurized milk level, during pump shutdowns, thus tending to reduce the pressure on the pasteurized milk side of the regenerator. A FDD 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 timing 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 USE OF SEPARATORS WITHIN HTST SYSTEMS

Separators in HTST pasteurization systems must be installed and operated in such a manner that they will not adversely effect the regenerator pressures, create a negative pressure on the FDD during operation or cause product flow through the holding tube during times when such flow would compromise a required public health safe guard.

1. A separator may be located between the outlet of a raw regenerator and the timing pump or between raw regenerator sections if the separator is automatically valved out of the system, and separator stuffing pump(s) are de-energized, when:
   a. The timing pump is not in operation; or,
   b. A dual stem FDD is in the inspect position; or,
   c. In a system with a dual stem FDD, in which the separator is located between sections of a raw regenerator, during the first ten (10) minutes of a required ten (10) minute time delay in CIP mode and during any period of diverted flow; or,
   d. The pressures in any raw regenerator sections, located after the separator, are out of compliance with the pressure requirements of this *Ordinance*.

NOTE: The second section of a split raw regenerator must freely drain back to the constant-level tank or to the floor in the event of a shut down.

2. A separator may not be located between the timing pump and the FDD.
3. A separator may be located on the pasteurized side of the FDD if:
   a. A properly installed atmospheric break is located between the FDD and the inlet of the separator.
   b. All product rises to at least 30.5 centimeters (12 inches) higher than the highest raw milk in the system and is open to the atmosphere at some point between the outlet of the separator and the inlet of any pasteurized side regenerator.
   c. All product rises to at least 30.5 centimeters (12 inches) higher than the highest raw milk in the system and is open to the atmosphere at some point between the outlet of any pasteurized side regenerator and the inlet of a separator.
   d. The separator is automatically valved out of the system, and the separator stuffing pump is de-energized:
      (1) When a dual stem FDD is in the first ten (10) minutes of a required ten (10) minute delay in CIP mode.
      (2) When the FDD is diverted in product or inspect mode.
      (3) When the timing pump is not in operation.
      (4) When the temperature is below the required pasteurization temperature and the FDD is not in the fully diverted position.
4. The following criteria applies to installations where a separator must be valved out:
   a. A valve must be located to isolate the product supply line from the separator.
   b. A valve must be located to prevent all flow exiting the separator from being returned to the pasteurization system down stream of the separator.

c. The valves required to move in order to accomplish the two (2) criteria listed above must move to the valved-out position, and any separator stuffing pumps must be de-energized, upon loss of air or power.

THE USE OF LIQUID INGREDIENT INJECTION WITHIN HTST SYSTEMS

Milk flavoring slurries and similar ingredients may be injected at a point between the outlet of the last raw regenerator and the timing pump in systems with separators after the last regenerator, if all of the following conditions are met:

1. The slurry injection valve(s) is (are) closed and the slurry pump is de-energized:
   a. When a dual stem FDD is in the first ten (10) minutes of a required ten (10) minute delay in CIP mode,
   b. When the FDD is in inspect mode,
   c. When the timing pump is not in operation,
   d. When the temperature is below the required pasteurization temperature and the FDD is not in the fully diverted position, and
   e. When the separator is bypassed.
2. The slurry injection valve(s) is (are) of the fail-safe type, spring-to-close and air-to-open, and are "block-and-bleed" design with a full port open to the atmosphere between the HTST isolation seat and the slurry pump when slurry is not being injected.
3. The slurry piping between the slurry pump and the injection point may rise to a height that is higher than the overflow level of the slurry supply tank(s) but is at least 30.5 centimeters (12 inches) lower than the required opening to the atmosphere on the pasteurized side.
4. The slurry supply tank has an overflow that is at least twice the diameter of the largest inlet pipe, or all inlet pipes are disconnected and the openings capped during operation of the slurry pump.
5. There is a check valve in the flow stream of the milk line from the last regenerator, typically after the separator, upstream of the injection point valve.
6. If the slurry contains milk and/or milk products, tanks used to blend and hold such slurry shall be completely emptied and cleaned after each four (4) hours of operation or less, unless it shall be stored at a temperature of 7ºC (45ºF) or less, or at a temperature of 66ºC (150ºF) or more and be maintained thereat until the time of injection.
7. If computers or programmable controllers are used to provide any of these required functions, they shall meet the applicable portion of Appendix H., V.
8. Appropriate test procedures shall be provided to evaluate the required inter-wiring and function.

NOTE: This Section describes one (1) method that has been reviewed and accepted for this purpose. It does not preclude other methods that may be reviewed and found acceptable.

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 (2) basic types:

1. Those employing a constant speed centrifugal pump and a control valve, or
2. Those employing an A-C variable frequency control for the centrifugal pump. In this case the timing pump may be a centrifugal or a 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 FDA or one (1) which is equally accurate, reliable and will produce six (6) consecutive measurements of holding time within 0.5 seconds 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 that shall indicate the status 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 FDD 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 I, 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 FDD 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 I, Test 11, 2.C at the frequency specified. The loss-of-signal provision shall be sealed.
6. When the legal flow rate has been reestablished, following an excessive flow rate, a time delay must be instituted which will prevent the FDD from assuming the forward flow position until at least a fifteen (15) seconds, for milk, or twenty-five (25) seconds, for eggnog and similar products, of 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-to-close and 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 control is used on the timing pump, the control valve is not needed as the flow rate of the 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 control systems, a sanitary product check valve is needed, in the sanitary milk pipeline 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 FDD 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 milk 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 FDD 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 FDD must move to the divert position and must remain in the diverted-flow position for at least ten (10) minutes, regardless of temperature, and the booster pump cannot run during this ten (10) minute time delay.
11. All systems shall be designed, installed and operated so that all applicable tests required by Section 7, Item 16p.(E) can be performed by the Regulatory Agency, at the frequency specified. (See Appendix I.) Where adjustment or changes can be made to these devices or controls, appropriate seals shall be applied by the Regulatory Agency after testing, so that changes cannot be made without detection.
12. Except for those requirements directly related to the physical presence of the timing pump, all other requirements of the most recent edition of this *Ordinance* are applicable.

PLACEMENT OF COMPONENTS: Individual components in the magnetic flow meter based timing systems shall comply with the following placement conditions:

1. The timing pump shall be located downstream from the raw milk regenerator section, if a regenerator is used.
2. The magnetic flow meter shall be placed downstream from the timing pump. There shall be no intervening flow promoting components between the timing pump and the meter.
3. The control valve, used with the constant speed timing pump, shall be located downstream of the magnetic flow meter.
4. The timing pump, the magnetic flow meter, the control valve, when used with the constant speed timing pump system, and the sanitary product check valve, when used with the A-C variable frequency control system, shall all be located upstream from the start of the holding tube.
5. All flow promoting devices, which are upstream of the FDD, such as the timing pump, constant speed or A-C variable frequency control type, booster pump, stuffer pump, separator and clarifier shall be properly interwired with the FDD so that they may run and produce flow through the system at sub-legal temperatures, only when the FDD is in the fully diverted position and when in "Product" run mode. Separators or clarifiers that continue to run, after they are de-energized, must be automatically valved-out of the system, with fail-safe valves, so they are incapable of producing flow.
6. There shall be no product entering or leaving the system, i.e., cream or skim milk from a separator or other product components, between the timing pump and the FDD.
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 the product. They should not be mounted on a high horizontal line that may be only partially full and thereby trap air.

8. The magnetic flow meter shall be piped in such a manner that at least ten (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.

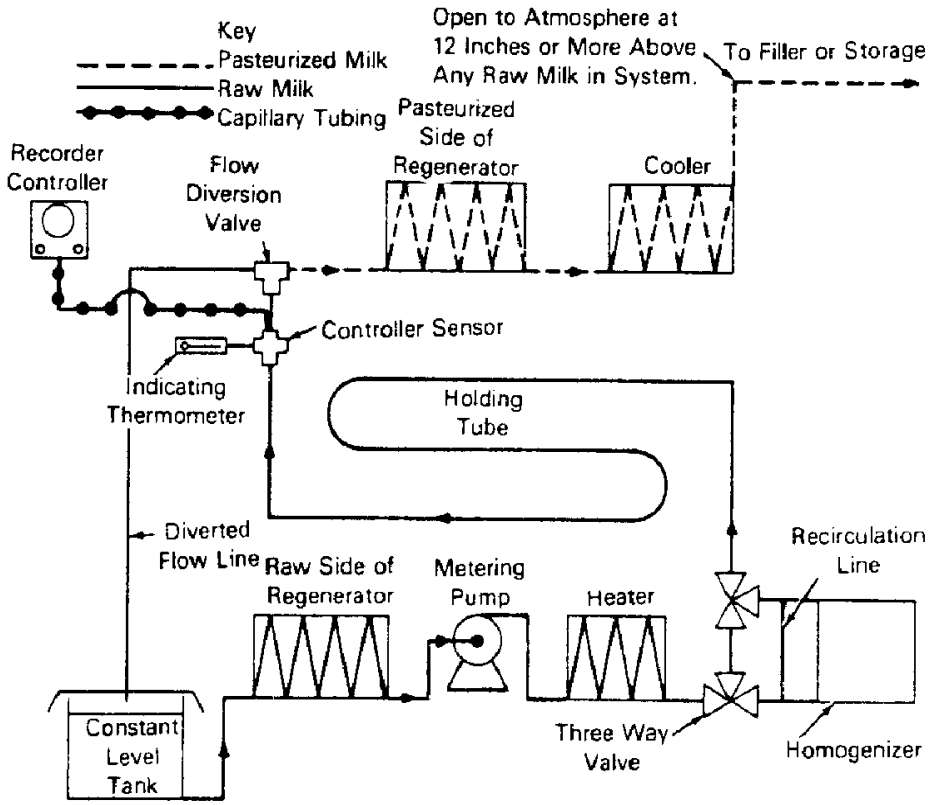

Figure 27. Milk-to-Milk Regeneration - Homogenizer Upstream from Holding Tube

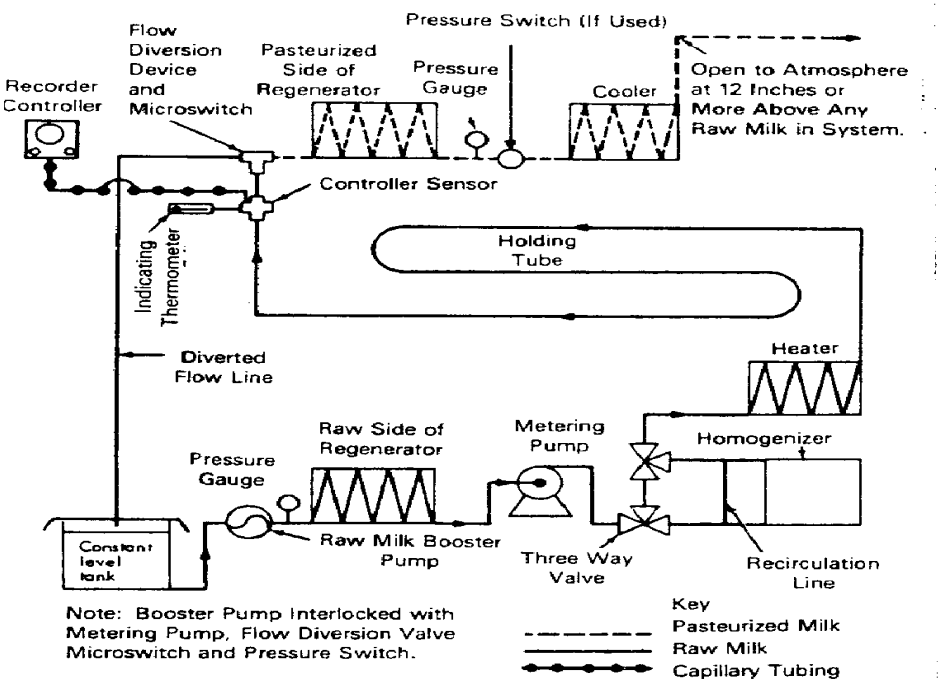

Figure 26. Milk-to-Milk Regeneration - Booster Pump

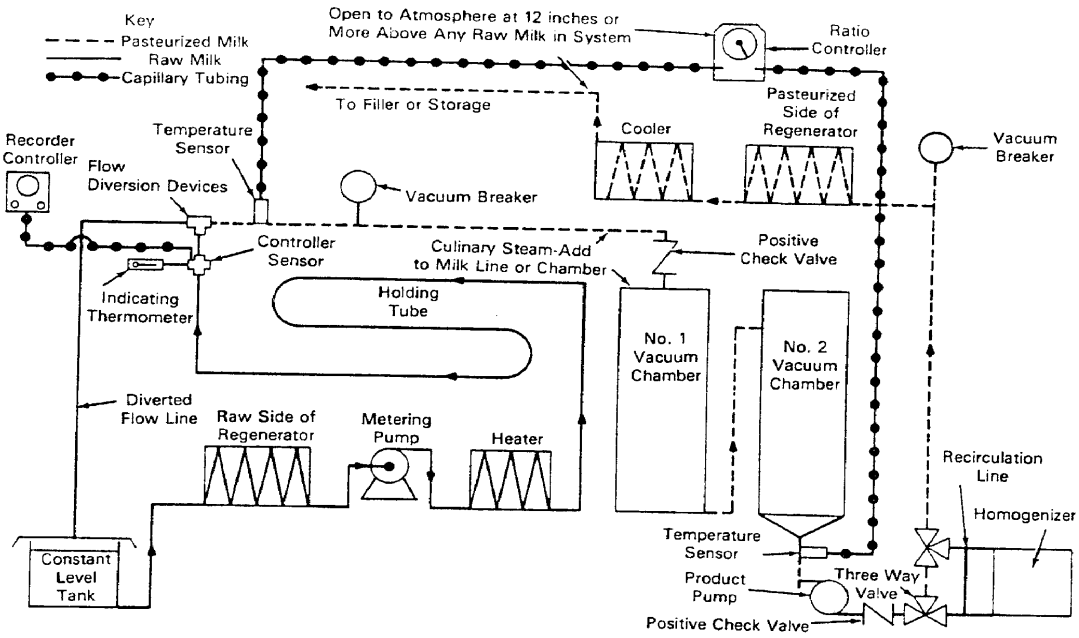

Figure 29. Milk-to-Milk Regeneration - Homogenizer and Vacuum Chambers Downstream from Flow-Diversion

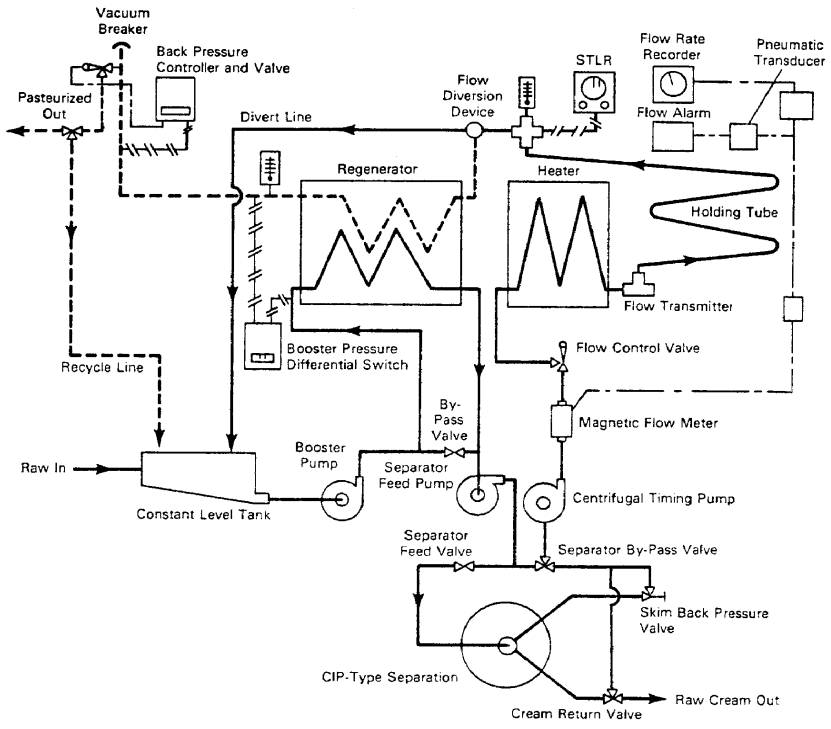

Figure 28. HTST System with a Magnetic Flow Meter Using a Constant Speed Centrifugal Pump and a Control Valve

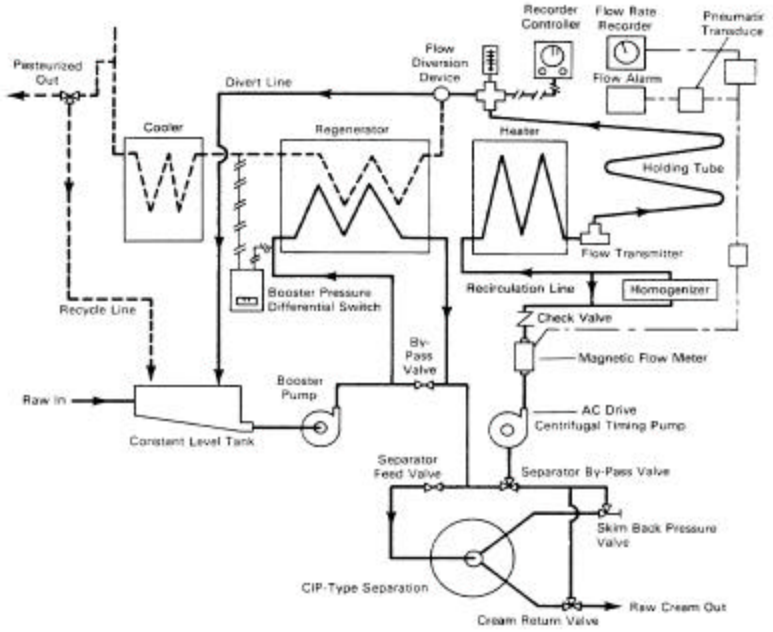

Figure 30. HTST System with a Magnetic Flow Meter Using an A-C Variable Speed Centrifugal Pump

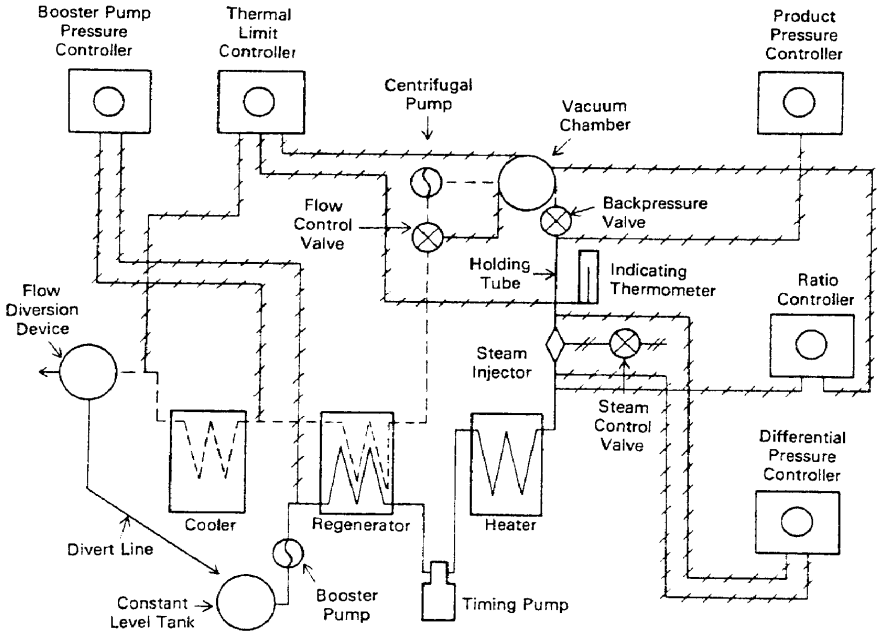

Figure 31. Controls for Steam Injection Pasteurizer

II. AIR UNDER PRESSURE - DIRECT CONTACT WITH MILK AND MILK PRODUCTS AND PRODUCT CONTACT SURFACES

MATERIAL

1. **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.

2. **Filter Performance:** The efficiency of intake filters shall be at least fifty percent (50%) as measured by the National Institute of Standards and Technology's "Dust Spot Method"[1] using atmospheric dust as the test aerosol.

The efficiency of either air pipeline filters or disposable filters shall be at least fifty percent (50%) as measured by the DOP (dioctyl 1-phthalate fog)[2] test.

3. **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

1. **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:

a. Use of a carbon ring piston compressor.

b. Use of oil-lubricated compressor with effective provision for removal of any oil vapor by cooling the compressed air.

c. Water-lubricated or non-lubricated 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.

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[1] Dill, R.S., A Test Method for Air Filters. Transactions of the American Society of Heating and Ventilation Engineers. 44:379, 1938.

[2] DOP-Smoke Penetration and Air Resistance of Filters. Military Standard No. 282. Section 102.9.l. Naval supply Depot. 5801 Tabor Avenue, Philadelphia, Pennsylvania 19120.

2. **Moisture Removal Equipment:** If it is necessary to cool the compressed air, an after-cooler shall be installed between the compressor and the air storage tank for the purpose of removing moisture from the compressed air.

3. **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.

4. **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 Figures 33-37, which depict various air supply systems).

NOTE: For additional details, see *3-A Accepted Practices for Supplying Air Under Pressure in Contact with Milk, Milk Products and Product-Contact Surfaces.*

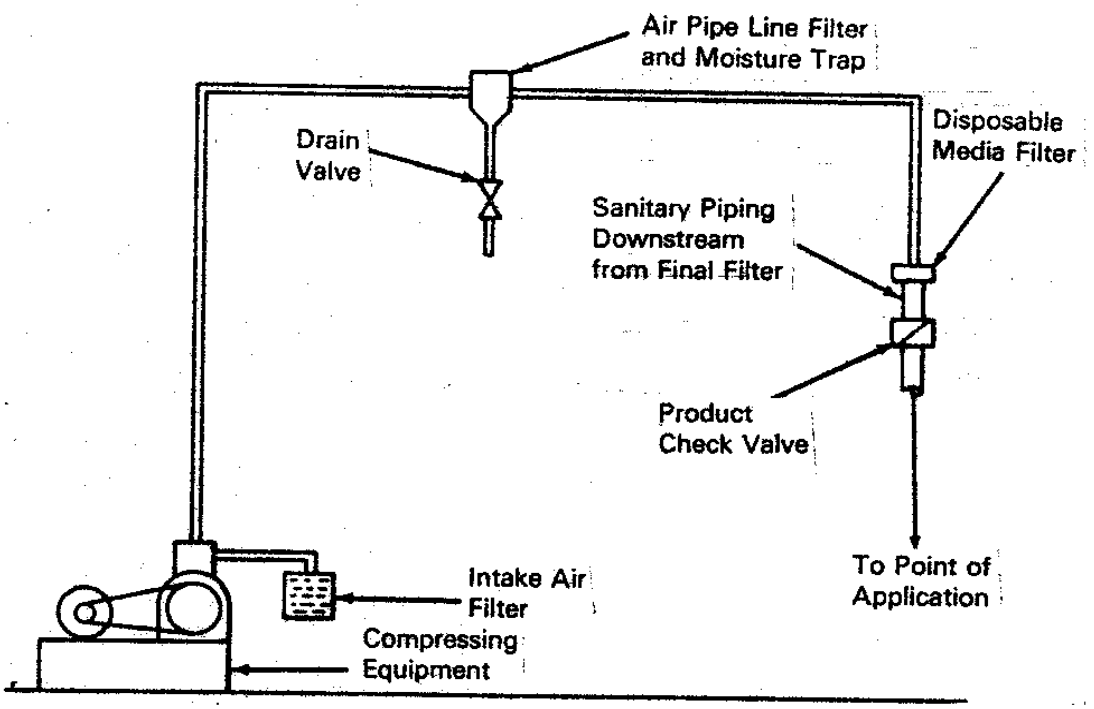


Figure 32. Individual Compression-Type Air Supply

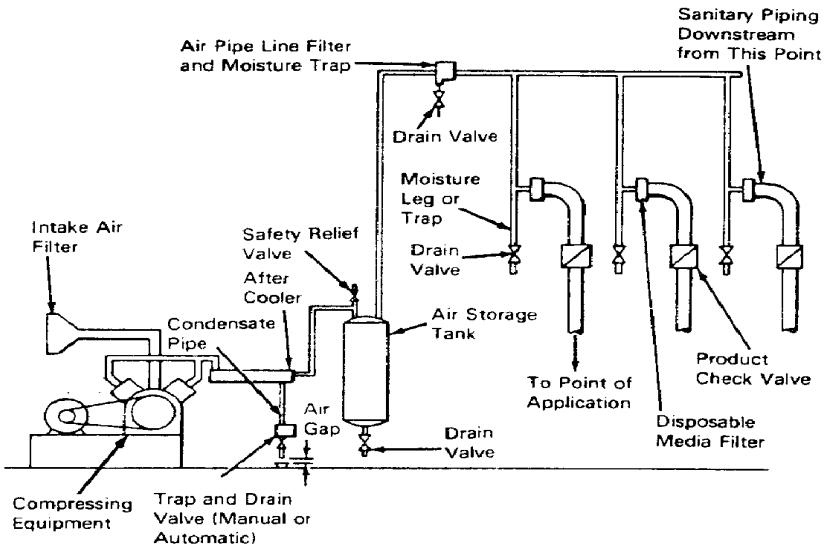


Figure 33. Central Compression-Type Air Supply

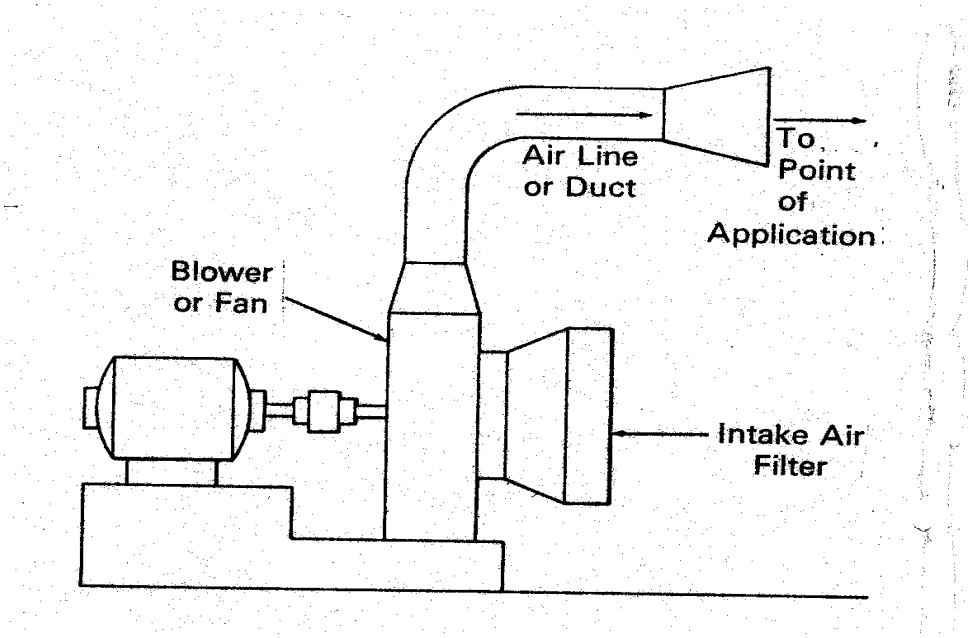


Figure 34. Individual Blower-Type Air Supply

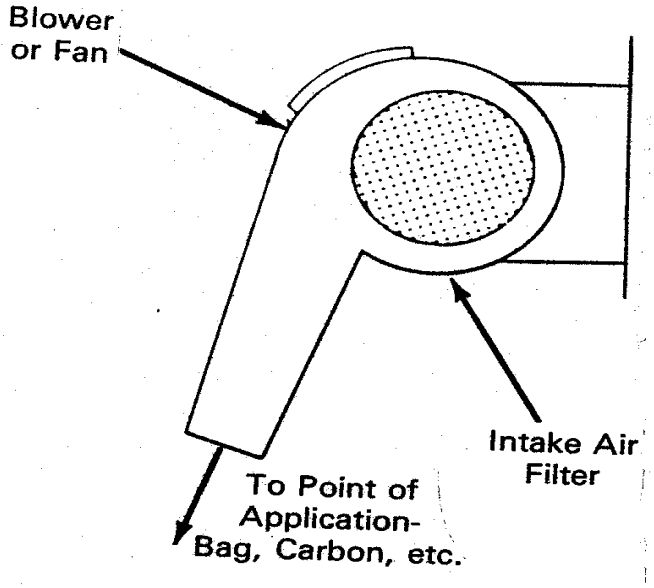


Figure 35. Individual Fan-Type Air Supply

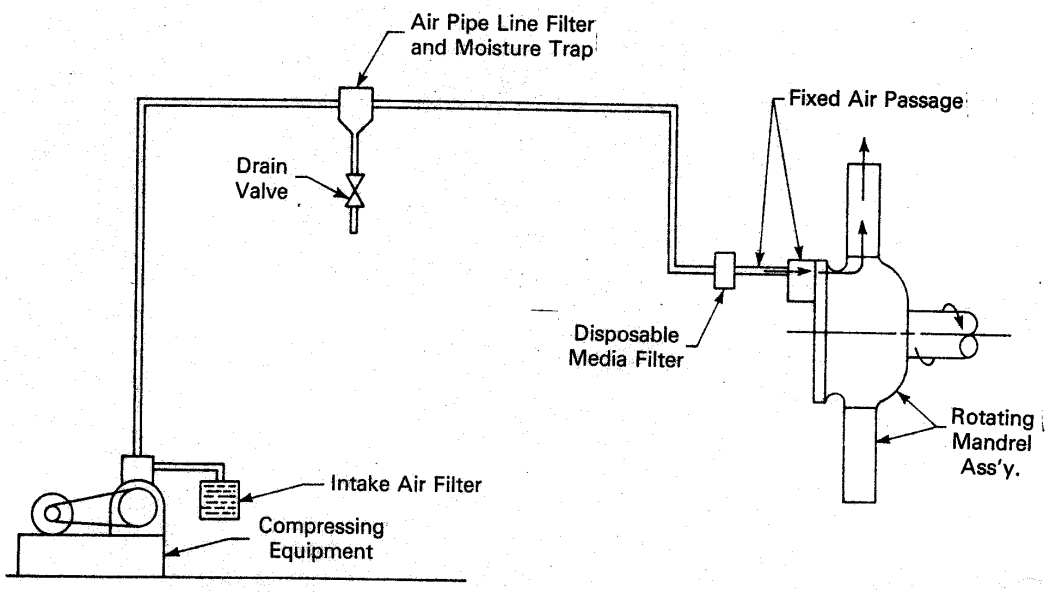


Figure 36. Rotating Mandrel Assembly

III. CULINARY STEAM - MILK AND MILK PRODUCTS

The following methods and procedures will provide steam of culinary quality for use in the processing of milk and milk products.

SOURCE OF BOILER FEED WATER

Potable water or water supplies, acceptable to the Regulatory Agency, will be used.

FEED WATER TREATMENT

Feed water 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 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 milk 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, diethylamino-ethanol, trisodium nitrilotriacetae, and hydrazine shall not be permitted for use in steam in contact with milk and milk 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

See Figure 37 for suggested piping assemblies for steam infusion or injection. Other assemblies that will assure a clean, dry saturated steam are acceptable.

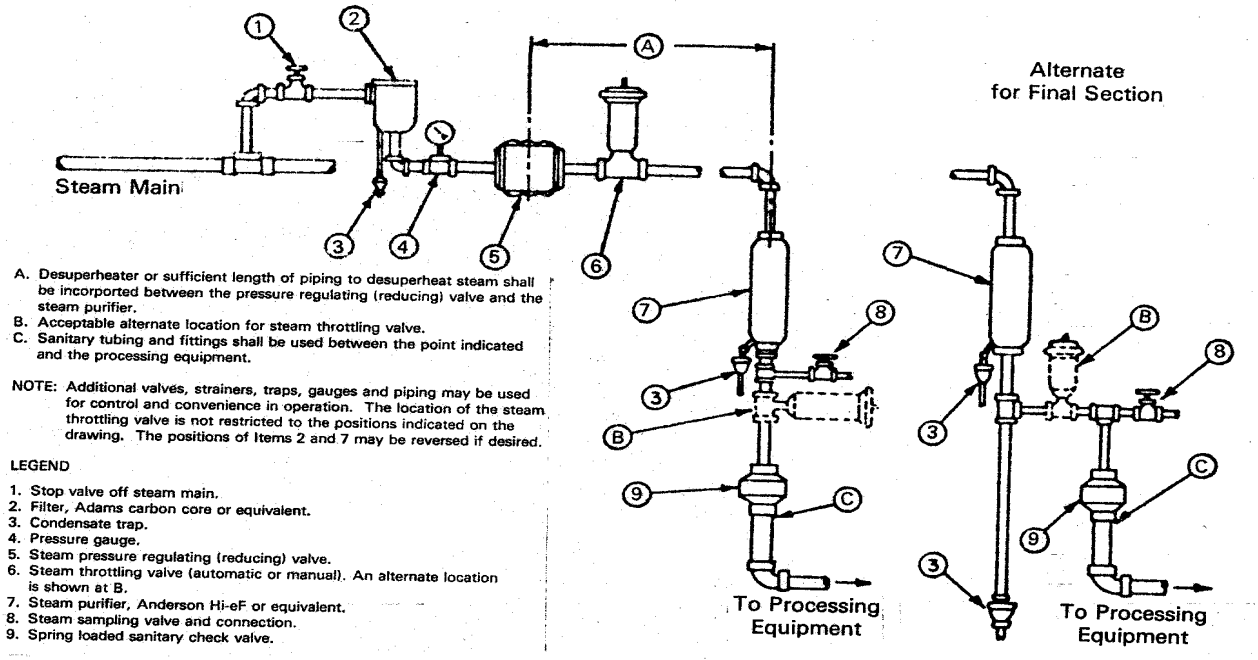


Figure 37. Culinary Steam Piping Assembly for Steam Infusion or Injection

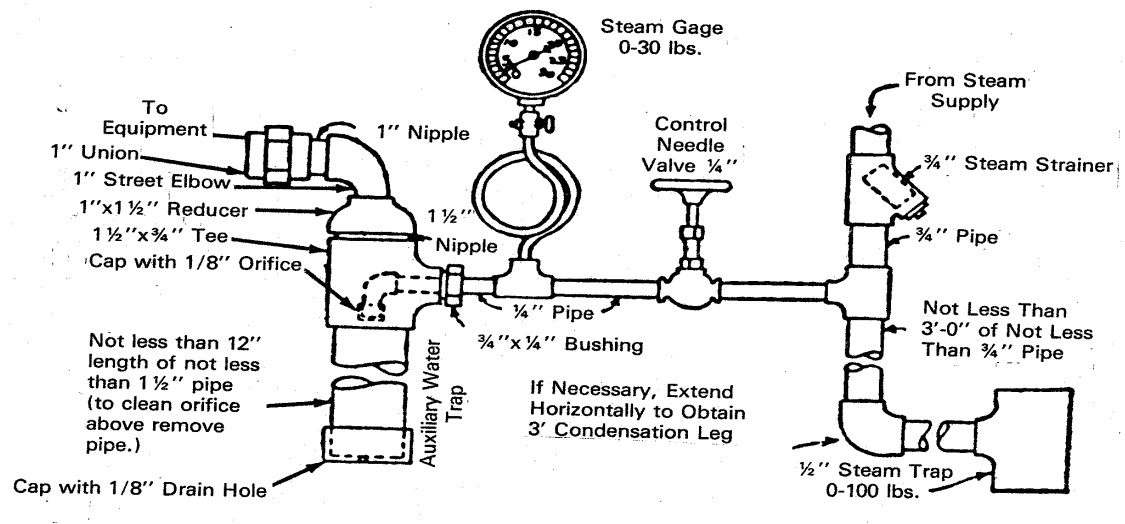


Figure 38. Culinary Steam Piping Assembly for Airspace Heating or Defoaming

IV. THERMOMETER SPECIFICATIONS

INDICATING THERMOMETERS FOR BATCH PASTEURIZERS

Type:

1. Mercury-Actuated; Direct-Reading:

a. Contained in a corrosion-resistant case, which protects against breakage and permits easy observation of the column and scale.

b. Filling above mercury - nitrogen or other suitable gas.

c. The mercury column shall be magnified to an apparent width of not less than 1.6 millimeters (0.0625 of an inch).

2. Digital:

a. No more than 0.2ºC (0.5ºF) drift over three (3) months use on a batch pasteurizer 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 the Regulatory Agency. 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 with the requirements for performance level characteristics of industrial devices. Vendors shall develop protocols for these tests with FDA concurrence.

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. Vendors shall develop protocols for these tests with FDA concurrence.

e. Both the probe and the display case shall be constructed so that they may be sealed by the 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 application tests under Appendix I of this *Ordinance*.

h. The sensing element shall be encased in appropriate material constructed in such a way that the final assembly meets the conditions of Item 11p of this *Ordinance.*

i. The device must be tested from the sensing probe through the final output.

Scale: Shall have a span of not less than fourteen (14) Celsius degrees (twenty-five (25) Fahrenheit degrees), including the pasteurization temperature, ± 2.5°C (5°F); graduated in 0.5°C (1ºF) divisions, with not more than nine (9) Celsius degrees (sixteen (16) Fahrenheit degrees) per 2.54 centimeters (1 inch) of span; protected against damage at 105°C (220°F). Provided, that on batch pasteurizers used solely for thirty (30) minute pasteurization of milk products at temperatures above 71°C (160°F), indicating thermometers with 1°C (2°F) scale graduations, with not more than six (6) Celsius degrees (twenty-eight (28) Fahrenheit degrees) 2.54 centimeters (1 inch) of span, may be used.

Accuracy: Within ± 0.2°C (±0.5°F), through the specified scale span. Provided, that on batch pasteurizers used solely for thirty (30) minute pasteurization of milk products at temperatures above 71°C (160°F), indicating thermometers shall be accurate to within .5°C (1°F) plus or minus. (See Appendix I., Test 1)

Submerged Stem Fitting: A pressure-tight seat against the inside wall of the holder; no threads exposed to milk or milk products; and the location of this seat to conform to the 3-A 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:
   a. Contained in a corrosion-resistant case, which protects against breakage and permits easy observation of the column and scale.
   b. Filling above mercury - nitrogen or other suitable gas.
   c. The mercury column shall be magnified to an apparent width of not less than 1.6 millimeters (0.0625 of an inch).
2. Digital:
   a. No more than 0.2°C (0.5°F) drift over three (3) months use on a 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 the Regulatory Agency. 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 with the requirements for performance level characteristics of industrial devices. Vendors shall develop protocols for these tests with FDA concurrence.
   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. Vendors shall develop protocols for these tests with FDA concurrence.
   e. Both the probe and the display case shall be constructed so that they may be sealed by the 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 I of this *Ordinance*.
   h. The sensing element shall be encased in appropriate material constructed in such a way that the final assembly meets the conditions of Item 11p of this *Ordinance.*
   i. The device must be tested from the sensing probe through the final output.

Scale: Shall have a span of not less than fourteen (14) Celsius degrees (twenty-five (25) Fahrenheit degrees), including the pasteurization temperature, ± 2.5°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 four (4) Celsius degrees (eight (8) Fahrenheit degrees) per 2.54 centimeters (1 inch) of scale. The digital thermometer readout shall display in units no greater than of 0.05°C (0.1°F).

Accuracy: Within ± 0.2°C (±0.5°F), throughout the specified scale span. (See Appendix I., Test 1)

Stem Fittings: A pressure-tight seat against the inside wall of the fittings; no threads exposed to milk. The probe is to be designed so that the sensitive area is discernible from the remainder of the stem. The 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 four (4) seconds. (See Appendix I. Test 7) The digital thermometer displays shall change at a rate that can be noted by the operator or Regulatory Agency during the thermometric lag test. (See Appendix I., Test 7)

Bulb: Corning normal, or equally suitable thermometric glass.

AIRSPACE INDICATING THERMOMETER FOR BATCH PASTEURIZERS

Type:

1. Mercury-Actuated; Direct-Reading:
   a. Contained in a corrosion-resistant case, which protects against breakage and permits easy observation of the column and scale.
   b. The bottom of the bulb chamber shall not be less than 51 millimeters (2 inches) and not more than 89 millimeters (3.5 inches), below the underside of the cover.
   c. Filling above mercury - nitrogen or other suitable gas.
   d. The mercury column shall be magnified to an apparent width of not less than 1.6 millimeters (0.0625 of an inch).
2. Digital:
   a. No more than 0.2ºC (0.5ºF) drift over three (3) months use on a batch pasteurizer 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 the Regulatory Agency. 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 with the requirements for performance level characteristics of industrial devices. Vendors shall develop protocols for these tests with FDA concurrence.
   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. Vendors shall develop protocols for these tests with FDA concurrence.

e. Both the probe and the display case shall be constructed so that they may be sealed by the 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 application tests under Appendix I of this *Ordinance*.

h. The sensing element shall be encased in appropriate material constructed in such a way that the final assembly meets the conditions of Item 11p of this *Ordinance.*

i. The device must be tested from the sensing probe through the final output.

j. The bottom of the bulb chamber is not less than 51 millimeters (2 inches) and not more than 89 millimeters (3.5 inches), below the underside of the cover.

Scale: Shall have a span of not less than fourteen (14) Celsius degrees (twenty-five (25)Fahrenheit degrees), including the pasteurization temperature of 66°C (150°F), ± 2.5°C (± 5°F); graduated in not more than 1°C (2°F) divisions, with not more than nine (9) Celsius degrees (sixteen (16) Fahrenheit degrees) per 2.54 centimeters (1inch) of scale; protected against damage at (105°C) 220°F.

Accuracy: Within ± 0.5^{O}C (± 1^{O}F), throughout the specified scale span. (See Appendix I., Test 1)

Stem Fittings: A pressure-tight seat or other suitable sanitary fitting with no threads exposed.

RECORDING THERMOMETERS FOR BATCH PASTEURIZERS

1. UTILIZING TEMPERATURES LESS THAN 71^{O}C (160^{O}F)

Case: Moisture proof under normal operating conditions in pasteurization plants.

Scale: Shall have a span of not less than eleven (11) Celsius degrees (twenty (20) Fahrenheit degrees), including pasteurization temperature, ± 2.5°C (±5°F), and 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 (140°F) and 69°C (155°F). Provided, that temperature-scale divisions of 0.5°C (1°F), spaced not less than 1millimeter (0.040 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 ten (10) minutes; and having a chord of straight-line length of not less than 6.3 millimeters (0.25 inches), between 63°C (145°F) and 66°C (150°F).

Temperature Accuracy: Within ± 0.5°C (± 1° F), between 60°C (140°F) and 69°C (155°F). (See Appendix I., 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 thirty (30) minutes at pasteurization temperature. Recorders for batch pasteurizers may be equipped with spring operated or electrically operated clocks. (See Appendix I., Test 3).

Pen-Arm Setting Device: Easily accessible and simple to adjust.

Temperature Sensing Device: Protected against damage at a temperature of 105°C (220°F).

Submerged Stem Fitting: A pressure-tight seat against the inside wall of the holder; no threads exposed to milk or milk products; and the distance from the underside of the 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 (1) revolution in not more than twelve (12) hours. Two (2) charts shall be used if operations extend beyond twelve (12) hours in one day. Circular charts shall be graduated for a maximum record of twelve (12) hours. Strip-charts may show a continuous recording over a twenty-four (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.

2. **UTILIZING TEMPERATURES GREATER THAN 71º (160ºF)**

Batch pasteurizers used solely for thirty (30) minute pasteurization of milk 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 inch) apart between 65°C (150°F) and 77°C (170°F), graduated in time-scale divisions of not more than fifteen (15) minutes and having a chord of straight-line length of not less than 6.3 millimeters (0.25 inch) between 71°C (160°F) and 77°C (170°F).
Temperature Accuracy: Within ± 1°C (± 2° F), between 71°C (160°F) and 77°C (170°F).
Chart Speed: A circular chart shall make one (1) revolution in not more than twenty-four (24) hours and shall be graduated for a maximum record of twenty-four (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 seventeen (17) Celsius degrees (thirty (30) Fahrenheit degrees), including the temperature at which diversion is set, ± 7°C (± 12°F); graduated in temperature scale divisions of 0.5°C (1°F), spaced not less than 1.6 millimeter (0.0625 inch) apart at the diversion temperature, ± 0.5°C (± 1°F). Provided, that temperature-scale divisions of 0.5°C (1°F), spaced not less than 1 millimeter (0.040 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 fifteen (15) minutes; and having an equivalent fifteen (15) minute chord or straight-line length of not less than 6.3 millimeters (0.25 inch) at the diversion temperature, ± 0.5°C (± 1°F).
Temperature Accuracy: Within ± 0.5°C (± 1°F), at the temperature at which the controller is set to divert ± 3°C (± 5°F). (See Appendix I., Test 2)
Power Operated: All recorder/controllers for continuous pasteurization shall be electrically operated.
Pen-Arm Device: Easily accessible and simple to adjust.
Pen and Chart Paper: Pen designed to give a line not over .07 millimeter (0.025 inch) wide and easy to maintain.
Temperature Sensing Device: Bulb, tube, spring or thermistor, protected against damage at a temperature of 105°C (220°F). Provided, that the recorder/controller temperature sensing devices, used on HHST systems, shall be protected against damage at temperatures of 149°C (300°F).

Stem Fitting: Pressure-tight seat against the inside wall of the pipe; no threads exposed to milk or milk products; and the distance from the underside of the ferrule to the sensitive portion of the bulb is to be not less than 76 millimeters (3 inches).
Chart Speed: A circular chart shall make one (1) revolution in not more than twelve (12) hours. Two (2) charts shall be used if operations extend beyond twelve (12) hours in one (1) day. Circular charts shall be graduated for a maximum record of twelve (12) hours. Strip-charts may show a continuous recording over a twenty-four (24) hour period.
Frequency Pen: The recorder/controller shall be provided with an additional pen-arm located on the outer edge of the chart, for recording the time at which the FDD is in the forward or diverted-flow 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 the same sensor as the recorder pen, however the cut-in and cut-out response shall be independent of pen-arm movement.
Controller Adjustment: A mechanism for the adjustment of the response temperature. It shall be designed so that the temperature setting cannot be altered or the controller manipulated without detection.
Thermometric Response: With the recorder/controller bulb at room temperature and then immersed in sufficiently agitated water or oil bath at 4ºC (7ºF) above the cut-in point, the interval between the moment when the recording thermometer reads 7ºC (12ºF) below the cut-in temperature and the moment of power cut-in shall be not more than five (5) seconds. (See Appendix I., 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 twenty-eight (28) Celsius degrees (fifty (50) Fahrenheit degrees), including normal storage temperatures, ± 3°C (± 5°F), with an 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 inch) apart between 2°C (35°F) and 13°C (55°F).
Accuracy: Within ± 1°C (± 2°F) throughout the specified scale range.
Stem Fitting: A pressure-tight seat or other suitable sanitary fittings with no threads exposed.

RECORDING THERMOMETERS USED ON STORAGE TANKS

Case: Moisture proof under operating conditions in processing plants.
Scale: Shall have a scale span of not less than twenty-eight (28) Celsius degrees (fifty (50) Fahrenheit degrees) including normal storage temperature, ± 3°C (± 5°F), graduated in not more than 1°C (2°F) divisions. Lines spaced not less than 1 millimeter (0.040 inch) apart, are permitted when the ink line is thin enough to be easily distinguished from the printed line. They shall be graduated in time scale divisions of not more than one (1) hour, having a chord of straight-line length of not less than 3.2 millimeters (0.125 inch) at 5°C (40°F). These charts 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), between the specified range limits.

Pen-Arm Setting Device: Easily accessible and simple to adjust.
Pen and Chart Paper: Designed to make a line not over .635 millimeters (0.025 inch) wide when in proper adjustment and easy to maintain.
Temperature Sensor: Protected against damage at 100°C (212°F).
Stem Fittings: A pressure-tight seat or other suitable sanitary fitting with no threads exposed.
Chart Speed: The circular chart shall make one (1) revolution in not more than seven (7) days and shall be graduated for a maximum record of seven (7) days. Strip chart shall move not less than 2.54 centimeters (1 inch) per hour and may be used continuously for one (1) calendar month.

RECORDING THERMOMETERS ON MECHANICAL CLEANING SYSTEMS

Location: Temperature sensor is in the return solution line downstream from the process.
Case: Moisture proof under operation conditions.
Scale: Shall have a range from 16°C (60°F) to 83°C (180°F), with extensions of scale on either side permissible and graduated in time-scale divisions of not more than fifteen (15) minutes. 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 inch) apart, above 44°C (110°F). Provided, that temperature-scale divisions of 1°C (2°F), spaced not less than 1 millimeter (0.040 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), above 44°C (110°F).
Pen-Arm Setting Device: Easily accessible and simple to adjust.
Pen and Chart Paper: Designed to make a line not over .635 millimeters (0.025 inch) wide and easy to maintain.
Temperature Sensor: Protected against damage at 100°C (212°F).
Stem Fitting: A pressure-tight seat against the inside wall of the pipe with no threads exposed to solution.
Chart Speed: Circular charts shall make one (1) revolution in not more than twenty-four (24) hours. Strip charts shall not move less than 25 millimeters (1 inch) per hour. More than one (1) 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 WHERE MILK AND MILK PRODUCTS ARE STORED

Scale Range: Shall have a span not less than twenty-eight (28) Celsius degrees (fifty (50) Fahrenheit degrees), including normal storage temperatures, ± 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 millimeters (0.0625 inches) apart between 0°C (32°F) and 13°C (55°F).
Accuracy: Within ± 1°C (± 2°F), throughout the specified scale ranges.

V. CRITERIA FOR THE EVALUATION OF COMPUTERIZED SYSTEMS FOR GRADE 'A' PUBLIC HEALTH CONTROLS

BACKGROUND

Computers are different from hard-wired controls in three (3) major categories. To provide adequate public health protection, the design of computerized public health controls must address these three (3) 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 FDD for only one (1) millisecond. During the next one hundred (100) milliseconds, or however long it takes the computer to cycle one (1) time through its tasks, the FDD remains in forward-flow, independent of temperature in the holding tube. Normally, this is not a problem, because most computers can cycle through one hundred (100) steps in their program, many times during one (1) 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 require tools and a technician to make wiring changes. Once the hard-wired system was properly installed and working, it was never changed. Sealing the access to the computer can solve the problem addressed above. A procedure is needed to ensure that the computer has the correct program when the Regulatory Agency reseals the computer.

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 **E**lectrically **A**lterable, **P**rogrammable, **R**ead-**O**nly **M**emory. Individual memory locations may be altered without erasing the remaining memory.

EEPROM: An **E**lectrically **E**rasable **P**rogrammable, **R**ead-**O**nly **M**emory. The entire memory is erased with one (1) electrical signal.

EPROM: An **E**rasable, **P**rogrammable, **R**ead-**O**nly **M**emory. 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 the user and/or the 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 and 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, micro-switches, 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 or 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 of any program instructions.
Output: Electrical signals from the computer that turn on or off valves, motors, lights, horns, and other devices 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 **A**ccess **M**emory is 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-**O**nly **M**emory is 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. A manually operated switch usually accomplishes this instruction.
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 Aseptic (UHT) pasteurization systems used for Grade 'A' milk and milk products. In addition, all systems shall conform to all other existing requirements of this *Ordinance*.

1. A computer or programmable controller used for the public health control of pasteurizers must be a system dedicated only to the public health control of that individual pasteurizer. The public health computer shall not have any 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 devices to prevent the public health outputs from being driven by the other computer system. Digital outputs from another computer may be connected to an input of the public health computer in order to request the operation of a device controlled by the public health computer.
5. Upon 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 (1) 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 Agency with procedures and instructions to confirm that the program currently in use by the computer is the correct program. The Regulatory Agency 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’s instructions must remind the Regulatory Agency 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 that 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 (1) second. Upon returning to public health control tasks, the computer shall complete at least one (1) 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 (1) second. Upon returning to public health control tasks, the computer shall complete at least one (1) full cycle of its public health control 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 (5) seconds, except that during the thermometric lag test, the temperature shall be printed or indicated fast enough that the Regulatory Agency can place the temperature sensor in a bath at a temperature 4ºC (7°F) above the diversion setting and accurately determine the point in time when the temperature rises to a point 7ºC (12ºF) below the diversion point setting so that the Regulatory Agency can start the timing of the thermometric lag test.

15. When the computer prints the event pen position, the position of the FDD, either 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 event 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 FDD.

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, within Appendix I of this *Ordinance*, can be performed by the Regulatory Agency for each instrument i.e.:

a. Recording Thermometers: Temperature accuracy; time accuracy; check against indicating thermometer and thermometric response.

b. FDD: Valve seat leakage; operation of valve stem(s); device assembly; manual diversion; response time and time delay intervals if used.

c. Booster Pumps: Proper wiring and proper pressure control settings

d. Flow Promoting Devices Capable of Generating Flow Through the Holding Tube: Holding time in the holding tube and 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 RAM. Some mechanical and electrical components also deteriorate with age. One solution is to have two (2) permanent programs in the computer; one (1) in RAM and one (1) in ROM. Through a self-diagnostic test, these two (2) programs could be compared routinely. If there were differences in the programs, the computer would go into default mode. Another solution would be to download the program from ROM to RAM at every start-up. A third solution would be to have the computer read the program directly from unchangeable ROM. However, this approach is practical only in large volume applications such as microwave ovens. For most small volume applications, the ROM's are field alterable, such as EPROMS, EEPROMS and 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 Agency 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 pasteurization system. For example, on magnetic flow meter based timing systems, the flush cycle on the detect stem of the FDD and the ten (10) minute delay for the booster pump and the FDD will permit the timing pump to run during CIP operations. The vendor must provide a protocol in the user's manual so that the installer, user, and/or Regulatory Agency can demonstrate that the program performs as designed under actual production conditions.

19. The logic diagrams for the FDD and the 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 plant personnel, may change mechanical cleaning programs. When using this method, the connections between the FDD, booster pump, and plant computer, must be provided with solenoid relays or similar devices for the FDD and booster pump outputs. This prevents them from being operated by the plant computer, except when the mode switch of the FDD is in the "CIP" position.

DIAGRAM LEGEND

t = Time
T = Temperature
MS = Microswitch
FDV = Flow Divert Valve
FDD = Flow-Diversion Device

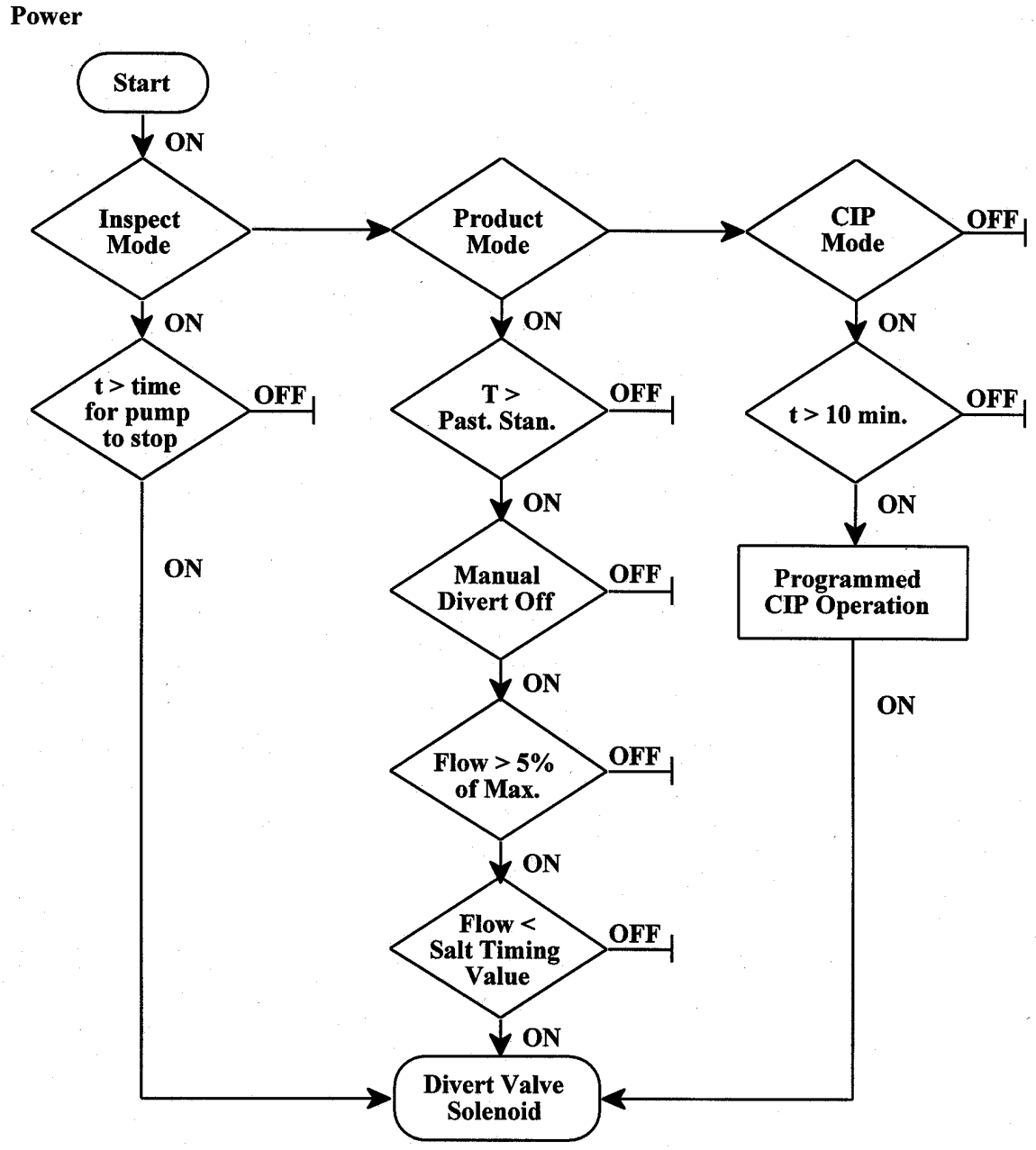


Figure 39. Logic Diagram: Flow-Diversion Device, Divert Valve Stem

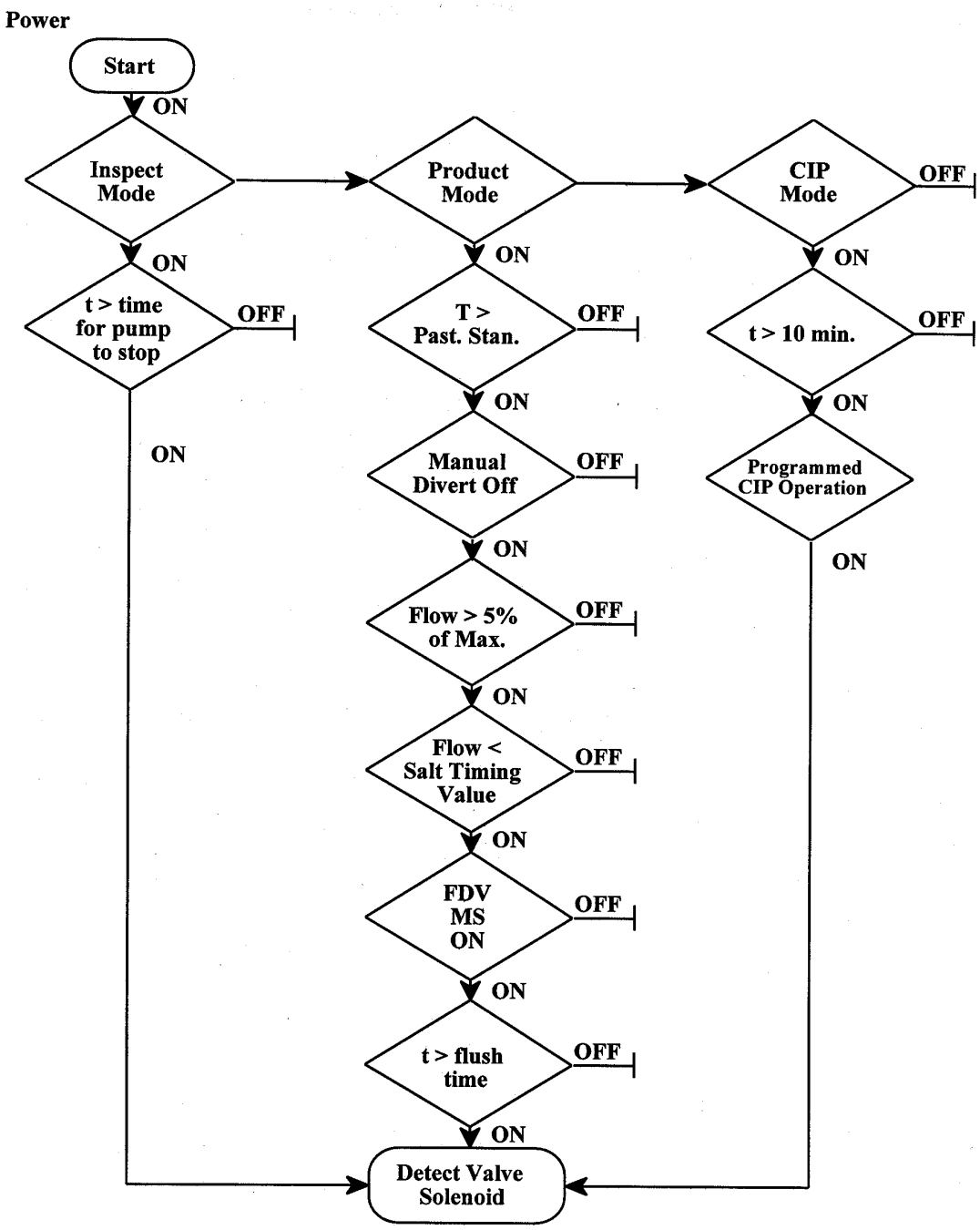


Figure 40. Logic Diagram: Flow–Diversion Device, Leak Detect Valve Stem

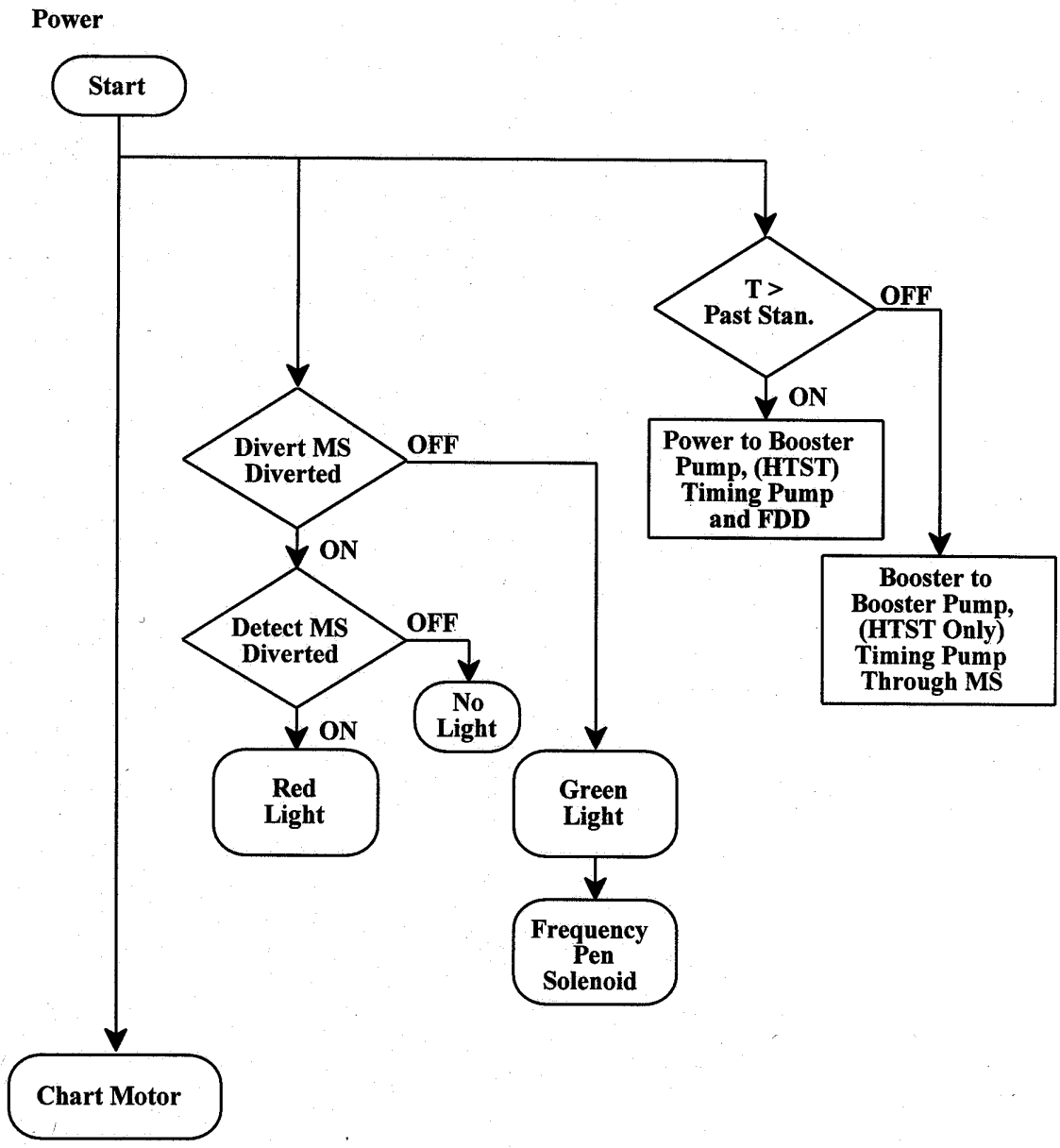
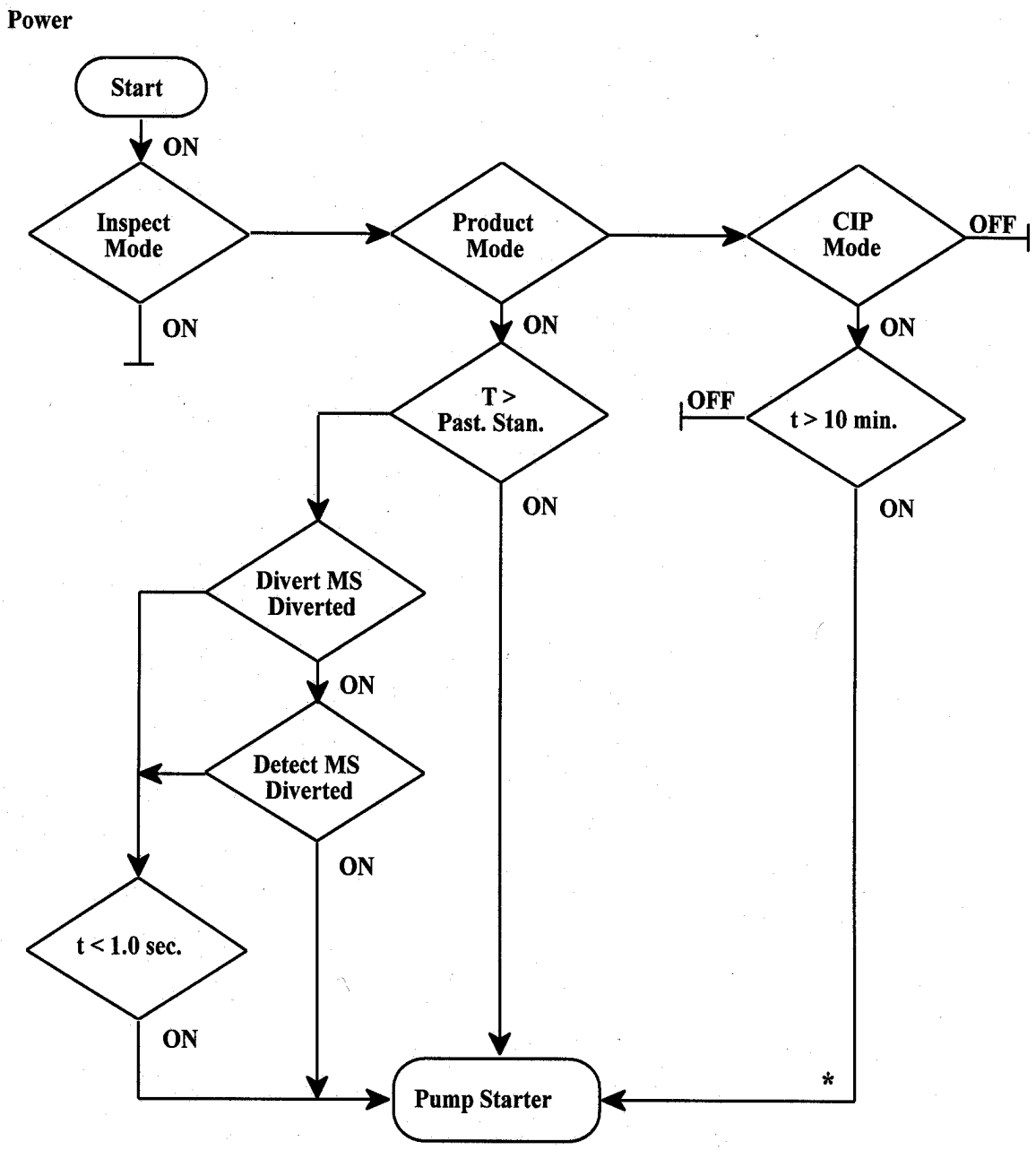
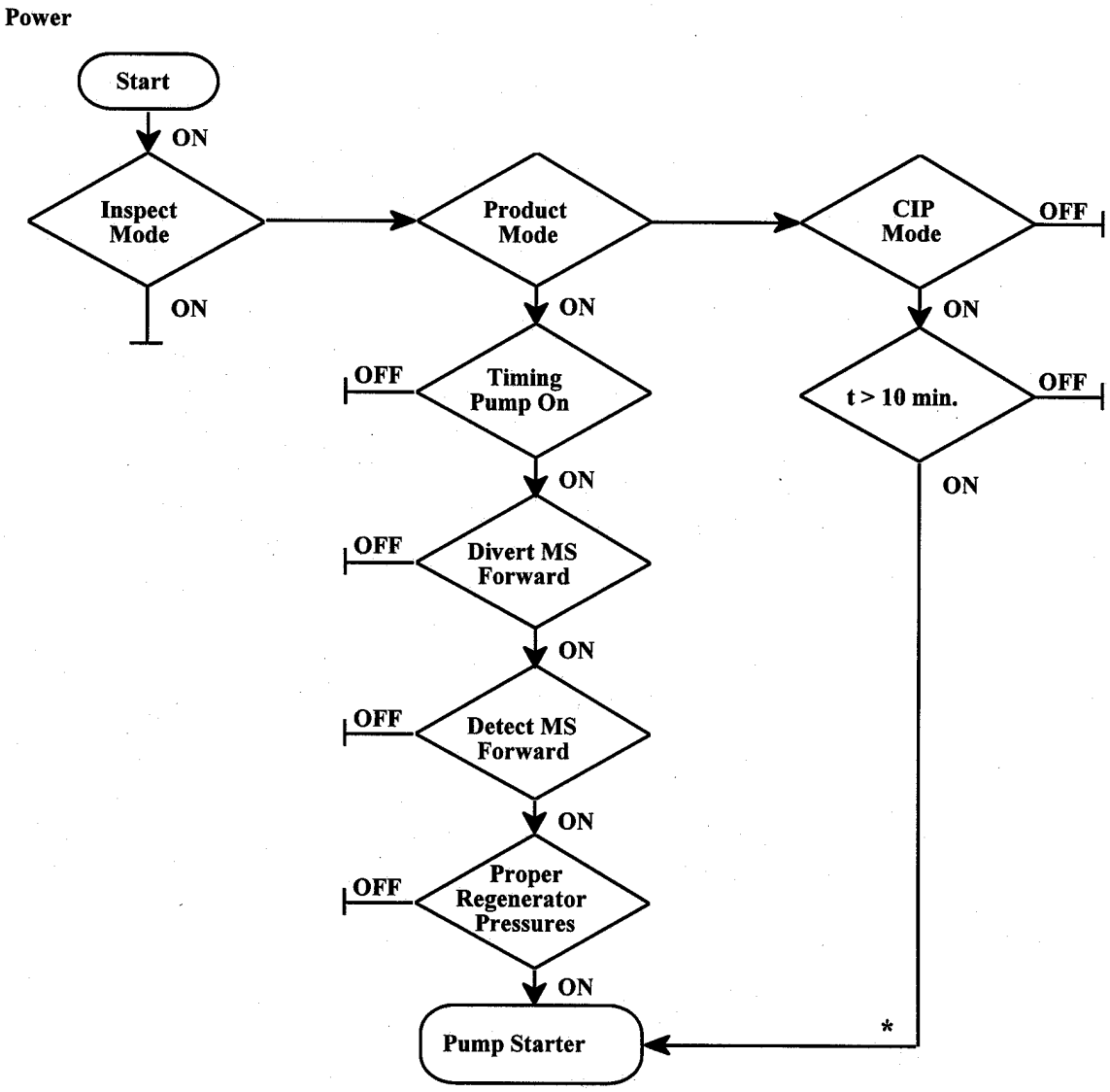


Figure 41. Logic Diagram: Safety Thermal Limit Recorder-Controller



* If the 10 min. time delay is not used when CIP is initiated, this path must be deleted.

Figure 42. Logic Diagram: Timing Pump



*** If the 10 min. time delay is not used when CIP is initiated, this path must be deleted.**

Figure 43. Logic Diagram: Booster Pump

APPENDIX I. PASTEURIZATION EQUIPMENT AND CONTROLS - TESTS

I. TESTING APPARATUS SPECIFICATIONS

TEST THERMOMETER

Type:

1. **Mercury-Actuated:** Readily cleanable; plain front; enameled back; length 30.5 centimeters (12 inches); immersion point to be etched on stem and mercury to stand in contraction chamber at 0ºC (32ºF).
Scale Range: At least 7ºC (12ºF) below and 7ºC (12ºF) above the pasteurization temperature at which the operating thermometer is used, with extensions of the scale on either side permitted and protected against damage at 149ºC (300ºF).
Temperature Represented by Smallest Scale Division: 0.1ºC (0.2ºF).
Number of Degrees per 25 Millimeters (1 inch) of Scale: Not more than four (4) Celsius degrees or not more than six (6) Fahrenheit degrees.
Accuracy: Within ± 0.1ºC (± 0.2ºF), throughout specified scale range. The accuracy shall be checked against a thermometer, which has been tested by the National Institute of Standards and Technology (NIST).
Bulb: Corning normal or equally suitable thermometric glass.
Case: Suitable to provide protection during transit and periods when not in use.

2. **Digital Test Thermometer:** Hand-held; high accuracy digital thermometer; and battery or AC line powered. Calibration is protected from unauthorized changes.
Range: -18ºC to 149°C (0ºF to 300°F); Temperature represented by smallest scale division, 0.01°C or ºF and digital display.
Accuracy: System accuracy of: ± 0.056°C (± 0.100°F); Probe accuracy of: ± 0.05°C (± 0.09°F); Repeatability of ± 0.005°C (± 0.009°F); Three (3) month stability: ± 0.025°C (± 0.045°F). Thermometer accuracy from 0ºC to 150°C (32ºF to 302°F): ± 0.05°C (± 0.09°F). Calibration uncertainty: ± 0.0047°C (± 0.00846°F). The accuracy shall be checked against a thermometer, which has been tested by NIST. A certificate of calibration shall be maintained with the unit.
Self-Diagnostic Circuitry: Circuitry shall provide constant monitoring of all sensing, input and conditioning circuits. The diagnostic circuitry should be capable of identifying the probe and its calibration information. Without a correct connection of the probe, the display shall alert the operator and no temperature will be displayed.
Electromagnetic Compatibility: Shall be documented for these devices for their intended use and available to the Regulatory Agency. Units to be used in the "field" shall have been tested for heavy industrial standards, as specified in the European Electromagnetic Compatibility Directive.
Immersion: Minimum immersion point shall be marked on the probe. During control tests, the probes shall be immersed to equal depths in a water or oil bath.
Case: Suitable to provide protection during transit and periods when not in use.

GENERAL PURPOSE THERMOMETER

Type: Pocket type.
Scale Range: 1ºC (30ºF) to 100ºC (212ºF), with extensions of the scale on either side permitted. Protected against damage at 105ºC (220ºF).
Temperature Represented by Smallest Scale Division: 1ºC (2ºF).
Accuracy: Within ± 1ºC (± 2ºF), 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 inch).
Number of Degrees per Inch of Scale: Not more than twenty-nine (29) Celsius degrees or not more than fifty-two (52) Fahrenheit degrees.
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 ten (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 sixty (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. (See Appendix M.)

TEST 1.

INDICATING THERMOMETERS - TEMPERATURE ACCURACY

Reference: Item 16p.(A, B, C and E)
Application: To all indicating thermometers used for the measurement of product temperature during pasteurization or aseptic processing, including airspace thermometers.
Frequency: Upon installation; at least once each three (3) months thereafter; whenever the thermometer has been replaced or the regulatory seal on a digital sensor or a digital control box has been broken.
Criteria: Within ± 0.25ºC (± 0.5ºF) for pasteurization and aseptic processing thermometers and ± 0.5ºC (± 1ºF) for airspace thermometers, in a specified scale range. Provided, that on batch pasteurizers used solely for thirty (30) minute pasteurization of products at temperatures above 71°C (160°F), indicating thermometers shall be accurate to within ± 0.5°C (± 1°F).
Apparatus:
1. Test thermometer meeting the specifications cited in Part I of this Appendix.
2. Water, oil or other suitable media bath and agitator.
3. Suitable means of heating the media bath.

Method: Both thermometers exposed to water, oil or other suitable media of uniform temperature. Indicating thermometer reading is compared to the reading of the test thermometer.
Procedure:
1. Prepare a quantity of water, oil or other suitable media in a bath, by raising the temperature of the media to within 2ºC (3ºF) of the appropriate pasteurization, or airspace temperature, or aseptic processing temperature.
2. Stabilize the bath temperature and agitate rapidly.
3. Continue agitation and insert indicating and test thermometers to indicated immersion point.
4. Compare both thermometer readings at the temperature within the test range.
5. Repeat the comparison of readings.
6. Record the thermometer readings, and the thermometer identification or location.
7. Install seals as appropriate on sensors and control boxes of digital thermometers.

Corrective Action: Do not run the test if the mercury column has been split or capillary tube is broken. The thermometer should be returned to the factory for repair. When the indicating thermometer differs from the test thermometer by more than 0.25ºC (0.5ºF) and the airspace thermometer by more than 0.5ºC (1ºF), 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.(A, B, C and E)
Application: To all recording and recorder-controller thermometers controllers used to record milk temperatures during pasteurization or aseptic processing.
Frequency: Upon installation; at least once each three (3) months thereafter; whenever the recording pen-arm setting requires frequent adjustment; when the sensing element has been replaced; or when a regulatory seal has been broken.

Criteria: Within ± 0.5ºC (± 1ºF), in specified scale range. Provided, that on batch pasteurizers used solely for thirty (30) minute pasteurization of products at temperatures above 71°C (160°F), the recording thermometers shall be accurate to within ± 1°C (± 2° F), between 71°C (160° F) and 77°C (170°F).

Apparatus:

1. The indicating thermometer previously tested against a known accurate thermometer.
2. Water, oil or other suitable media bath and agitator.
3. Suitable means of heating the media bath.
4. Ice.

NOTE: When this Test is performed on recorder-controllers used with HHST pasteurization or aseptic processing systems that operate at or above the boiling point of water, an oil or other suitable media bath shall be substituted for the processing (operating) temperature water mentioned in steps "Procedures" 1, 4, 5, 6, and 7 as well as the boiling water mentioned in "Procedures" 2, 3 and 5. The temperature of the oil bath that 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 0.5ºC (1ºF), or 1°C (2°F) as provided in "Criteria" above, of its previous setting, after exposure to high heat and melting ice.

Procedure:

1. 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 five (5) minutes, two (2) minutes for electronic recording thermometers, at a constant temperature. The bath shall be rapidly agitated throughout the stabilization period.
2. Prepare a second media bath by heating to the boiling point, or in the case of HHST or aseptic systems, to a temperature above the normal operating range but below the highest temperature division on the chart, and maintain temperature. Prepare a third container with melting ice. Place all media baths within working distance of the temperature-sensing element(s).
3. Immerse the recording thermometer sensing element into the boiling water, or in the case of HHST or aseptic processing systems into the media bath described above, for not less than five (5) minutes, two (2) minutes for electronic recording thermometers.
4. Remove the recording thermometer sensing element from the boiling water or other media bath and immerse it in the media bath at a temperature within the temperature range for the process being used. Allow a five (5) minute, two (2) minutes for electronic recording thermometers, stabilization period for both indicating and recording thermometers. Compare readings of the indicating and recording thermometers. The recording thermometer reading should be within ± 0.5ºC (± 1ºF) or ± 1°C (± 2°F) as provided above, of the indicating thermometer reading.
5. Remove the recording thermometer sensing element from the bath in the temperature range for the process being used, and immerse in melting ice for not less than five (5) minutes, two (2) minutes for electronic recording thermometers.
6. Remove the recording thermometer sensing element from the ice water and immerse in bath at a temperature range for the process being used. Allow a five (5) minute, two (2) minutes for

electronic recording thermometers, stabilization period for both indicating and recording thermometers. Compare readings of the indicating and recording thermometers. The recording thermometer reading should be within ± 0.5ºC (± 1ºF), or ± 1°C (± 2°F) as provided above, of the indicating thermometer reading.

7. Re-seal the regulatory controls as necessary and record the indicating and recording thermometer readings obtained from "Procedures" 1, 4, and 6.

Corrective Action: If the recording thermometer pen does not return to ± 0.5ºC (± 1ºF), or ± 1°C (± 2ºF) as provided above, of indicating thermometer reading at "Procedures" 4 and 6, the recording thermometer shall be repaired or replaced as necessary.

TEST 3.

RECORDING THERMOMETERS - TIME ACCURACY

Reference: Item 16p.(A, B, C and E)

Application: To all recording and recorder-controller thermometers used to record the time of pasteurization or aseptic processing, including those used to record flow rates in magnetic flow meter based timing systems.

Frequency: Upon installation; at least once each three (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:

1. A watch, graduated at intervals not to exceed one (1) minute, and accurate to within five (5) minutes in twenty-four (24) hours.
2. 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 thirty (30) minutes with a watch of known accuracy. For recorders utilizing electric clocks, check the cycle on the faceplate of the clock with a known cycle and observe that the clock is in operating condition.

Procedure:

1. Determine if the chart is appropriate for the recording thermometer. Insure that the recording pen is aligned with the time arc of the chart at both the center and the outside edge.
2. Inscribe a reference mark at the pen point on the recording chart and record the time.
3. At the end of thirty (30) minutes by the watch, inscribe a second reference mark at the pen point position on the chart.
4. Determine the distance between the two (2) reference marks and compare the distance with the time-scale divisions on the recording chart at the same temperature.
5. For electric clocks, remove the faceplate and compare the cycle specification on the faceplate with the current cycle utilized.
6. Re-seal the regulatory controls as necessary; enter the findings on the chart and initial and record the 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.(A, B, C and E)
Application: To all recording and recorder-controller thermometers used to record product temperatures during pasteurization or aseptic processing.
Frequency: Upon installation and at least once each three (3) months by the Regulatory Agency; and daily by the plant operator.
Criteria: The recording thermometer and recorder-controller thermometer shall not read higher than the indicating thermometer.
Apparatus: No supplementary materials required.
Method: This test requires only that the reading of the recording thermometer or the recorder-controller thermometer be compared with the indicating thermometer at a time when both are exposed to a stabilized pasteurization or aseptic processing temperature.
Procedure:
1. While the indicating and recording thermometers or recorder-controller thermometers are stabilized at the same pasteurization or aseptic processing temperature, read the indicating thermometer.
2. Immediately inscribe on the recording thermometer or recorder-controller thermometer chart a line intersecting the recorded temperature arc at the pen location. Record on the chart the indicating thermometer temperature and initial.
3. Record the indicating and recording thermometer or recorder-controller thermometer readings.
Corrective Action: If the recording thermometer or recorder-controller thermometer reads higher than the indicating thermometer, the pen or temperature adjusting mechanism shall be adjusted by the operator.

TEST 5.

FLOW-DIVERSION DEVICE - PROPER ASSEMBLY AND FUNCTION

Reference: Item 16p.(B, C and 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 FDD. Parts 1 to 4 and 6 to 8 apply to all FDD's used with continuous-flow pasteurizers. Parts 5 and 9 apply only to FDD's used with HTST pasteurizers.
Frequency: Upon installation; at least once each three (3) months thereafter; or when a regulatory seal has been broken.
Criteria: The FDD shall function correctly in operating situations and shall de-energize the timing 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: Suitable tools for the disassembly of the FDD and the sanitary piping.
Method: Observe the valve seat(s) of the FDD for leakage.
Procedure:
1. With the system operating on water, place the FDD in the diverted-flow position.
2. For single stem FDD's, disconnect the forward flow piping and observe the valve seat for leakage. Check the leak escape ports to see if they are open.
3. For dual stem FDD's, observe the leak- detect line discharge or sight glass for leakage.
Corrective Action: If leakage is noted, the FDD 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 the FDD valve stem(s) for ease of movement.
Procedure: When a stem-packing nut is used, tighten it as much as possible. Operate the system at maximum normal operating pressure and place the FDD in forward and diverted flow several times. Note the freedom of action of the valve stem.
Corrective Action: If the valve action is sluggish, suitable adjustment or repair shall be made. The stem shall move freely in all positions, when the stem-packing nut is fully tightened.

5.3 DEVICE ASSEMBLY - SINGLE STEM DEVICE

Apparatus: Sanitary fitting wrench.
Method: When the FDD is improperly assembled and in diverted flow (below cut-out temperature), observe the function of the timing pump and all other flow promoting devices capable of causing flow through the holding tube.
Procedure:
1. With the system in operation below the cut-in temperature, unscrew by one-half turn, the 13H hex nut that holds the top of the valve to the valve body. This should de-energize the timing pump and all other flow promoting devices which are capable of causing flow through the holding tube. This test shall be conducted without piping connected to the forward-flow port of the FDD. (This allows movement of the top of the valve when the hex nut is loosened.) Re-tighten the 13H hex nut.
2. With the system in operation below the cut-in temperature, remove the connecting key, located at the base of the valve stem. The timing pump and all other flow promoting devices, which are capable of causing flow through the holding tube should be de-energized.
3. Attempt to restart the timing 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

NOTE: The test procedure presented in this Section is typical of tests accepted by FDA for various specific types of FDD's. Testing details, which may vary, are provided in individual FDD operator's manuals that have been reviewed by FDA and are specified by part number in FDA's Coded Memoranda (M-b's). In each of these FDA accepted test methods, if the words "metering pump" or "timing pump" are used they shall be understood to mean "timing pump and all other flow promoting devices, which are capable of causing flow through the holding tube".

Apparatus: None
Method: Observe the function of the timing pump and all other flow promoting devices, which are capable of causing flow through the holding tube when FDD is improperly assembled.
Procedure:
1. With the FDD in diverted-flow, caused by temperature, and the FDD properly assembled, move the FDD to the forward-flow position and disconnect the stem from the actuator.
2. Move the FDD to the diverted-flow position and turn on the timing pump and all other flow promoting devices, which are capable of causing flow through the holding tube. The timing pump and all other flow promoting devices must be de-energized and must not run. If any pump starts momentarily and then stops, it may indicate the improper wiring of the one (1) second time delay as allowed in 16p.(B).2.b.(10). Separators must be effectively valved out of the system.
3. Reassemble the FDD by moving it to the forward-flow position and reconnecting the stem to the actuator.
4. 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 FDD assembly and wiring is required to locate and correct the cause.

5.5 MANUAL DIVERSION
(Booster pump installed in the HTST system)

Apparatus: None.
Method: Observe the response of the system to manual diversion.
Procedure:
1. With the HTST system in operation and the FDD in the forward-flow position, press the manual diversion button. This should:
   a. Cause the FDD to assume the divert position,
   b. De-energize the booster pump, and
   c. The pressure differential between raw and pasteurized milk in the regenerator should be maintained.
2. 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.
3. Re-seal the regulatory controls as necessary.
Corrective Action: If the above described actions do not occur, 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:
1. Water, oil or other suitable media bath.
2. Suitable means of heating the media bath.
3. Stopwatch.

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 FDD takes the fully diverted-flow position.

Procedure:
1. With the water, oil or suitable media bath at a temperature above cut-out temperature, allow the water, oil or other suitable media to cool gradually. The moment the cut-out mechanism is activated, start the watch. The moment the FDD takes the fully-diverted position, stop the watch.
2. Re-seal the regulatory controls as necessary and record the results.

Corrective Action: If the response time exceeds one (1) second, immediate corrective action must be taken.

5.7 TIME DELAY INTERLOCK WITH TIMING PUMP

Application: To all dual stem FDD's with a manual forward-flow switch.

Apparatus: None.

Method: Determine that the device does not assume a manually induced forward-flow position, while the timing pump or any other flow-promoting device, which is capable of causing flow through the holding tube is operating.

Procedure: With the system operating in forward-flow, move the control switch to the "Inspect" position and observe that the following events automatically occur in sequence:
1. The FDD immediately moves to the diverted-flow position and the timing pump and all other flow promoting devices, which are capable of causing flow through the holding tube are de-energized, or in the case of separators, are effectively valved-out of the system
2. The FDD remains in the diverted-flow position while the timing pump and all other flow promoting devices, which are capable of causing flow through the holding tube are running down or in the case of a separator, valving out.
3. The FDD may assume the forward-flow position only after the timing pump stops turning, and all other flow promoting devices, which are 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.
4. Repeat the above procedure by moving the control switch to the "Cleaned-in-Place (CIP) position.
5. Record the 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 FDD is moved from "Process" to "CIP", the FDD shall move immediately to the diverted position. It shall remain in the diverted position for at least ten (10) minutes, with all public health controls required in "Process" mode functioning, before starting its normal cycling in the "CIP" mode. In HTST systems, the booster pump shall be de-energized during the ten (10) minute time delay.

Apparatus: Stopwatch.

Method: Determine that the set point on the time delay relay is equal to or greater than ten (10) minutes.

Procedure:

1. Operate the pasteurizer in forward-flow, with the mode switch on the FDD in the "Process" position, using water above pasteurization temperature. For 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.
2. Move the mode switch on the FDD to the "CIP" position. The FDD should move immediately to the diverted position. Start the stopwatch when the FDD moves to the diverted position. Check all controls that are required to be in operation when the system is in the "Process" 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.
3. Stop the stopwatch when the CIP timer times out. On most systems this is when the FDD moves to the forward position for its initial cycle in the "CIP" mode. At this time the system may be operated without the controls normally required during product processing. For example, the booster pump may start at this time.
4. Record the results.
5. Install and seal the enclosure over the time delay relay.

Corrective Action: If the FDD does not remain in the diverted position for at least ten (10) minutes after the mode switch is moved from "Process" to "CIP", increase the set point on the time delay relay and repeat this test procedure. All public health controls required when the system is in "Process" mode and in diverted flow must be functional during these ten (10) minutes. If any of the public health controls are not functional during these ten (10) minutes, adjustments or repairs are needed. In HTST systems, if the booster pump runs at any time during the ten (10) minute delay, the booster pump wiring is in need of repair.

5.9 LEAK DETECT VALVE FLUSH - TIME DELAY

Application: The minimum one (1) second delay applies to HTST continuous flow pasteurizers in which space between the divert and leak-detect valve is not self-draining in the diverted flow position.

The maximum of five (5) seconds for this delay is not applicable if:

1. The minimum acceptable holding time in diverted flow can be achieved without the use of a restriction in the divert line; or
2. The timing system is magnetic flow meter based.

Criteria: The leak detect valve will be flushed for at least one (1) second and not more that five (5) seconds after the divert valve moves to the forward-flow position and before the leak detect valve moves to the forward position.

Apparatus: Stop watch.

Method: Observe the movement of the divert and leak-detect valves to the forward-flow position and measure the time interval between the movement of the two (2) valves.

Procedure:

1. Move the FDD from the diverted-flow position to the forward-flow position either by:
   a. Raising the temperature above the cut-in set point; or
   b. Operating the HTST pasteurizer above the cut-in temperature in manual divert mode and then releasing the manual divert.
2. When the divert valve begins to move to the forward-flow position, start the watch.
3. When the detect valve begins to move to the forward-flow position, stop the watch.
4. Record the elapsed time.
5. If the elapsed time is at or above one (1) second and at or below five (5) seconds, seal the time delay.

Corrective Action: If the elapsed time is less than one (1) second or greater than five (5) seconds, appropriate changes to the system or system controls must be made.

TEST 6.

LEAK PROTECTOR VALVE

Reference: Item 16p.(A and 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 three (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:

1. During normal operation, while milk pressure is exerted against the valve inlet, fully close the valve and disconnect the outlet piping.

NOTE: Care must be taken to avoid contamination of the valves or the piping.

2. Observe whether or not any milk is leaking past the valve seat into the valve outlet.

3. In the case of plug-type valves, turn the valve to the just-closed position, and examine the leakage into the valve outlet.
4. Reconnect the outlet piping.
5. Record the 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, or any other necessary steps shall be taken to prevent leakage.

TEST 7.

INDICATING THERMOMETERS ON PIPELINES - THERMOMETRIC RESPONSE

Reference: Item 16p.(B and E)

Application: To all HTST indicating thermometers located on pipelines and used for the 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:

1. Stopwatch;
2. The indicating thermometer previously tested against a known accurate thermometer;
3. Water bath and agitator; and
4. Suitable means of heating the water bath.

Method: By measuring the time required for the reading of the thermometer being tested to increase 7ºC (12ºF) through a specified temperature range. This range must include the pasteurization temperature. The temperature used in the water bath will depend upon the scale range of the thermometer to be tested.

Procedure:

1. Immerse the indicating thermometer in the water bath, heated to a temperature at least 11ºC (19ºF) higher than the minimum scale reading on the indicating thermometer. The bath temperature should be 4ºC (7ºF) higher than the maximum required pasteurization temperature for which the thermometer is used.
2. Immerse the indicating thermometer in a bucket of cold water for several seconds to cool it.

NOTE: Continuous agitation of the water baths during the performance of Procedures 3, 4 and 5 is required. The elapsed time between the end of Procedure 1 and the beginning of Procedure 3 should not exceed fifteen (15) seconds, unless a constant temperature bath is used to prevent the hot water bath from cooling significantly.

3. Insert the indicating thermometer into a hot water bath to the proper bulb immersion depth.
4. Start the stopwatch when the indicating thermometer reads 11ºC (19ºF) below the bath temperature.
5. Stop the stopwatch when the indicating thermometer reads 4ºC (7ºF) below the bath temperature.
6. Record the thermometric response time for the office record.

For Example: For a thermometer used at pasteurization temperature set points of 71.7ºC (161ºF) and 74.4ºC (166ºF), a water bath at a temperature of 78.3ºC (173ºF) could be used. 10.6ºC (19ºF) lower than a 78.3ºC (173ºF) water bath would be 67.8ºC (154ºF); 3.9ºC (7ºF) lower than a 78.3ºC (173ºF) water bath would be 74.4ºC (166ºF). Hence, after immersing the thermometer that has been previously cooled, in the 78.3ºC (173ºF) bath, the stopwatch is started when the thermometer reads 67.8ºC (154ºF) and stopped when it reads 74.3ºC (166ºF).

NOTE: The test included the pasteurization temperature set points of 71.7ºC (161ºF) and 74.4ºC (166ºF). If the pasteurization temperature set points had been 71.7ºC (161ºF) and 79.4ºC (175ºF), it would not have been possible to include both set points within a 6.7ºC (12ºF) span. With these set points the test would have to be done separately for each set point.

Corrective Action: If the response time exceeds four (4) seconds, the thermometer should be replaced or returned for repair.

TEST 8.

RECORDER/CONTROLLER - THERMOMETRIC RESPONSE

Reference: Item 16p.(B and E)
Application: To all continuous-flow pasteurizers, except those in which the FDD is located at the end of the cooler section.
Frequency: Upon installation and at least once each three (3) months thereafter.
Criteria: Five (5) seconds, under specified conditions.
Apparatus:
1. Stopwatch;
2. The indicating thermometer previously tested against a known accurate thermometer;
3. Water bath and agitator; and
4. Suitable means of heating the water bath.

Method: Measure the time interval between the instant when the recording thermometer reads 7ºC (12ºF) below the cut-in temperature and the moment of cut-in by the recorder/controller. This measurement is made when the sensing element is immersed in a rapidly agitated water bath maintained at 4ºC (7ºF) above the cut-in temperature.
Procedure:
1. 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 the pasteurization temperature.
2. Determine the cut-in temperature of the recorder/controller, either while in normal operation or by using a water bath. (See Test 10)
3. Remove the sensing element and allow it to cool to room temperature.
4. Heat the water bath to 4ºC (7ºF) above the cut-in temperature, while vigorously agitating the bath to insure a uniform temperature.
5. Immerse the recorder/controller bulb in the bath. Continue agitation during Procedures 6 and 7 below.
6. Start the stopwatch when the recording thermometer reaches a temperature of 7ºC (12ºF) below the cut-in temperature.

7. Stop the stopwatch when the recorder/controller cuts in.
8. Re-seal the regulatory controls as necessary and record the thermometric response time for office record.
Corrective Action: If the response time exceeds five (5) seconds, the recorder/controller should be repaired.

TEST 9.

REGENERATOR PRESSURE CONTROLS

Reference: Item 16p.(D and E)

9.1 PRESSURE SWITCHES

(Used to control the operation of the booster pump)

Application: To all pressure switches controlling the operation of a booster pump on HTST pasteurizer systems employing regenerators.
Frequency: Upon installation; each three (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 pneumatic testing device may be made from a discarded 50 millimeters (2 inches) - 7BX sanitary tee, with two (2) additional 13H nuts, one (1) 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 a 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 that may cause damage. This may 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 should 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 the adjustment of pressure switch 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:
1. Determine the maximum pressure of the booster pump.
    a. Install the sanitary pressure gauge in a tee at the discharge of the booster pump;

b. Operate the pasteurizer with water; with the FDD in forward-flow; the timing pump operating at the 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 timing pump, it should be bypassed while this determination is made.

c. Note the maximum pressure indicated by the pressure gauge under these conditions.

2. Check and set the pressure switch.

a. Install a sanitary pressure gauge of known accuracy on the pneumatic testing device to which the pressure switch sensing-element should also be connected.

b. Remove the seal and cover to expose the adjustment mechanism on the pressure switch.

c. 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.

d. 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 1. of this procedure. Where adjustment is necessary, refer to the manufacturer's instructions for the adjusting procedures. After adjustment, recheck the actuation point and readjust if necessary.

e. Replace the cover, seal the pressure switch and restore the sensing element to its original location.

f. Record the maximum booster pump pressure developed and the pressure switch setting for the office record.

9.2 DIFFERENTIAL PRESSURE CONTROLLER

Application: Test 9.2.1 applies to all differential pressure controllers used to control the operation of booster pumps on HTST systems, or used to control the operation of FDD's on HHST systems and aseptic processing systems, when a vacuum breaker is not located downstream from the holding tube.

Test 9.2.2 applies only to HTST systems.

Test 9.2.3 applies to the testing of HHST systems in which the differential pressure controller is used to control the operation of the FDD. Test 9.2.3 also applies to aseptic processing systems in which the differential pressure controller is used to control the FDD, product divert system, product divert valve or other acceptable control system.

Frequency: Upon installation; each three (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 FDD on HHST or aseptic processing systems, and improper pressure occurs in the regenerator, the FDD shall move to the diverted-flow position and remain in diverted flow until the proper pressures are re-established in the regenerator and all product-contact surfaces between the holding tube and FDD 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 in PRESSURE SWITCHES can be used for checking and adjusting the differential pressure switch setting. (See Test 9.1)
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 THE DIFFERENTIAL PRESSURE CONTROLLER PROBES

Procedure:
1. 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 the pointer(s), or the digital display(s), to read 0 kPa (0 psi).
2. 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 (2) 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 the 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 the pressure was applied. If not, the instrument requires adjustment or repair.
3. 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:
1. Connect the pasteurized pressure sensor to a testing tee with the other end of the tee capped.

NOTE: If there is water in the HTST system, ensure that the recorder/controller probe and the pasteurized sensor ports are capped before the timing pump is turned on.

2. Turn on the timing pump and the booster pump.
3. Place the recorder/controller probe in hot water, which is above the cut-in temperature.
4. Turn up the air supply on the tee to provide an adequate pressure differential to start the booster pump.
5. 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 FDD remains in the forward flow position and the timing pump continues to operate.
6. Reseal the regulatory controls as necessary and record the 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 FDD IN AN HHST SYSTEM; OR AN ACCEPTABLE ALTERNATIVE DEVICE, OR SYSTEM IN ASEPTIC PROCESSING EQUIPMENT

Application:
1. To all differential pressure controllers used to control the operation of FDD's on HHST systems when a vacuum breaker is not located downstream from the holding tube, and:
2. To all differential pressure controllers used to control the operation of FDD's, product divert systems, product divert valve(s) or other acceptable control systems used in aseptic processing equipment.

Apparatus: A sanitary pressure gauge and a pneumatic testing device, described in PRESSURE SWITCHES can be used for checking and adjusting the differential pressure switch setting. (See Test 9.1)

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 side" for purposes of this Test.

Procedure:
1. Wire the test lamp in series with the signal from the pressure differential switch to the FDD.
2. Calibrate the pressure switch and probes. (Use Test 9.2.1.)
3. 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.
   a. The test lamp should be lit. If not, increase the pasteurized or aseptic pressure, or lower the raw product pressure, until the test light is lit.
   b. Gradually lower the pasteurized or aseptic side, or raise the raw product pressure until the test light turns off.
   c. The test light should turn off when the pasteurized or aseptic pressure is at least 14 kPa (2 psi) higher than the raw product pressure.
   d. Note the differential pressure at the point the light turns off.
   e. Gradually raise the pasteurized or aseptic pressure, or lower the raw product pressure, until the test light turns on.
   f. The test light should not turn on until the pasteurized or aseptic pressure is at least 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.

4. Seal the instrument and record the Test results for the office record.

9.3 ADDITIONAL HTST TESTS FOR BOOSTER PUMPS - INTERWIRING

Application: To all booster pumps used for HTST systems.

Criteria: The booster pump shall be wired so it cannot operate if the FDD is in the diverted position or if the timing pump is not in operation.

Apparatus:

1. A sanitary pressure gauge and pneumatic testing device as described in Test 9.1 Pressure Switches;
2. Water bath and agitator;
3. Suitable means of heating the water bath.

9.3.1 BOOSTER PUMPS -INTERWIRED WITH FDD

Method: Determine if the booster pump stops by dropping the temperature and causing the FDD to divert.

Procedure:

1. Connect the pasteurized pressure sensor to a testing tee with the other end of the tee capped.

NOTE: If there is water in the HTST system, ensure that the recorder/controller probe and the pasteurized sensor ports are capped before the timing pump is turned on.

2. Turn on the timing pump and the booster pump.
3. Place the recorder/controller probe in hot water, which is above the cut-in temperature.
4. Turn up the air supply on the tee to provide an adequate pressure differential to start the booster pump.
5. Remove the recorder/controller probe from the hot water.
6. When the FDD moves to the diverted flow position, the booster pump must stop. Ensure that the pressure differential remains adequate and the timing pump continues to operate.
7. Reseal the regulatory controls as necessary and record the Test results for the office records.

Corrective Action: If the booster pump fails to stop when the FDD 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 TIMING PUMP

Method: Determine if the booster pump stops when the timing pump is off.

Procedure:

1. Connect the pasteurized pressure sensor to a testing tee with the other end of the tee capped.

NOTE: If there is water in the HTST system, ensure that the recorder/controller probe and the pasteurized sensor ports are capped before the timing pump is turned on.

2. Turn on the timing pump and the booster pump.
3. Place the recorder/controller probe in hot water, which is above the cut-in temperature.
4. Turn up the air supply on the tee to provide an adequate pressure differential to start the booster pump.
5. Turn off the timing pump. The booster pump must stop. Ensure that the pressure differential remains adequate and the FDD remains in the forward flow position.
6. Reseal the regulatory controls as necessary and record the Test results for the office record.

Corrective Action: If the booster pump fails to stop when the timing 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, C and E).
Milk-flow controls shall be tested for milk temperature at cut-in and cut-out by one (1) 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 FDD is located at the end of the cooler section.
Frequency: Upon installation; at least once each three (3) months thereafter by the Regulatory Agency; daily by the plant operator; or when a regulatory seal has been broken.
Criteria: No forward flow until the pasteurization temperature has been reached. Flow diverted before the temperature drops below the 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:
1. Cut-in temperature.
   a. 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 0.5ºC (1ºF) every thirty (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.
   b. Observe the indicating thermometer reading at the moment forward flow starts, i.e., the FDD moves. Observe that the frequency pen reading is synchronized with the recording pen on the same reference arc.
   c. Record the indicating thermometer reading on the recording thermometer chart and initial. The Regulatory Agency shall record Test findings.
2. Cut-out temperature.
   a. 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 0.5ºC (1ºF) per thirty (30) seconds. Observe the indicating thermometer reading at the instant forward flow stops.
   b. Re-seal the regulatory controls as necessary and record the indicating thermometer reading on the recording thermometer 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 recorder/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 "FDD" when it is referenced in this Test.
Frequency: Upon installation; every three (3) months thereafter; and whenever the thermal controller seal is broken.
Criteria: The pasteurizer or aseptic processor shall not operate in forward flow unless the pasteurization or aseptic processing temperature has been achieved. The product flow shall be diverted at a temperature 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 (2) sensing elements signal forward flow (cut-in) and diverted flow (cut-out).
Procedure:
1. Wire the test lamp in series with the control contacts of the holding tube sensing element. Immerse this sensing element in the constant temperature bath. Raise the bath temperature at a rate not exceeding 0.5ºC (1ºF) every thirty (30) seconds. Observe the temperature reading at the cut-in temperature. Record the temperature for the office record.
2. 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 0.5ºC (1ºF) per thirty (30) seconds. Observe the temperature reading on the thermal limit 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.
3. Repeat the procedure for the FDD sensing element. When proper cut-out temperature has been verified for both sensing elements, seal the thermal limit 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 "FDD" 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 the pasteurization or aseptic processing temperature has been achieved. The product flow shall be diverted at a temperature 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 (3) sensing elements signals forward flow (cut-in) and diverted flow (cut-out).

Procedure:
1. Wire the test lamp in series with the control contacts of the holding tube sensing element. Immerse this sensing element in the constant temperature bath. Raise the bath temperature at a rate not exceeding 0.5ºC (1ºF) every thirty (30) seconds. Observe the temperature reading on the thermal limit controller when the test lamp lights, cut-in temperature. Record the temperature for the office record.
2. 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 0.5ºC (1ºF) per thirty (30) seconds. Observe the temperature reading on the thermal limit 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.
3. Repeat the procedure for the other two (2) sensing elements, i.e., the vacuum chamber and the FDD. 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 (3) sensing elements, seal the thermal limit controller system.

TEST 11.

CONTINUOUS FLOW HOLDING TUBES - HOLDING TIME

Reference: Item 16p.(B, C and E)
Continuous flow holding tubes shall be tested for holding times by one (1) of the following applicable tests:

11.1 HTST PASTEURIZERS
(Except for magnetic flow meter based timing systems)

Application: To all HTST pasteurizers employing a holding time of fifteen (15) seconds or longer.
Frequency: Upon installation; semi-annually 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 the replacement of the pump, motor, belt, drive or driven pulleys, or a decrease in the number of HTST plates or the capacity of holding tube; or whenever a check of the capacity of the holding tube indicates a speedup.
Criteria: Every particle of milk shall be held for at least fifteen (15) seconds in both the forward- and diverted-flow positions.
Apparatus:
1. Electrical conductivity measuring device, which is capable of detecting change in conductivity and equipped with standard electrodes;
2. Table salt;
3. A suitable apparatus for injecting the salt solution;
4. An accurate timing device.

Method: The holding time is determined by timing the interval for an added trace substance to pass through the holding tube. 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:

1. 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.
2. Adjust the variable speed pump to its maximum capacity, preferably with a new belt and full size impellers. Check the homogenizer for seals, and/or gears or pulley identification. Check the AC variable speed timing pump control box for seals. For systems that employ a liquid ingredient injection (slurry) system as described in Appendix Section H, the slurry pump must be energized and running at its maximum speed and the slurry supply tank must be completely filled with water.
3. Install one (1) electrode at the inlet to the holding tube and the other electrode in the holding tube outlet.
4. Operate the pasteurizer, using water at pasteurization temperature, with the FDD in the forward-flow position.
5. Quickly inject saturated sodium chloride solution into the holding tube inlet.
6. The timer should start when it detects a change in conductivity and the beginning of the holding tube.
7. The timer should stop when it detects a change in conductivity and the end of the holding tube.
8. Record the results.
9. Repeat the test six (6) or more times, until six 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 this Test. Should consistent readings not be obtained, use the fastest time as the holding time for water.
10. Repeat Procedures 4 through 9 for the holding time on water in diverted flow.

For all gear driven timing pumps; or for those homogenizers used as timing pumps, when the measured holding time for water is less than 120% of the legal holding time, complete Procedures 11, 12 and 13. For those homogenizers used as timing pumps, when the measured holding time for water is 120% or more of the legal holding time Procedure 11 is optional and 12 and 13 are not required.

11. With the pump at the same speed and all other equipment adjusted as in Procedure 1, 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.)
12. Repeat Procedure 11 using milk.
13. Compute the holding time for milk from one (1) of the following formulas, either by volume or by weight. Compute separately for forward flow and diverted flow. Re-seal the regulatory controls as necessary.

BY VOLUME

The holding time for milk is equal to the holding time for water; times the 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.

$$Tm = Tw(Vm/Vw)$$

Where: 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.

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 the 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.

$$Tm = 1.032xTw(Wm/Ww)$$

Where: 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 a measured weight of milk.
Ww = Time, usually in seconds, that it takes to pump the same measured weight of water.

14. Record the 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 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 FDD. Governors shall be sealed on motors that do not provide a constant speed as provided in Item 16p.(B)5.b.

11.2A MAGNETIC FLOW METER BASED TIMING SYSTEMS CONTINUOUS FLOW - HOLDING TIME

Application: To all HTST pasteurizers with a magnetic flow meter based timing system, used in lieu of a timing 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:

1. Electrical conductivity measuring device, which is capable of detecting change in conductivity and equipped with standard electrodes;
2. Table salt;
3. A suitable apparatus for injecting the salt solution;
4. An accurate timing device.

Method: The holding time is determined by timing the interval for an added trace substance to pass through the holding tube.

Procedure:

1. 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 as to provide the minimum resistance to the flow.
2. Adjust the set point on the flow alarm to its highest possible setting.
3. Adjust the set point on the flow recorder/controller to a flow rate estimated to yield an acceptable holding time.
4. Install one (1) electrode at the inlet to the holding tube and the other electrode at the holding tube outlet.
5. Operate the pasteurizer, using water, above the pasteurization temperature, with the FDD in forward-flow.
6. Quickly inject the saturated sodium chloride solution into the holding tube inlet.
7. The timer should start when it detects a change in conductivity and the beginning of the holding tube.
8. The timer should stop when it detects a change in conductivity and the end of the holding tube.
9. Record the results.
10. 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 the instruments and connections; and check for air leakage on the suction side of the pump, located at the raw product supply tank. Repeat this Test. If six (6) consecutive readings cannot be achieved within 0.5 seconds of each other, the pasteurizing system is in need of repair.
11. With the flow recorder/controller at the same set point as in Procedure 3, 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 the 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. This procedure is not a required Test; it is at the option of the Regulatory Agency.
12. Re-seal the 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, the set point on the flow recorder/controller shall be decreased, or an adjustment made in the holding tube, and the timing test repeated until a satisfactory holding time is achieved.

11.2B CONTINUOUS FLOW HOLDING TUBES - FLOW ALARM

Application: To all continuous flow pasteurization and aseptic processing systems using a magnetic flow meter based timing system to replace a timing pump. When testing aseptic processing systems, the "product divert system" or "product divert valve" or "acceptable control system" may be substituted for the "FDD" 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 FDD to assume the diverted position, even though the temperature of the milk in the holding tube is above the 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 Procedure 3 or 4 of this Test).
Procedure:
1. 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.
2. Adjust the set point on the flow alarm slowly downward until the frequency pen on the flow recorder/controller indicates that flow has been diverted.

NOTE: When performing this Test on systems that operate above the boiling point of water, be sure that the system is cooling to avoid the possibility of serious burns.

3. Observe that the FDD moved to the diverted position, while water passing through the holding tube remained above the pasteurization or aseptic processing temperature.
4. Re-seal the 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 FDD does not move to the diverted position, when the frequency pen of the recorder/controller indicates a diversion, a modification or repair of the control wiring is required.

11.2C CONTINUOUS FLOW HOLDING TUBES - LOW FLOW/LOSS-OF-SIGNAL ALARM

Application: To all continuous flow pasteurization and aseptic processing systems using a magnetic flow meter based timing system to replace a timing pump. When testing aseptic processing systems, the "product divert system" or "product divert valve" or "acceptable control system" may be substituted for the "FDD" 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/controller and the position of the FDD.

Procedure:

1. Operate the pasteurizer or aseptic processing equipment in forward flow, at a flow rate below the flow alarm set point and above the low flow/loss-of-signal alarm set point, using water.
2. Disrupt power to the magnetic flow meter or decrease the flow through the flow meter below the low flow/loss-of-signal alarm set point. Observe that the FDD and both the safety thermal limit recorder/controller frequency pen and the flow rate frequency pen assume the diverted flow position.
3. Re-seal the regulatory controls as necessary and record the results for the office record.

Corrective Action: If the valve does not divert or the pens do not move, adjustment of the low flow/loss-of-signal alarm or a modification or repair of the control wiring is required.

11.2D CONTINUOUS FLOW HOLDING TUBES - FLOW OUT-IN AND CUT-OUT

Application: To all HTST pasteurizers using a magnetic flow meter based timing system to replace a timing 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 low flow/loss-of-signal alarm set point.

Apparatus: None.

Method: By observing the recorder/controller readings along with the action of the frequency pen on the recorder/controller.

Procedure:

1. Operate the pasteurizer in forward flow, at a flow rate below the flow alarm set point and above the low flow/loss-of-signal alarm set point, using water above the pasteurization temperature.
2. Using the flow recorder/controller, increase the flow rate slowly until the frequency pen on the recorder/controller indicates a flow diversion, flow cut-out point. The FDD will also assume the diverted position. Observe the reading of flow rate from the recorder/controller at the instant flow cut-out occurs, as indicated by the frequency pen.
3. With the pasteurizer operating on water, above the pasteurization temperature, and with the FDD diverted because of excessive flow rate, slowly decrease the flow rate until the frequency pen on the flow recorder/controller indicates the start of a forward flow movement, flow cut-in point. Because of the time delay relay described in Test 11.2, the FDD will not move immediately to the forward flow position. Observe the reading from the recorder/controller at the instant flow cut-in occurs, as indicated by the frequency pen.
4. Re-seal the regulatory controls as necessary and record the 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 HOLDING TUBES - TIME DELAY RELAY

Application: To all HTST pasteurizers using a magnetic flow meter based timing system to replace a timing 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 Test 11.2D, 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 the time delay equal to or greater than the minimum holding time.
Procedure:
1. Operate the pasteurizer in forward flow, at a flow rate below the flow alarm set point and above the low flow/loss-of-signal alarm set point, using water above the pasteurization temperature.
2. Using the flow recorder/controller, increase the flow rate slowly until the frequency pen on the flow recorder/controller indicates a diversion movement and the FDD moves to the diverted position. There shall be no time delay between the movements of the frequency pen and the FDD.
3. With the pasteurizer operating on water, above the pasteurization temperature, with the FDD diverted because of excessive flow rate, slowly decrease the flow rate.
4. Start the stopwatch the instant the frequency pen on the flow recorder/controller indicates the start of a forward flow movement.
5. Stop the stopwatch the instant the FDD starts to move to the forward flow position.
6. Record the results for the office record.
7. Install and seal the 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 Test 11.2E.

11.3 CALCULATED HOLD FOR INDIRECT HEATING

Application: To all HHST pasteurizers using indirect 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, i.e., replacement of the 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 the 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 value

in Table 13. to determine the required holding tube length. Holding tube lengths for HHST pasteurizers with indirect heating for a pumping rate of 1 gallon/second are:

Table 13. Holding Tube Length - HHST Pasteurizers - Indirect Heating

Holding Time (sec.)	Tubing Size (inches)				
	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

Procedure:

1. 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 resistance to the flow. Remove in-line filters; make sure the booster pump is operating and that vacuum equipment in the system is operating at the 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 fifteen (15) minutes, and tighten the pipe connections on the suction side of the timing pump, tight enough to exclude the entrance of air. With the pasteurizer operating on water, adjust the timing pump to its maximum capacity, preferably with a new belt and full-size impellers.
2. 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 determine that the measurements are consistent.
3. Repeat Procedures 1 and 2 in diverted flow by collecting the effluent at the discharge of the divert line.
4. 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. Multiply this value with the appropriate value in Table 13 to determine the required holding tube length.
5. The holding tube my include fittings. The centerline length of the fitting is treated as an equivalent length of straight pipe. The centerline distance may be measured by forming a flexible steel tape along the centerline of the fitting. Determine the total length of the holding tube by adding the equivalent lengths of the fittings to the measured lengths of straight 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.
6. Re-seal the regulatory controls as necessary.

Alternate Procedure for Measuring Flow Rate: 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 constant level tank and turn off the product pump feeding the constant level tank. Suspend a sanitary dipstick in the constant level

tank and operate the pasteurizer at maximum capacity. Record the time required for the water level to move between two (2) graduations on the dipstick. The volume of water is calculated from the dimensions of the constant level tank and the drop in water level. Flow rate is determined as follows: Divide the volume of water removed from the constant level tank by the time, in seconds, required to remove it. Then use Table 13. to calculate the required holding tube length.

Alternate Procedures for Determination of Holding Tube Length for Non-Standard Pipe Size: Alternatively, if the holding tube is of non-standard pipe sizes, the holding tube length may be accurately calculated from the following equation:

$$L = 588\ Qt/D^2$$

Where: L = Holding tube length (inches)
Q = Pumping rate (gallons per second)
t = Holding time standard (seconds)
D = Inside diameter of holding tube (inches)

After the minimum required holding tube length is obtained from the calculation above, the length of the holding tube is measured to determine that it is at least as long as the calculated length. The holding tube may include fittings or, for the shorter holding times, may be a fitting. The centerline length of the fitting is treated as an equivalent length of straight pipe. The centerline distance may be measured by forming a flexible steel tape along the centerline of the fitting.

Corrective Action: If the length of the holding tube is shorter than the calculated length, reseal the timing pump at a slower maximum speed, or lengthen the holding tube, or both, and repeat this Procedure.

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, i.e., replacement of pump, motor, belt, driver or driven pulley, or a 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.

Criteria: Every particle of product shall be held for the minimum holding time in both forward and diverted flow positions.

Apparatus: No supplemental materials needed.

Method: Fully developed laminar flow and a temperature increase by steam injection of 67ºC (120ºF) are assumed, the processor chooses the temperature-time standard and the required holding tube length is calculated from an experimental determination of the pumping rate.

Procedure:

1. 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 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 fifteen (15) minutes, and tighten the pipe connections on the suction side of the timing pump to exclude the entrance of air. With the pasteurizer operating on water, adjust the timing pump to its maximum capacity.

2. 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 to determine that the measurements are consistent.

3. Repeat Procedure 1 and 2 in diverted flow by collecting the effluent at the discharge of the divert line.

4. 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. Multiply this value with the appropriate value in Table 15. to determine the required holding tube length. Holding tube lengths for direct contact heating pasteurizers with a pumping rate of 1 gallon/second are:

Table 14. 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	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	9.40	5.90	4.0
0.01	8.10	3.36	1.88	1.18	0.8

5. The holding tube my include fittings. The centerline length of the fitting is treated as an equivalent length of straight pipe. The centerline distance may be measured by forming a flexible steel tape along the centerline of the fitting. 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. If the temperature sensor is located at the beginning of the holding tube, the holding tube shall also be protected against heat loss by material that is impervious to water.

6. Re-seal the regulatory controls as necessary.

Alternate Procedure for Measuring Flow Rate: 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 constant level tank and turn off the product pump feeding the constant level tank. Suspend a sanitary dipstick in the constant level tank and operate the pasteurizer at maximum capacity. Record the time required for the water level to move between two graduations on the dipstick. The volume of water is calculated from the dimensions of the constant level tank and the drop in water level. Flow rate is determined as follows: Divide the volume of water, in gallons, removed from the constant level tank by the time, in seconds, required to remove it. Then use Table 15. to calculate the required holding tube length.

Alternate Procedures for Determination of Holding Tube Length for Non-Standard Pipe Size: Alternatively, if the holding tube is of non-standard pipe sizes, the holding-tube length may be accurately calculated from the following equation:

$$L = (588\ Qt \times 1.12)/D^2$$

Where: L = Holding-tube length (inches)
Q = Pumping rate (gallons per second)
t = Holding time standard (seconds)
D = Inside diameter of holding tube (inches).
1.12 = 12% expansion for steam

After the minimum required holding tube length is obtained from the calculation above, the length of the holding tube is measured to determine that it is at least as long as the calculated length. The holding tube may include fittings or, for the shorter holding times, may be a fitting. The centerline length of the fitting is treated as an equivalent length of straight pipe. The centerline distance may be measured by forming a flexible steel tape along the centerline of the fitting.

Corrective Action: If the length of the holding tube is shorter than the calculated length, reseal the timing 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 PRESSURE RELIEF 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; every three (3) months thereafter; or when a regulatory seal has been broken.

Criteria: Every particle of product shall be held for the minimum holding time in both forward and diverted flow positions.

Apparatus: No supplemental materials needed.

Method:

1. The steam infuser shell or feed line shall be equipped with a pressure relief 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.
2. 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 ensure a minimum product residence time at least as long as that specified in the chosen HHST standard.
3. The size of the opening in the orifice or restriction and the setting of the 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.

4. The Regulatory Agency 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:

1. 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 as to provide the minimum resistance to the flow.
2. The steam pressure in the infuser shall be raised to a level just below the pressure relief point on the valve.
3. Any back-pressure valves or other variable restrictions in the holding tube shall be normally placed into the fully open position.
4. All air bleeds to the vacuum chamber shall be closed so that the chamber will be operating under maximum vacuum.
5. Before the tests are begun, operate the pasteurizer at maximum flow for a sufficient time to purge the air from the system, about fifteen (15) minutes, and tighten the pipe connections to exclude the entrance of air.
6. 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.
7. Repeat the Test to determine that the measurements are consistent.
8. Repeat Procedures 1 through 5 in diverted flow by collecting the effluent at the discharge of the divert line.
9. 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.
10. Multiply this value, gallons per second, with the appropriate value in Table 15. to determine the required holding tube length.
11. Holding tube lengths for direct contact heating pasteurizers with a pumping rate of 1 gallon/second are specified in Table 13.
12. 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 14. Determine the total length of the holding tube by adding the equivalent lengths of the fittings to the measured lengths of straight pipe.
13. Make sure that the holding tube slopes upward at least 6.35 millimeters (0.25 inch) per foot.
14. If the temperature sensor is located at the beginning of the holding tube, the holding tube shall also be protected against heat loss by material that is impervious to water.
15. 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.
16. Re-seal the regulatory controls as necessary.

Corrective Action: If the length of the holding tube is shorter than the calculated length, reseal the timing pump at a slower maximum speed, or lengthen the holding tube, or both, and repeat the Procedure.

TEST 12.

THERMAL LIMIT CONTROLLER FOR CONTROL - SEQUENCE LOGIC

References: Items 16p.(B) and 16p.(E)
Thermal limit controllers used with HHST and aseptic processing systems that have the FDD located downstream from the regenerator and/or cooler shall be tested by one (1) of the following applicable tests at the frequency prescribed:

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 "FDD" when it is referenced in this Test.
Frequency: Upon installation; 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. Upon start up, surfaces shall be exposed to fluid at pasteurization temperature, 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 re-achieved until the product surfaces downstream from the holding tube have been re-sanitized, or in the case of aseptic processing equipment, resterilized.
Apparatus: A constant temperature bath of water, or oil, and the test lamp from the pneumatic testing device described in Test 9.1 may 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 (2) sensing elements from a bath heated above the cut-in temperature.
Procedure:
1. Heat the 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 FDD. Some processors may have time delays built into their control logic in excess of that required for public health reasons. If so equipped, by-pass these timers or account for their effect in delaying forward flow.
2. Immerse the sensing element of the FDD 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.
3. 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 one (1) second for continuous flow pasteurization systems. For aseptic processing systems no delay is required if the filed process includes a documented sterilization period.
4. Remove the sensing element of the FDD from the bath. The test lamp should remain lighted, i.e., forward flow.

5. Remove the holding tube sensing element from the bath. The test lamp should turn off immediately, i.e., diverted flow.
6. Re-immerse the sensing element of the holding tube in the bath. The test lamp should remain unlighted, i.e., diverted flow.
7. Re-seal the regulatory controls as necessary.
Corrective Action: If the control-sequence logic of the thermal limit controller does not follow these Procedures, the instrument shall be reconfigured 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 "FDD" when it is referenced in this Test.
Frequency: Upon installation; 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. Upon start up, surfaces shall be exposed to fluid at pasteurization temperature, 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 re-achieved 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 (3) sensing elements from a bath heated above the cut-in temperature.
Procedure:
1. 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 FDD. Some processors have time delays built into their control logic, in excess of that required for public health reasons. If so equipped, 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.
2. Immerse the sensing element from the FDD in the bath that is above the cut-in temperature. The test lamp should remain unlighted, i.e., diverted flow. Remove this sensing element from the bath.
3. 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.
4. Immerse the two (2) sensing elements located at the vacuum chamber and the FDD, into the bath. The test lamp should remain unlighted, i.e., diverted flow. Leave the two (2) sensing elements in the bath.

5. Immerse the third sensing element located at the holding tube, into the bath. The test lamp should light up, i.e., forward flow, after a minimum time delay of one (1) second for continuous flow pasteurization systems. For aseptic processing systems no delay is required if the filed process includes a documented sterilization period.
6. Remove the FDD sensing element from the bath. The test lamp should remain lighted, i.e., forward flow.
7. Remove the vacuum chamber sensing element from the bath. The test lamp should remain lighted, i.e., forward flow.
8. Remove the remaining, holding tube, sensing element from the bath. The test lamp should turn off, i.e., diverted flow, immediately.
9. Re-immerse the holding tube sensing element into the bath. The test lamp should remain unlighted, i.e., diverted flow.
10. Re-seal the regulatory controls as necessary.
Corrective Action: If the control-sequence logic of the thermal limit controller does not follow these Procedures, the instrument shall be reconfigured to conform to this logic.

TEST 13.

SETTING OF CONTROL SWITCHES FOR PRODUCT PRESSURE IN THE HOLDING TUBE

Reference: Item 16p.(B) and 16p.(E)
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 "FDD" 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:
1. From Figure 44. 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.
2. 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.

3. Apply air pressure to the sensing element and determine the pressure gauge reading at the cut-in point of the switch, which should turn on the test lamp. (If the pressure switch is short circuited, the lamp will be lit before air pressure is applied.)
4. Determine that the cut-in pressure on the switch is equivalent to or greater than the required pressure from Figure 44. If adjustment is necessary, refer to the manufacturer's instructions.
5. After adjustment, repeat the Procedure.
6. When the results are satisfactory, seal the pressure switch setting and record the results for the office record.

For each HHST pasteurizer or aseptic processing system temperature, the product pressure switch setting is as follows:

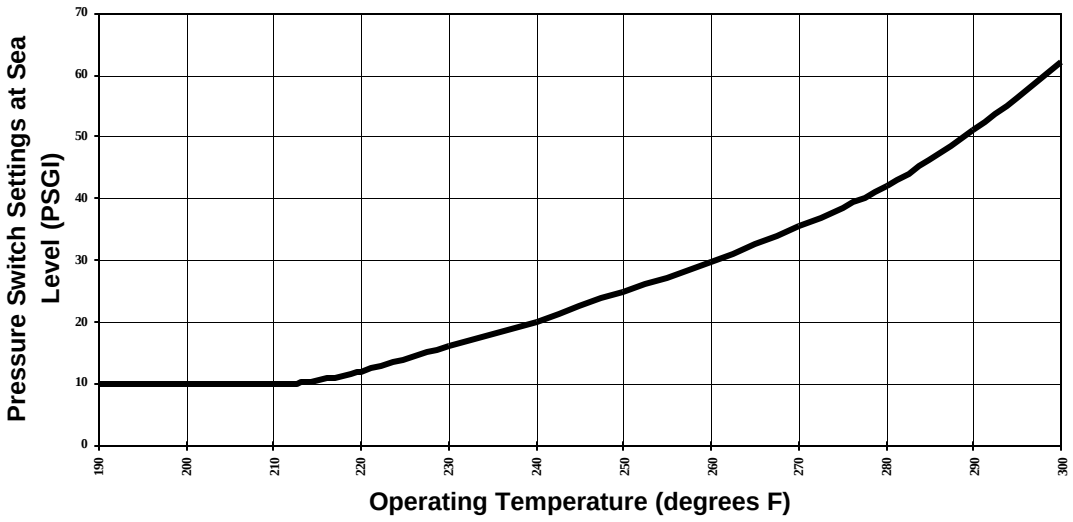


Figure 44. Pressure Switch Setting

This pressure setting shall be adjusted upward by the difference between local normal atmospheric pressure and sea level.

TEST 14.

SETTING OF CONTROL SWITCHES FOR DIFFERENTIAL PRESSURE ACROSS THE INJECTOR

Reference: Item 16p(B) and 16p(E)
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 "FDD" when it is referenced in this Test.
Frequency: Upon installation; every three (3) months thereafter; and whenever the differential pressure controller seal is broken.
Criteria: The pasteurizer or aseptic processor shall not operate in forward flow unless the product pressure drop across the injector is at least 69 kPa (10 psi).

Apparatus: A sanitary pressure gauge and a pneumatic testing device described in Test 9.1 can be used for checking and adjusting the differential pressure controller.
Method: Adjust the differential pressure switch to prevent forward flow, unless the differential pressure across the injector is at least 69 kPa (10 psi).
Procedure:
1. 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, which is installed prior to the steam injection, on the pneumatic testing device.
2. 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.
3. Wire the test lamp in series with the differential controller microswitch or use the method provided by the instrument manufacturer to monitor the cut-in signal.
4. Apply air pressure to the sensing element and determine, from the test lamp, the pressure gauge reading at the cut-in point of the differential pressure switch.
5. The differential pressure cut-in on the controller shall be at least 69 kPa (10 psi). If adjustment is necessary, refer to the manufacturer's instructions.
6. After adjustment, repeat the Procedure.
7. When the results are satisfactory, seal the instrument and record the results for the office record.

TEST 15.

ELECTRO MAGNETIC INTERFERENCE FROM HAND-HELD COMMUNICATION DEVICES

Application: To all electronic controls used to assure compliance with public health safeguards on pasteurization and aseptic processing equipment that are installed in milk plants where hand-held communication devices are used.
Frequency: Upon installation; alteration of the electronic controls; every three (3) months thereafter; and whenever the type or wattage of the hand-held communication device(s) used in that facility is changed.
Criteria: The use of hand-held devices shall have no adverse effect on the public health safeguards.
Apparatus: One (1) hand-held device representing each make and model used in the facility. The device must be operating at maximum output, fully charged.
Method: By observing the actual effect of the hand-held communication device, it can be determined if that device can be used near that equipment without compromising a public health safeguard.
Procedure:
1. Position the hand-held communication device 30.5 centimeters (12 inches) in front of the electronic control where the public health safeguard resides.
2. Place the communication device in the “send” mode for five (5) seconds and observe the effect on the public health safeguards. There should be no adverse effect. An adverse effect is any change that may adversely affect a public health safeguard.
3. If applicable, repeat the Procedure with the operator access door open

4. Repeat the above Procedures for each hand-held communication device identified in the Apparatus Section.
5. Repeat the Procedure for each electronic control used to regulate a pasteurization or aseptic processing public health safeguard.

> **For Example:** For a temperature set point, operate the pasteurizer or aseptic processor on water in diverted flow in the "Product" mode, at a steady temperature within 5ºF of the lowest cut-in temperature. In this example, an adverse effect is defined as forward-flow movement of the FDD or any artificial increase in temperature.

Corrective Action: Have the facility check for shielding, grounding and other installation concerns and retest. Until a solution, acceptable to the Regulatory Agency, can be found that does not adversely affect the public health safeguards, the hand-held device may not be used in the area of the public health safeguards.

APPENDIX J. STANDARDS FOR THE FABRICATION OF SINGLE-SERVICE CONTAINERS AND CLOSURES FOR MILK AND MILK PRODUCTS

PREFACE

Single-service containers and closures have been used in the dairy industry for many years. Industry applied quality assurance controls for manufacturing and handling of the materials have made it possible for these products to reach the point of use in a sanitary condition free from toxic materials, which may migrate into milk or milk products.

Within recent years, single-service container manufacturers have introduced new materials, equipment, and design concepts for these containers and closures. Evaluation of the industry's basic manufacturing and handling techniques and establishment of sanitation criteria assure that single-service containers and closures and the materials from which they are formed are safe and in compliance with bacteriological standards of Item 12p. of this *Ordinance.*

STANDARDS FOR THE FABRICATION OF SINGLE-SERVICE CONTAINERS AND CLOSURES FOR MILK AND MILK PRODUCTS

A. PURPOSE AND SCOPE

The use of these standards will ensure the production of sanitary containers and closures for milk and milk products, as defined in this *Ordinance*.

These standards shall apply to all blank fabricators, converters, printers, closure manufacturers, plastic laminators, sheet formers, blow molders, vacuum formers, plastic extruders, injection molders, preformers, manufacturers of valves, tubes, dispensing devices, and sample containers and similar plants. These also apply to the installation, operation, cleaning, sanitization and maintenance of equipment used in compounding materials for the fabrication, production, handling and storage of single-service containers and closures.

Milk and food plants manufacturing and/or selling containers to other milk or milk products plants as defined in this *Ordinance* shall meet all the requirements of these standards. These requirements shall not apply to paper mills or resin manufacturing plants.

Grade “A” milk and milk product plants as defined in this *Ordinance* shall use single-service containers and closures from plants certified in the latest semi-annual publication of the *Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers* (IMS List).

B. DEFINITIONS

The following definitions shall be employed in the application of these sanitation standards:

1. "Single-Service Container" shall mean any container having a milk or milk product-contact surface and used in the packaging, handling or storage of Grade “A” milk and milk products which is intended for one use only.
2. "Closure" shall mean a cap, lid, seal, tube, valve, lid material or other device in or on a container used for the purpose of enclosing or dispensing the contents.

3. "Paper Stock" shall mean any paper made from the following materials:
   a. Paper and paperboard manufactured from clean, sanitary virgin chemical or mechanical pulp or from "broke and trim" of such paper and paperboard, provided they have been handled, treated and stored in a clean, sanitary manner, or reclaimed fiber using acceptable or approved protocol in compliance with 21 CFR 176.260; and
   b. Components meeting the requirements of the FFD&CA as amended.
4. "Broke and Trim" shall mean paper and paperboard that have been discarded anywhere in the process of manufacture, such as on paper-making machines in the form of trim. This may also include unprinted trim from the converting process, provided the trim has been handled, treated and transported in a clean, sanitary manner.
5. "Plastic Molding, Forming, Extrusion, and Laminating Resins" shall mean:
   a. Resins or an intimate admixture of resins with other ingredients which meet the requirements of the FFD&CA as amended; and
   b. Plastic composed solely of clean cuttings or regrind, provided they have been handled and maintained in a clean, sanitary manner.

This definition shall not preclude the use of recycled plastic material when it complies with a protocol that has been reviewed and accepted by FDA.

6. "Regrind" shall mean clean plastic material, that is trimmed from the container or closure, and imperfectly formed containers or closures, which result from the manufacture of single-service containers and closures, provided it is handled in a clean, sanitary manner. This may be in its trimmed or molded form and ground in a suitable grinder within the plant. It shall not include any material, container or closure which comes from an unapproved source or whose source, chemical content or treatment is unknown, or which may have poisonous or deleterious material retained in the plastic, which migrates to the food at levels exceeding regulatory levels. Regrind, when transported from one (1) approved plant to another, will be shipped in suitable, clean, sealed, properly labeled containers. This definition shall not preclude the use of regrind plastic material when it complies with a protocol that has been reviewed and accepted by FDA.
7. "Production Scrap" shall mean material which remains from the manufacture of single-service containers or closures, that has been handled or treated in such a manner that it does not comply with the definition for "broke and trim" or "regrind", but may be collected for recycling. It may contain material such as containers or trim that have fallen on the floor.
8. "Coatings" shall mean any layer or covering which is applied to the product-contact surface.
9. "Product-Contact Surface" shall mean those surfaces of the container or closure that the product comes in contact with.
10. "Nontoxic Materials" shall mean materials that are free of substances, which may render the milk injurious to health or which may adversely affect the flavor, odor, composition or bacteriological quality of the product and meet the requirements of the FFD&CA as amended.
11. "Metals" shall mean those metals that are nontoxic, nonabsorbent and corrosion-resistant under conditions of intended use.
12. "Sanitization" shall mean the application of any effective method or substance to a clean surface for the destruction of pathogens and of other microorganisms as far as is practicable. Such treatment shall not adversely affect the equipment, the milk or milk product, or the health of consumers. Chemical sanitizers shall meet the requirements contained in Part I of Appendix F of this *Ordinance*.

13. "Single-Service Articles" shall mean articles that are constructed wholly, in part, or in combination from paper, paperboard, molded pulp, plastic, metals, coatings or similar materials and intended by the manufacturer for one (1) usage only.
14. "Preformed Container" shall mean a container in completed form ready for filling.
15. "Manufacturer" shall mean any person or company in the business of manufacturing a single-service container or closure for use by a milk plant for the packaging of a finished Grade "A" milk or milk product.
16. "Component Part" shall mean any item that by itself, does not perform any function, but when assembled with one (1) or more component parts or closures, becomes a part of the single-service container or closure. These may include, but are not limited to blanks, sheeting, filling valve parts, tubes, dispensing devices and sampling containers. All material used for fabrication of a component part must meet the requirements of the FFD&CA as amended.
17. "Sample Set" shall mean:
    a. For the rinse test, a minimum of four (4) containers shall be tested.
    b. For the swab test, a minimum of four (4), 50 square centimeter areas of surface from separate containers shall be tested. In the case of containers or closures with a product-contact surface area smaller than 50 square centimeters, more than four (4) containers or closures to equal at least 50 square centimeters times four (4) will be required to be swabbed.
18. "Manufacturing Line" shall mean a manufacturing process such as extrusion, blow-mold, etc.

C. BACTERIAL STANDARDS AND EXAMINATION OF SINGLE-SERVICE CONTAINERS AND CLOSURES

1. Paper stock shall meet the bacteriological standard of not more than two hundred fifty (250) colonies per gram as determined by the disintegration test. The paper stock supplier shall certify that their paper stock was manufactured in compliance with this Standard. This applies only to the paper stock prior to lamination.
2. Where a rinse test can be used, the residual microbial count shall not exceed fifty (50) per container, except that in containers less than 100 mL, the count shall not exceed ten (10), or not over fifty (50) colonies per 8 square inches (1 per square centimeter) of product-contact surface when the swab test is used, in three (3) out of four (4) samples taken at random on a given day. All single-service containers and closures shall be free of coliform organisms.
3. During any consecutive six (6) months, at least four (4) sample sets shall be collected in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days, and analyzed at an Official, Commercial or Industry Laboratory approved by the State Milk Laboratory Certifying Agency specifically for the examinations required under these Standards. (See Item 12p. of this *Ordinance* for sampling of containers and closures in pasteurization plants).
4. When a single-service container or closure is made from one (1) or more component parts as defined in this document, only those final assembled products that may have product-contact surface(s), must be sampled and tested for compliance with Section C.

Procedures for obtaining samples and for the laboratory examination of these products are contained in the latest edition of SMEDP and shall be in substantial compliance with these methods. Such procedures and examinations shall be evaluated in accordance with the current revision of the EML. A list of approved laboratories may be found in the IMS List which is published semiannually by FDA.

D. FABRICATION PLANT STANDARDS

NOTE: To be used in conjunction with Form FDA 2359c, "Single-Service Manufacturing Plant Inspection Report" (See Appendix M.)

1. FLOORS

a. The floor shall be smooth, impervious, and maintained in a state of good repair.

b. The joints between the walls and floor shall be tight, impervious and shall have coved or sealed joints.

c. Where floor drains are provided, they shall be properly trapped and floors sloped to drain.

2. WALLS AND CEILINGS

a. Walls and ceilings of fabricating areas shall have a smooth, cleanable, light-colored surface.

b. Walls and ceilings in fabricating and storage areas shall be kept in good repair.

3. DOORS AND WINDOWS

a. All outside openings shall be effectively protected against the entry of insects, rodents, dust and airborne contamination.

b. All outer doors shall be tight and self-closing.

4. LIGHTING AND VENTILATION

a. All rooms shall be adequately lighted either by natural light, artificial light, or both. A minimum of twenty (20) foot-candles should be maintained in fabricating areas and five (5) foot-candles in storage areas. Packaging, sealing, wrapping, labeling and similar procedures are considered part of the fabricating area.

b. Ventilation shall be sufficient to prevent excessive odors and the formation of excessive water condensation.

c. The intake of all pressure ventilation systems in fabricating areas, whether they are positive or exhaust shall be properly filtered.

5. SEPARATE ROOMS

a. All fabricating areas shall be separate from non-fabricating areas to protect against contamination. Provided, that if the entire plant meets all sanitation requirements and no source of cross contamination exists, separation between areas is not required.

b. All regrinding of plastic and the shredding, packaging or baling of paper trim shall be conducted in rooms separate from the fabricating room, except that they may be conducted within a designated area of the fabricating room, provided such operations are kept clean and free of dust.

6. TOILET FACILITIES - SEWAGE DISPOSAL

a. Disposal of sewage and other wastes shall be in a public sewage system or in a manner in compliance with Local and State regulations.

b. All plumbing shall comply with the Local and State plumbing regulations.

c. Toilet rooms shall have solid, self-closing doors and shall not open directly into fabricating areas.

d. The toilet room and fixtures shall be maintained in a clean and sanitary condition and kept in good repair.

e. Each toilet room shall be well lighted and adequately ventilated. Air ventilation ducts from toilet facilities shall vent to the outside.

f. Proper handwashing facilities shall be provided in toilet rooms.

g. All windows shall be effectively screened when open.

h. Signs shall be posted in all toilet rooms reminding employees to wash their hands before returning to work.

i. Eating and/or storage of food are prohibited in toilet rooms.

7. WATER SUPPLY

a. The water supply, if from a public system, shall be approved as safe by the State Agency responsible for water quality, and in the case of individual water systems, comply with at least the specifications outlined in Appendix D of this *Ordinance***.**

b. There shall be no cross-connection between a safe water supply and any unsafe or questionable water supply or any source of pollution through which the safe water supply might become contaminated.

c. Samples for bacteriological testing of individual water supplies are taken upon the initial approval of the physical structure; each twelve (12) months thereafter; and when any repair or alteration of the water supply system has been made. The examination of the sample shall be conducted in an officially designated laboratory.

8. HANDWASHING FACILITIES

a. Hot and cold and/or warm running water, soap, air dryers or individual sanitary towels shall be convenient to all fabricating areas. Provided, that solvent or soft soap dispensers, containing sanitizers, may be used if water is not available. When individual sanitary towels are used, covered trash containers shall be provided.

b. Handwashing facilities shall be kept clean.

9. PLANT CLEANLINESS

a. The floors, walls, ceilings, overhead beams, fixtures, pipes and ducts of production, storage, regrind, baling and compacting rooms shall be clean.

b. All production areas, warehouse, toilet, lunch and locker rooms shall be free of evidence of insects, rodents, and birds.

c. Machines and appurtenances shall be kept clean. Provided, that minor accumulations of paper, plastic or metal dust and other production soils incidental to normal fabricating operations do not violate this requirement.

10. LOCKER AND LUNCHROOMS

a. Locker and lunchrooms shall be separate from plant operations and be equipped with self-closing doors.

b. Eating and/or storage of food are prohibited in fabricating and storage areas.

c. Locker and lunchrooms shall be kept in a clean and sanitary condition.

d. Cleanable refuse containers, properly labeled, shall be provided, which are covered, impervious, leak-proof and readily accessible.

e. Proper handwashing facilities shall be convenient to locker rooms and lunchrooms.

f. Signs shall be posted reminding employees to wash their hands before returning to work.

11. DISPOSAL OF WASTES

a. All refuse and garbage shall be stored in covered, impervious and leak-proof containers. This requirement does not pertain to production scrap.

b. All waste containers shall be clearly labeled for their intended purpose and contents.

c. Where possible, garbage and assorted rubbish should be stored outside the building in covered, impervious, cleanable containers. If stored inside the building, it must be contained in similar receptacles, but in an area separate from fabricating areas.

12. PERSONNEL-CLEANLINESS

a. Hands shall be thoroughly washed before commencing plant functions and as often as may be required to remove soil and contamination, and before returning to work after visiting the toilet room or lunchroom.

b. All personnel shall wear clean outer garments and effective hair restraints.

c. No person affected with any disease in a communicable form, or while a carrier of such disease, and no person with an infected cut or lesion shall work in any processing area in any capacity where there is a likelihood of such person contaminating product or product-contact surfaces with pathogenic organisms. (See Section 13 and 14 of this *Ordinance*).

d. The use of tobacco products is prohibited in fabricating, regrind and storage areas.

13. PROTECTION FROM CONTAMINATION

a. Upright, open formed containers and closures shall be protected from contamination by the use of overhead shields.

b. Whenever air under pressure is directed at resin or a product-contact surface, it shall be free of oil, dust, rust, excessive moisture, extraneous materials and odor and shall otherwise comply with the applicable requirements of Appendix H of this *Ordinance.*

c. Air that is directed at product or product-contact surfaces by fans or blowers shall be filtered and shall otherwise comply with the applicable requirements of Appendix H of this *Ordinance*.

d. Only pesticides approved for use in food plants and registered with the EPA shall be used for insect and rodent control.

e. Pesticides shall be used in accordance with the manufacturer's directions and used so as to preclude the contamination of containers or closures.

14. STORAGE OF FINISHED PRODUCT AND MATERIAL IN PROCESS

a. Blanks, roll stock and all other single-service containers, closures and articles shall be stored in a manner to provide protection from contamination by use of pallets, slip-sheets or other methods and away from any wall a sufficient distance to facilitate inspection, cleaning and pest control activities. Any roll stock having dirty or soiled outer turns and/or edges shall have sufficient turns discarded prior to use and the edges trimmed to provide protection from contamination.

b. Single-service articles in process shall be protected from contamination by use of a single-service cover sheet or other protective device. This includes chip-board, dividers, separators, bags and other items that can become contact surfaces.

c. Appropriate clean, dry storage facilities shall be provided for single-service containers, closures, paper for wrapping, adhesives, blanks and other production material to provide protection from splash, insects, dust and other contamination.

d. Where containers and closures are pre-formed in plants other than the original fabricating facility:

(1) Containers, blanks and closures shall be stored in the original cartons and sealed until used; and

(2) Partially used cartons of containers, blanks and closures shall be resealed until used.

e. Containers used for the storage of resin, regrind, broke and trim, intended for reuse, shall be covered, clean, impervious and properly identified. Reuse of storage containers, such as gaylords, is permitted provided plastic liners are used.

f. In-process storage bins that touch the product-contact surface of containers or closures shall be constructed of cleanable, nonabsorbent material and kept clean.

15. FABRICATING, PROCESSING AND PACKAGING EQUIPMENT

The requirements of this Section pertain to all equipment and processes used in the fabrication of containers and closures, irrespective of the materials used and whether or not mentioned herein. Some of this equipment includes grinders, rollers, reamers and cutters, molders and fittings, extruders, silos, resin bins and hoppers, printing equipment, blanking equipment and sealing equipment.

a. Rolls, dies, belts, tables, mandrels, transfer tubing and all other contact surfaces shall be kept clean, sanitary and reasonably free of accumulation of paper, plastic or metal dust and other production soils. Equipment designed for milk plant use, which is utilized for pre-forming containers, shall be clean and sanitized prior to operation.

b. All materials in process for containers and closures shall be protected from contamination by condensate or dripping from overhead pipes or equipment components.

c. Makeshift devices such as tape, rope, twine, paperboards, etc., shall not be used. All fasteners, guides, hangers, supports and baffles shall be constructed of impervious, cleanable materials and kept in good repair.

d. Take-off tables and other container contact surfaces shall be constructed of cleanable material, kept clean and in good repair.

e. Waxing shall be performed so as to assure that containers or closures are completely coated and the wax shall be kept at a temperature of 60ºC (140ºF) or higher.

f. All grinders, shredders and similar equipment used for regrinding shall be installed above the floor or installed in such a manner that they are protected, so that floor sweepings and other contaminants cannot enter the grinder or shredder.

g. Storage tanks, silos, gaylords or bins used for plastic resins shall be so constructed to protect the resin from contamination. All air vents shall be filtered to prevent the entrance of dust or dirt. Air tubes used to conduct resin shall be supported above ground to prevent their becoming submerged in water. Air tubes used to convey resin shall have end caps, attached by chain or cable, that prevent contamination. This Item also applies to all raw materials handled in like manner.

16. EQUIPMENT AND MATERIALS FOR CONSTRUCTION OF CONTAINERS AND CLOSURES

a. Single-service containers and closures for milk and milk products shall not be fabricated on equipment used for the manufacture of products made of non-food-grade materials, unless such equipment has been thoroughly cleaned and/or purged of all non-food-grade material by a process that will not contaminate the food-grade material.

b. Only plastic sheeting and extrusions, plastic laminated paper, metal and paperboard blanks, or combinations thereof, from a manufacturing and/or fabricating plant conforming to these standards, shall be used. Fabricating plants listed in the current IMS List shall be considered in compliance with this Item.

c. Only sanitary, nontoxic lubricants shall be used on container-closure contact surfaces. Excess lubricant shall be removed from surfaces close to shafts, rollers, bearing sleeves and mandrels. These lubricants shall be handled and stored in a manner that will prevent cross contamination with non-food-grade lubricants. Such storage areas shall be clean and adequately ventilated.

d. The manufacture of single-service containers and closures for milk and milk products shall be carried on in such a manner that there will be no cross contamination of raw material or regrind with non-food-grade materials.

e. Containers, resin and flashing on the floor and floor sweepings of production materials are prohibited from being reused. This shall not preclude the use of these materials when it complies with a protocol that has been reviewed and accepted by FDA.

17. WAXES, ADHESIVES, SEALANTS AND INKS

a. Waxes, adhesives, sealants and inks used for containers and closures shall be handled and stored in a manner that will prevent cross contamination with similar non-food-grade materials. Such storage areas shall be clean and adequately ventilated.

b. Unused materials shall be covered and properly stored.

c. Waxes, adhesives, sealants and inks shall not impart odor or taste to the milk or milk products and shall not contaminate the product with microorganisms or toxic or injurious substances. All materials that are applied to the product-contact surface shall comply with the requirements of 21 CFR Parts 175-178.

d. Transfer containers shall be kept clean and shall be properly identified and covered.

18. HANDLING OF CONTAINERS AND EQUIPMENT

Handling of fabricated containers, and container and closure-contact surfaces shall be kept to a minimum. Handlers shall sanitize their hands frequently or wear clean, single-use gloves.

19. WRAPPING AND SHIPPING

a. Blanks, closures, halves, nested or pre-formed containers and parts such as valves, hoses, tubes and other fittings shall be properly packaged or containerized prior to shipping.

b. The outer package or containerized units shall protect the contents from dust and other contamination.

c. Transportation vehicles used to ship finished materials from the single-service container or closure plant or within the plant shall be clean and in good repair and shall not have been used for the transportation of garbage, waste or toxic materials.

d. Paperboard containers, wrappers, and dividers that contact the surface of the container or closure shall not be reused for this purpose.

e. All packaging materials that contact the product-contact surface of the container or closure shall comply with the requirements of 21 CFR Parts 175-178 and the bacteriological standards of Section C of these Standards, but the materials do not have to be manufactured at a listed single-service plant.

20. IDENTIFICATION AND RECORDS

a. Outer wrappings shall be identified with the name and city of the plant where the contents are fabricated, except those manufactured in, and which are only for use in the same facility. In the cases where several plants are operated by one firm, the common firm name may be utilized, provided that the location of the plant at which the contents were fabricated is also shown either directly or by the FIPS numerical code on the outer wrapper.

b. Records of all required bacteriological tests of containers and closures shall be maintained at the plant of manufacture for two years and results shall be in compliance with Section C of these Standards.

c. The fabricating plant shall have on file information from suppliers of raw material, waxes, adhesives, sealants and inks indicating that the material complies with the requirements of 21 CFR Parts 175 - 178.

d. The fabricating plant shall have on file information from the suppliers of packaging materials specified in Section 19, Item e. of these Standards indicating that the material complies with the requirements of 21 CFR Parts 175-178 and the bacteriological standards of Section C of these Standards.

e. Multi-plant corporations may have all the required information at a central location as long as it can be transmitted to the site upon request.

21. SURROUNDINGS

a. Exterior surroundings shall be neat and clean and free from conditions that might attract or harbor flies, other insects and rodents.

b. Driveways, lanes and areas serving the plant vehicular traffic are graded, drained and free from pools of standing water.

APPENDIX K. RESERVED FOR FUTURE USE

APPENDIX L. APPLICABLE REGULATIONS, STANDARDS OF IDENTITY FOR MILK AND MILK PRODUCTS AND THE *FEDERAL FOOD, DRUG, AND COSMETIC ACT*

21 CFR PART 101 – FOOD LABELING
21 CFR PART 108 – EMERGENCY PERMIT CONTROL
21 CFR PART 110 – CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD
21 CFR PART 113 – THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS
21 CFR PART 130.10 - Requirements for foods named by use of a nutrient content claim and a standardized term
21 CFR 131.3 Definitions - Cream, Pasteurized and Ultra-pasteurized
21 CFR 131.110 Milk
21 CFR 131.111 Acidified Milk
21 CFR 131.112 Cultured Milk
21 CFR 131.150 Heavy Cream
21 CFR 131.155 Light Cream
21 CFR 131.157 Light Whipping Cream
21 CFR 131.160 Sour Cream
21 CFR 131.162 Acidified Sour Cream
21 CFR 131.170 Eggnog
21 CFR 131.180 Half-and-Half
21 CFR 131.200 Yogurt
21 CFR 131.203 Lowfat Yogurt
21 CFR 131.206 Nonfat Yogurt
21 CFR 133.128 Cottage Cheese
21 CFR 133.129 Dry Curd Cottage Cheese

Federal Food, Drug, and Cosmetic Act, as amended Sec. 402. [342] Adulterated Food
Federal Food, Drug, and Cosmetic Act, as amended Sec. 403. [343] Misbranded Food

APPENDIX M. REPORTS AND RECORDS

The following forms are available at:
http://www.fda.gov/opacom/morechoices/fdaforms/cfsan.html

FORM FDA 2359	Milk Plant Inspection Report
FORM FDA 2359a	Dairy Farm Inspection Report
FORM FDA 2359b	Milk Plant Equipment Test Report
FORM FDA 2359c	Single-Service Manufacturing Plant Inspection Report
FORM FDA 2399	Milk Sample Collector Evaluation Form
FORM FDA 2399a	Milk Tank Truck, Hauler Report and Sampler Evaluation Form
FORM FDA 2399b	Milk Tank Truck Inspection Form

APPENDIX N. DRUG RESIDUE TESTING AND FARM SURVEILLANCE

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. The random bulk milk pickup tanker sampling program shall represent and include, during any consecutive six (6) months, at least four (4) samples collected in at least four (4) separate months, except when three (3) months show a month containing two (2) sampling dates separated by at least twenty (20) days. 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 Milk Products of this *Ordinance*. 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 (6) 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's milk 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**

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 sampling program. Alternately, the Regulatory Agency or Laboratory Evaluation Officer may take known samples with them on the audit visit and observe the industry analyst test the samples. Receiving locations that choose to certify all receiving analysts, certified under the provisions of the NCIMS Laboratory Certification Program, are exempt from the sample collection requirements of this Section.

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. 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 the 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 Guide (CPG 7126.20). The Regulatory Agency shall determine the producer(s) responsible for the violation.

Suspension: Any time milk is found to test as a confirmed positive for a drug residue, the Regulatory Agency shall immediately suspend the producer's Grade "A" 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 Regulatory Agency may accept certification from the violative producer's milk marketing cooperative or purchaser of milk as satisfying the penalty requirements.
Reinstatement: The Grade "A" producer's permit may be reinstated, or other action taken, to allow the 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. The farm inspection is completed by the Regulatory Agency or its agent to determine the cause of the residue and actions taken to prevent future violations including:

1. On-farm changes in procedures necessary to prevent future occurrences as recommended by the Regulatory Agency.
2. Discussion and education on the Drug Residue Avoidance Control measures outlined in Appendix C. of this *Ordinance.*

Permit Revocation: After a third violation in a twelve (12) month period, the Regulatory Agency shall initiate administrative procedures pursuant to the revocation of the producer's Grade "A" permit under the authority of Section 3 – Permits of this *Ordinance*, due to repeated violations.

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. They do not dictate any result; they

do not limit the Agency's discretion in any way; and 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 FFD&CA as amended . "Safe levels" do not:

1. Bind the courts, the public, including milk producers, or the Agency, including individual FDA employees; 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

AOAC First Action and AOAC Final Action methods are accepted in accordance with Section 6 of this *Ordinance*. 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 of this *Ordinance*.
One (1) 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.

APPENDIX O. VITAMIN FORTIFICATION OF FLUID MILK PRODUCTS

PROCESS/METHODS OF VITAMIN ADDITION

Vitamin fortification can be accomplished by the addition of vitamins at many different points in the processing system, preferably after separation, including the pasteurizing vat, to the HTST constant level tank, or on a continuous basis into the pipeline after standardization and prior to pasteurization in accordance with the manufacturer's recommendations. Both batch addition and addition with metering pumps can be used. The batch procedure requires accurate measurement of the volume of milk to be fortified, accurate measurement of the vitamin concentrate, and proper mixing. When a vitamin metering pump(s) is used with an HTST unit or an HHST unit the pump(s) must be installed so as to be activated only when the unit is in forward flow. The addition of vitamins must be accomplished prior to pasteurization in accordance with the manufacturer's recommendations.

The problem of under fortification is often related to the point in the system where fortification takes place. Vitamins A and D are fat-soluble and will gradually become more concentrated in the milk fat portion of the milk. Both oil and water base vitamins are susceptible to this migration problem.

If vitamins are added in the proper amount before separation and standardization, and the product is separated and standardized, then the low fat product will tend to be under fortified and the high fat product over fortified. Water-soluble vitamin concentrates can minimize this problem if vitamins are added before separation. Processors who use this procedure should perform confirmatory assays to ensure proper fortification levels of each product.

Many HTST systems are now being used with in-line fat standardization, which also makes possible switching, without stopping, from products being fortified with Vitamin D to those being fortified with both A and D. These systems require metered injection of the proper vitamins at a point after standardization and before pasteurization. Sanitary positive displacement pumps are available for this purpose.

There are two (2) types available:

1. The first is, a piston type metering pump without valves. It is equipped with a micrometer, which allows accurate and reproducible amounts of vitamins to be added based on the rate of product flow through the system.
2. The other type is a peristaltic pump that offers precise control. This precise control is possible since the volume can be controlled by the tubing size and the pump speed. This system simplifies cleaning, since only the tube is in contact with the vitamin concentrates.

These pumps have a history of reproducibility and reliability. All metering pumps should be designed to conform with this *Ordinance*.

The recommended injection point is after separation and prior to homogenization. This allows the homogenization process to distribute the vitamins throughout the milk. A check valve is recommended to prevent milk from contaminating the vitamin concentrate.

Separate pumps, tubing and check valves, are recommended when multiple types of vitamin concentrates are injected. (See Figure 45)

Pumps should be calibrated based on the pasteurization system flow rate. If flow rates change for different milk products, additional vitamin pumps may be needed. Re-calibration of the metering pumps is not recommended without verifying the accuracy. Routine calibration of metering pumps is recommended. The following are recommended to achieve desired vitamin fortification levels:

1. Management must be committed to proper fortification and concerned with both over and under levels.
2. Design the system correctly for proper addition in which concentrate is added after standardization and before pasteurization.
3. Written procedures and training should be provided to all employees responsible for vitamin fortification for each product to be fortified. These procedures should focus on product start-up and product change-over.
4. Maintain accurate records of vitamins used and products produced, checked daily against theoretical use. Care should be taken that adequate fortification of small run products like skim milk is not masked by much larger volumes of reduced fat (2%) or other partly skimmed milk products.

METERING PUMPS

Use an accurate, sanitary, positive displacement metering pump with a scheduled cleaning procedure after use. For batch addition, use only accurate, calibrated measuring devices, such as plastic graduated cylinders, or pipettes. Measuring devices should be sized to the amount of concentrate added, i.e., if 8 mL is added, a 10 mL graduated cylinder would be appropriate. Measuring devices should be rinsed with the product being fortified to insure no residual concentrate is left.

Use a check valve on the injection line to prevent milk from being pushed back into the line. This depends on the pump displacement.

Check the meter calibration regularly, including both the pump and the tubing, by determining delivery rate accuracy. Use only properly calibrated tubing for peristaltic pump systems and replace the tubing regularly.

Storage vessels used for supplying vitamin concentrate to metering pumps should be emptied on a regular basis. A regular systematic cleaning and sanitizing schedule must be maintained for these vessels, pumps and tubing.

Vitamin concentrates should be stored and held in accordance with the manufacturer's recommendations for maximum shelf life.

Vitamin metering pumps should be interwired with the flow divert and recycle valves to prevent operation during divert and/or recycle flows.

Analyze finished products regularly. Results should be reported in International Units (I.U.)/Quart. Because of the sensitivity and difficulty in performing these tests, it is necessary to procure the services of a competent laboratory; one that is familiar with the handling and testing of vitamin fortified dairy products.

Care must be taken when reprocessing reclaimed product so vitamin A and/or D levels do not exceed the label claims by more than 150%.

GOOD MANUFACTURING PRACTICES

Good manufacturing practices require that the vitamin A and D levels be in compliance with the CFR.

TESTING METHODS

Test methods used for the detection of vitamins A and/or D_3 shall be acceptable to FDA or other official methodologies that give statistically equivalent results to the FDA methods. Vitamin analysis shall be conducted in a laboratory accredited by FDA and acceptable to the Regulatory Agency.

TYPE OF CONCENTRATES AVAILABLE

A number of different types of concentrates are available. All contain vitamin D and/or vitamin A palmitate with a carrier consisting of any of the following: butter oil, corn oil, evaporated milk, non-fat dry milk, polysorbate 80, propylene glycol and glycerol monooleate. It is best to store all concentrates under refrigeration unless manufacturer's directions indicate otherwise. To achieve adequate dispersion, viscous concentrates should be brought to room temperature before addition.

NEED FOR ADDITION

Vitamin A is fat-soluble. It will dissolve when mixed with fat and will not dissolve in water. For this reason, Vitamin A is found in whole milk and to a lesser degree in low fat and absent in non-fat milk, unless these products are fortified.

Vitamin D is the major regulator of calcium absorption in the intestine. Fortification of fresh milk with Vitamin D is acknowledged to have virtually eliminated rickets in milk drinking children. Since normal levels of Vitamin D are necessary for optimal calcium absorption in children, it is also known that these levels are required as one increases in age. It has been associated with reducing the incidence of osteoporosis in premenopausal women.

Vitamin A performs many functions. One is to enable the retina of the eye to respond to dim light. Deficiency of Vitamin A produces night blindness. Vitamin A is also involved in the ability of the eye to discern color.

Vitamins A and D can be a potential threat to public health if consumed at excessive levels. Over fortification with levels of Vitamin A over 6,000 I.U. and Vitamin D over 800 I.U. should be considered harmful; therefore, it is necessary to accurately control the proper level of fortification.

PROBLEMS INVOLVED WITH FORTIFICATION

Milk and milk products that contain a large proportion of fat are relatively good dietary sources of Vitamin A, but as is the case with other natural foods, the Vitamin D content of unfortified milk is quite low. As with other milk components, Vitamin A and D levels are affected by breed, season, diet, lactation and in the case of Vitamin D, animal exposure to sunlight.

In general, when lactating animals are transferred from pasture to winter rations in the fall, a decline in the Vitamin A and D levels can be expected in the raw milk. This occurs slowly through the winter season until the animals are once more on pasture in the spring. With the proper selection of feed and diet concentrates this effect can be kept to a minimum. Natural levels of Vitamin A range from 400 I.U. in winter to 1200 I.U. in summer, and Vitamin D, 5 I.U. in winter to 40 I.U. in summer. These are approximate ranges to indicate possible seasonal variations. Because of seasonal and other variations in natural vitamin levels it is necessary to monitor the level of fortification to assure that levels are within good manufacturing practices.

Vitamin concentrate potency degrades with time. Concentrates should be stored in accordance with manufacturer's recommendation to maintain label potency. Vitamin concentrate potency should be verified by the vitamin supplier.

Vitamin D is very stable in homogenized whole milk and is not affected by pasteurization or other processing procedures. Vitamin D in fortified homogenized whole milk will remain constant with little or no loss of vitamin potency during long periods of proper storage. No loss of vitamin D will be experienced under normal shelf life periods.

Vitamin A and D fortified skim milk products are subject to decreases in vitamin A, because the vitamin is no longer protected by fat as it is in whole milk. In fluid skim or low fat milk, added vitamin A deteriorates gradually during normal storage of the milk at 4.4°C (40°F) in the dark but is destroyed rapidly when the milk is exposed to sunlight in transparent glass bottles or translucent plastic containers. The photo destruction of added vitamin A is dependent on the intensity and wave-length of light and the milk source. The use of amber or brown glass bottles, pigmented plastic containers formulated with specific light barriers and colored paper cartons retard this destruction. Vitamin A losses in reduced fat milk (2%) from five (5) dairy plants ranged from 8% to 31% when they were exposed to 200 foot-candles of fluorescent light for twenty-four (24) hours in opaque plastic containers. Use of pigmented containers or gold shields over fluorescent tubes practically eliminated these losses.

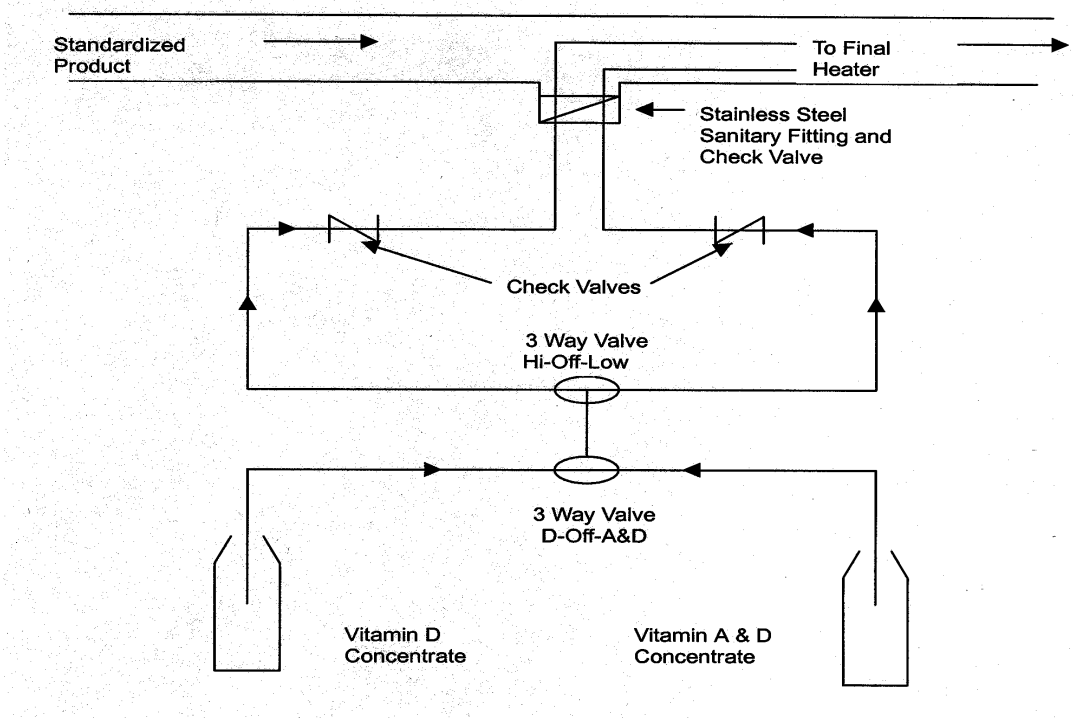


Figure 45. Vitamin Fortification

NOTE: Figure 45 details a two (2) speed vitamin fortification installation using two (2) pumps and two (2) vitamin concentrate sources. This enables changing from different vitamin concentrates and different speed pumps via the adjustment of three-way valves.

RECOMMENDATIONS

1. Use a sanitary check valve(s) to separate milklines from vitamin concentrates.
2. All milk contact surfaces should be of a sanitary design, easily cleanable and available for inspection.

APPENDIX P. PERFORMANCE-BASED DAIRY FARM INSPECTION SYSTEM

PREFACE

A performance-based inspection system is an option to the traditional routine inspection frequency of least once every six (6) months on Grade "A" dairy farms. This option provides States with a choice. For some States, inspecting every farm routinely twice a year may provide effective regulatory oversight and make efficient use of inspection resources. In other States, however, an optional system, which determines routine farm inspection frequency based on producer milk quality and inspection performance may be more desirable, equally effective, and make the most efficient use of limited inspection resources. The overall inspection effort devoted to a performance-based farm inspection system may be more or less than the traditional inspection system, which requires a routine inspection at least once every six (6) months per farm.

INSPECTION INTERVAL AND CRITERIA

Dairy farms will be categorized at least every three (3) months using the previous twelve (12) month farm inspection and milk quality data. The following criteria will be used to categorize farms into four (4) inspection intervals as defined below:

1. Minimum One (1) Year Inspection Interval: (One (1) inspection each twelve (12) months)
All criteria below must have been met for the previous twelve (12) months:

a. No more than one (1) sample with SPC >25,000, but less than 100,000
b. All SCC samples ≤ 500,000
c. No cooling temperature violations
d. No drug residue violations
e. No "critical control point" violations observed during farm inspections. Critical violations are identified on the Dairy Farm Inspection Report as:
   (1) 10-Cleaning and 11-Sanitization
   (2) 15(d)-Drugs properly labeled and 15(e)-Drugs properly used and stored
   (3) 18-Cooling (Significant Violations)
f. No violation that creates a substantial risk of adulteration or an imminent health hazard.
g. No more than five (5) violations documented on any inspection sheet.
h. No consecutive inspection violations on any inspection Item.
i. No record of suspended permit, certification or license due to inspection, milk quality or drug residue deficiencies.
j. Bacteriologically safe water supply at the time of categorization.

NOTE: Farms in this category who are re-categorized to a six (6) month inspection interval for a single violation of one (1) milk quality parameter (SCC > 500,000 or cooling temperature violation) may be re-categorized to the one (1) year inspection interval if all ten (10) criteria listed above are met for the next six (6) months.

2. Minimum Six (6) Month Inspection Interval: (One (1) inspection each six (6) months)
All criteria below must have been met for the previous twelve (12) months:

a. May have more than one (1) sample with SPC >25,000
b. May have one (1) or more SCC sample >500,000
c. No more than one (1) warning letter issued due to non-compliance of two (2) out of four (4) previous official sample results for SPC and SCC
d. No cooling temperature violations
e. No drug residue violations
f. No "critical control point" violations observed during farm inspections. Critical violations are identified on the Dairy Farm Inspection Report as:
(1) 10-Cleaning and 11-Sanitization
(2) 15(d)-Drugs properly labeled and 15(e)-Drugs properly used and stored
(3) 18-Cooling (Significant Violations)
g. No violation that creates a substantial risk of adulteration or an imminent health hazard.
h. No more than five (5) violations documented on any inspection sheet.
i. No consecutive inspection violations on any inspection Item.
j. No record of suspended permit, certification or license due to inspection, milk quality or drug residue deficiencies.
k. Bacteriologically safe water supply at the time of categorization.

NOTE: Farms meeting the criteria for one (1) year or six (6) month inspection intervals but with less than twelve (12) months of farm inspection and milk quality history, i.e. new farms, will be assigned to a six (6) month inspection interval.

3. Minimum Four (4) Month Inspection Interval: (One (1) inspection each four (4) months)
Any criteria listed below, results in the farm being placed into this inspection interval for twelve (12) months from the next re-categorization:

a. More than one (1) warning letter issued due to non-compliance of two (2) out of four (4) previous official sample results for SPC and SCC.
b. Farm conditions that caused the Regulatory Agency to take official regulatory action, i.e., warning letter, intent to suspend, reinspection, etc.
c. One (1) drug residue violation.
d. "Critical control point" violations observed during farm inspections. Critical violations are identified on the Dairy Farm Inspection Report as:
(1) 10-Cleaning and 11-Sanitization
(2) 15(d)-Drugs properly labeled and 15(e)-Drugs properly used and stored
(3) 18-Cooling (Significant Violations)
e. A violation that creates a substantial risk of adulteration or an imminent health hazard.
f. More than five (5) violations on any inspection.
g. Unsafe water supply at the time of categorization.

4. Minimum Three (3) Month Inspection Interval: (One (1) inspection each three (3) months)
Any criteria listed below results in the farm being placed into this inspection interval for twelve (12) months from the next re-categorization:

a. More than one (1) drug residue violation.

b. Any farm suspended from the market by the Regulatory Agency during the previous twelve (12) month evaluation period for any reason other than drug residue violations.

c. More than one (1) incident where violative farm conditions or milk quality parameters resulted in the Regulatory Agency taking official regulatory action, i.e., warning letter, intent to suspend, reinspection, etc.

NOTE: The above guidelines for Grade "A" farm inspection intervals are not intended to prevent farm inspections at more frequent intervals if in the judgment of the Regulatory Agency more frequent intervals are necessary.

INDEX

Page