

3-A® Accepted Practices for the Sanitary Construction, Installation, Testing and Operation of High-Temperature Short-Time and Higher-Heat Shorter-Time Pasteurizer Systems, Number 603-07

Standard Developer
3-A Sanitary Standards, Inc. (3-A SSI)
In Collaboration With
United States Public Health Service (USPHS)/
United States Food and Drug Administration (USFDA)
United States Department of Agriculture – Dairy Programs (USDA)
European Hygienic Engineering & Design Group (EHEDG)

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Nothing in these 3-A Accepted Practices shall be interpreted or construed in any way as changing the published effective requirements recommended by the United States Public Health Service Grade A Pasteurized Milk Ordinance, or any Federal, State, or Local legal code. These 3-A Accepted Practices were developed to provide manufacturers, processors, and milk and milk product control authorities with specifications for the proper construction and installation of new High-Temperature Short-Time Pasteurizer Systems and Higher-Heat Shorter-Time Pasteurizer Systems or any components thereof, which may be installed on or after the effective date of these revised Practices.

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Foreword

This 3-A Accepted Practice is to establish minimum sanitary (hygienic) requirements for the Sanitary Construction, Installation, Testing and Operation of High-Temperature Short-Time and Higher-Heat Shorter-Time Pasteurizer Systems. Standard English is the official language of 3-A Sanitary Standards and 3-A Accepted Practices.

This 3-A Accepted Practice is for voluntary use by directly and materially affected organizations such as equipment and machinery fabricators, processors, regulatory agencies and by 3-A SSI to assure adequate public health protection exist for the devices and covered products. 3-A Sanitary Standards, Inc. use these documents as the source for sanitary criteria as part of 3-A Symbol authorization.

This 3-A Accepted Practice was developed jointly by 3-A SSI, the United States Public Health Service (USPHS)/United States Food and Drug Administration (USFDA), the United States Department of Agriculture – Dairy Programs (USDA), and the European Hygienic Engineering & Design Group (EHEDG).

It is our purpose to encourage inventive genius and provide a forum to discuss new developments. Suggestions for improvement and new technology are welcome any time for consideration by the 3-A Sanitary Standards Committees. Please forward comments to the 3-A SSI, 1451 Dolley Madison Boulevard, Suite 210, McLean, VA 22101-3850, USA. By fax: 703-761-6284. By e-mail to: 3-ainfo@3-a.org.

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Glossary of Abbreviations and Symbols

(According to ANSI Y1.1 and ANSI Y10.9)

ACI	--	Alloy Cast Institute
AISI	--	American Iron and Steel Institute
ASTM	--	Formerly American Society for Testing and Materials
°C	--	Degree Celsius
CFR	--	Code of Federal Regulations
CIP	--	Clean-In-Place
cm	--	Centimeter(s)
E	--	exponential number
EPA	--	Environmental Protection Agency
°F	--	Degree Fahrenheit
fl oz	--	Fluid Ounce(s)
FDA	--	Food and Drug Administration
FDD	--	Flow-Diversion Device
g	--	Gram(s)
gal	--	Gallon(s)
GPM	--	Gallons per Minute
HHST	--	Higher-Heat Shorter-Time
hr	--	Hour(s)
HTST	--	High-Temperature Short-Time
in.	--	Inch(es)
kg	--	Kilogram(s)
kPa	--	Kilopascal
L	--	Liter(s)
lb	--	Pound(s)
LPH	--	Liter(s) per Hour
m	--	meter(s)
Max	--	Maximum
MBTS	--	Meter-Based Timing System
min	--	Minute(s)
mL	--	Milliliter(s)
mm	--	Millimeter(s)
No.	--	Number
p	--	Page
pp	--	Pages
PMO	--	Grade A Pasteurized Milk Ordinance
ppm	--	Parts per Million
psig	--	Pounds per Square Inch Gauge
rev	--	Revised
RPM	--	Revolutions per Minute
sec	--	Second(s)
STLR	--	Safety Thermal Limit Recorder

A SCOPE

A1 These 3-A Accepted Practices shall pertain to high-temperature short-time (HTST) and higher-heat shorter-time (HHST) pasteurization equipment, appurtenances, and controls used in a complete pasteurization system for milk and milk products. In addition to pasteurization, such systems may include flavor control, vacuum treatment, homogenization, clarification, separation, or other processes, which if included, are to be installed so that they do not influence required time, temperature, flow and pressure relationships.

A2 In order to conform to these 3-A Accepted Practices, HTST or HHST pasteurizer systems shall conform to the following design, material, fabrication and installation criteria.¹

A3 An Appendix is also included covering Application to Install, Operation, Determination of Holding time and Pressure Relationships, Stainless Steel Materials, Product Contact Surface Finish and a list of 3-A Sanitary Standards and Accepted Practices referred to in the text. (NOTE: Numbered end notes and references are assembled in Appendix, Section R, on pages ____ to ____.)

B DEFINITIONS

B1 *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 of the temperatures given in the following table and holding continuously at or above that temperature for at least the corresponding specified time:

<u>Temperature</u>	<u>Time</u>	
*161.0° F (72.0° C)	15.0 sec	(HTST Pasteurization)
191.0° F (89.0° C)	1.0 sec	(HHST Pasteurization)
194.0° F (90.0° C)	0.5 sec	(HHST Pasteurization)
201.0° F (94.0° C)	0.1 sec	(HHST Pasteurization)
204.0° F (96.0° C)	0.05 sec	(HHST Pasteurization)
212.0° F (100.0° C)	0.01 sec	(HHST Pasteurization)

* If the fat content of the milk product is 10% or more, or if it contains added sweeteners, or if the product is a condensed or concentrated milk or milk product, or a concentrated whey or whey product, the specified temperature shall be increased by 5.0° F (3.0° C). Provided that, eggnog and frozen dessert mix shall be heated to at least the following temperature and time specifications:

<u>Temperature</u>	<u>Time</u>
175.0° F (80.0° C)	25.0 sec (HTST Pasteurization)
180.0° F (83.0° C)	15.0 sec (HTST Pasteurization)

Provided that cream for butter making shall be heated to at least 185.0° F (85.0° C) and held continuously at or above that temperature for at least 15.0 sec. Provided further, that nothing in this definition shall be construed as barring any other pasteurization process which has been recognized by the Food and Drug Administration (FDA) to be equally efficient and which is approved by the regulatory control authority. These requirements are minimum for both time and temperature to pasteurize milk and milk products. Higher temperature and/or longer times may be utilized provided that both minimums are met.

B2 *Fail-safe Valve or Device:* Shall mean a valve or device designed to move to and/or maintain a safe position in the event of air or actuating power failure.

B3 *Product:* Shall mean milk and milk products.

B4 *Product Contact Surfaces:* Shall mean all surfaces which are exposed to the product or surfaces from which liquids may drain, drop, diffuse or be drawn into the product.

B5 *Nonproduct Contact Surfaces:* Shall mean all other exposed surfaces.

B6 *Safe Water:* Shall mean water from a supply properly located, protected and operated, and shall be of a safe, sanitary quality. The water shall meet the standards prescribed in the National Primary Drinking Water Regulation of the Environmental Protection Agency (EPA) as referenced in 40 CFR Parts 141, 142 and 143.

B7 *Regulatory Control Authority:* Shall mean the State or local agency having regulatory jurisdiction for the licensing of dairy processing facilities, or the validation for compliance (testing, timing and sealing) with legal pasteurization criteria as set forth in the FDA GRADE A PASTEURIZED MILK ORDINANCE (PMO), and State regulations.

B8 *Timing Pump:* Shall mean the sanitary, positive displacement-type pump, or the pump in the meter-based timing system that controls the rate of flow through the HTST or HHST pasteurizer system.

B9 *Meter Based Timing System (MBTS):* The MBTS shall be a flow regulating system consisting of a primary flow-promoting (timing) pump, a control valve or check valve, and a



magnetic flow meter, which uses an electrical signal to control the flow rate of the product through the holding tube of the HTST or HHST system.

B10 *Close Coupled:* Shall mean mating surfaces or other juxtaposed surfaces that are less than twice the nominal diameter or cross section of the mating surfaces or a maximum of 5 in (127mm).

B11 *Indirect Regenerator:* Shall mean a regenerator in which heat transfer occurs from product to heat transfer medium to product.

B12 *Valved out:* Shall mean application of automatic fail safe valves to cause isolation of equipment's product supply lines and discharge lines from a pasteurization system.

B13 *Sanitizing or Sanitization:* Shall mean a process applied to a cleaned surface which is capable of reducing the numbers of the most resistant human pathogens by at least 5 log₁₀ reductions (99.999%) to 7 log₁₀ reductions (99.999%) by applying accumulated hot water, hot air, or steam, or by applying an EPA-registered sanitizer according to label directions. Sanitizing may be effected by mechanical or manual methods.

C COMPONENTS

C1 Required component equipment for the HTST or HHST pasteurizer system shall consist of the following:

C1.1 Raw Product Constant Level Tank;

C1.2 Heating Equipment;

C1.3 Heating Medium System;

C1.4 Timing Pump or Timing System: The product flow through the holding tube shall be controlled by means of a timing pump or a meter-based timing system (MBTS);

C1.5 Holding Tube;

C1.6 Flow-Diversion Device (FDD);

C1.7 Safety Thermal Limit Recorder (STLR);

C1.8 Temperature Controller;

C1.9 Indicating Thermometers;

C1.10 Connecting Sanitary Pipe and Fittings

C2 Optional component equipment may be required for certain product processes that synchronize well with

HTST or HHST pasteurizer systems. Therefore, the necessary equipment and associated controls may be connected as part of the complete HTST or HHST pasteurizer system as follows:

C2.1 Regenerative Equipment;

C2.1.1 Vacuum Breaker;

C2.2 Cooling Equipment;

C2.3 Cooling Medium System;

C2.4 Control Panel;

C2.5 Raw Product Booster Pump;

C2.5.1 Raw Product Booster Pump Control;

C2.6 Homogenizer;

C2.7 Clarifier;

C2.8 Separator;

C2.9 Filters and Strainers;

C2.10 Surge Tank;

C2.11 Flavor Control or Vacuum Treatment Equipment, with or without direct product heating by steam injection or infusion;

C2.12 Auxiliary Pumps; and

C2.13 Other Processing Equipment or Component Parts.

D MATERIALS FOR PRODUCT CONTACT SURFACES

D1 The materials of product contact surfaces of Component Equipment, or Optional Component Equipment for which there are 3-A Sanitary Standards or 3-A Accepted Practices shall conform to the material criteria of the applicable 3-A Sanitary Standards or 3-A Accepted Practices.

D2 All other product contact surfaces shall be stainless steel of the American Iron and Steel Institute (AISI) 300 Series or the corresponding Alloy Cast Institute ACI types (See Appendix, Section O) or other equally corrosion resistant metal that is non-toxic and nonabsorbent, or heat resistant glass, except that:

D2.1 Rubber and rubber-like materials may be used in sealing applications and in parts having the



same functional purposes.

D2.2 Rubber and rubber-like materials when used for these specified applications shall conform to the applicable provisions of the 3-A Sanitary Standards for Multiple-Use Rubber and Rubber-like Materials, Used as Product Contact Surfaces in Dairy Equipment, Number 18-.

D2.3 Plastic materials may be used in sealing applications and in parts having the same functional purposes.

D2.4 Plastic materials when used for these specified applications shall conform to applicable provisions of the 3-A Sanitary Standards for Multiple-Use Plastics Materials, Used as Product Contact Surfaces for Dairy Equipment, Number 20-.

E FABRICATION

E1 The fabrication criteria of Component Equipment or Optional Component Equipment for which there are 3-A Sanitary Standards or 3-A Accepted Practices shall be those of the applicable 3-A Sanitary Standards or 3-A Accepted Practices.

E2 All other component equipment or optional component equipment shall conform to the following fabrication criteria:

E2.1 All product contact surfaces shall have a finish at least as smooth as a No. 4 ground finish on stainless steel sheets and be free of imperfections such as pits, folds and crevices in the final fabricated form. (See Appendix, Section P.)

E2.2 All product contact surfaces designed to be mechanically cleaned shall be designed so that the product contact surfaces and all nonremovable appurtenances thereto can be mechanically cleaned and are easily accessible for inspection.

E2.3 All product contact surfaces not designed to be mechanically cleaned shall be easily accessible for cleaning and inspection either when in an assembled position or when removed. Removable parts shall be readily demountable.

E2.4 All internal angles of less than 135.0° on product contact surfaces shall have minimum radii of 1/4 in. (6.35 mm) except where smaller radii are required for essential functional reasons. In no case shall radii be less than 1/32 in. (0.794 mm).

E2.5 Nonproduct contact surfaces shall have a smooth finish, be free of pockets and crevices, and be readily cleanable. Those surfaces which are to be coated shall be effectively prepared for coating.

Parts removable for cleaning having both product contact and non-product contact surfaces shall not be painted.

E3 Raw Product Constant Level Tank

E3.1 The raw product constant level tank shall conform to the applicable provisions of 3-A Sanitary Standards for Uninsulated Tanks for Milk and Milk Products, Number 32-, and the following criteria:

E3.2 The tank shall be of such design and capacity that air will not be drawn into the pasteurizer with the product when operating at maximum sealed capacity of the timing pump or the timing system.

E3.3 The tank shall be equipped with an automatic device or system of sanitary construction to control the raw product level. A manual override of this device may be provided for testing of product flow rate.

E3.4 The raw product constant level tank shall be fabricated so that the contents will drain to the outlet before the outlet becomes uncovered.

E3.5 All pasteurized product 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 shall be equivalent to at least two times the diameter of the largest of these pipelines. For purposes of this section, an overflow is defined as the flood rim of the constant level supply tank or any unrestricted opening below the flood rim of the constant level supply tank which at least two times the diameter of the largest of these pipelines or four times the area if other than round.

E4 Heating and Cooling Equipment

E4.1 The product heating and cooling equipment shall conform to 3-A Sanitary Standards for Plate Type Heat Exchangers for Milk and Milk Products, Number 11-, 3-A Sanitary Standards for Tubular Heat Exchangers for Milk and Milk Products, Number 12-, or 3-A Sanitary Standards for Scraped Surface Heat Exchangers, Number 31-, and 3-A Sanitary Standards for Fittings Used on Milk and Milk Products Equipment and Used on Sanitary Lines Conducting Milk and Milk Products (rev.) (Steam Injection Heaters), Number 63-.

Note: The inclusion of cooling equipment in

- HTST or HHST pasteurizer systems is optional.
- E4.2 For HTST systems, if a regenerator is employed, the deflector plates in the lowest point of the raw product channel shall be drilled with at least 1/16 in. (1.59 mm) holes, so that a continuous opening is available through the entire length of the raw product channel through which drainage may occur.
- E5 **Timing Pump or Meter-Based Timing System. (MBTS)**
- E5.1 The timing pump shall have its driving mechanism so designed that in case of wear, belt stretch, or any other condition affecting the capacity of the pump, the capacity will not increase.
- E5.2 Both variable and fixed capacity driving mechanisms are permitted, and shall be so designed as to permit sealing to prevent pump operation at greater capacity than that which gives legal holding time. Operation at any lower capacity shall be permitted.
- E5.3 Flow meters shall conform to the 3-A Sanitary Standards for Flow Meters for Milk and Liquid Milk Products, Number 28-.
- E5.4 The components of the MBTS shall be designed to function as follows:
- E5.4.1 The magnetic flow meter (tube and transmitter) shall produce a linear signal proportional to flow through the holding tube.
- E5.4.2 A high flow alarm with an adjustable set point shall be included in the system to cause the FDD to be moved to the divert position whenever excessive flow causes the product holding time to be less than the legal holding time for the pasteurization process being used.
- E5.4.3 A flow recorder shall be provided and shall meet the following requirements:
- E5.4.3.1 The case shall be moisture-proof (under operating conditions encountered in pasteurization plants) unless installed in a protected area.
- E5.4.3.2 The flow recorder shall be capable of recording a flow rate at least 5.0 GPM (18.93 LPM) but not less than 5.0% above the high flow alarm setting.
- E5.4.3.3 All flow rate recorder clocks shall be electrically operated.
- E5.4.3.4 The flow rate shall be recorded in true engineering units (not as a percent of maximum flow rate). Each division shall represent a maximum of 1.0% of the maximum recorded flow rate.
- E5.4.3.5 Spacing of scale divisions shall be not less than 0.0625 of an in. (1.59 mm) apart at the high alarm flow rate. Provided, that the flow rate scale divisions spaced not less than 0.040 in. (1 mm) apart are permitted when the recorded line is thin enough to be easily distinguished from the printed line, graduated in the required time-scale divisions. (See E5.4.3.6 and E5.4.3.7)
- E5.4.3.6 Time represented by smallest time-scale division shall be not more than 15.0 min chord or straight line.
- E5.4.3.7 Equivalent 15.0 min chord or straight-line length shall be not less than 1/4 in. (6.0 mm) at the high alarm flow rate.
- E5.4.3.8 Pen and chart paper shall be designed to give a continuous line not over 0.025 in. (0.64 mm) wide when in proper adjustment. The chart marking device shall be easy to maintain.
- E5.4.3.9 Chart-speed for a circular chart shall be not more than one revolution in 12.0 hr and shall be graduated for a maximum record of 12.0 hr. Strip type charts may show a continuous recording for a 24.0 hr period. When a recorder uses a microprocessor or a computer to regulate the speed of the chart drive motor, the controls or method of set-up for this recorder shall be equipped with a locking, sealable switch that prevents accidental or unauthorized changes in chart rotation or speed when placed in the "Run" or sealable position.
- E5.4.3.10 The flow rate recorder shall be provided with an additional pen-arm, or other device, for recording upon the chart the full record of the time during which the FDD is in the forward-flow and the diverted-flow positions with respect to flow rate. The flow rate recording pen and the diversion pen shall be synchronized on the same chord time divisions. A multiple alarm flow recorder, if used, shall be provided with a third pen to record on the chart the high flow alarm setting.

- E5.4.4 A low flow or loss of signal alarm shall be included in the system to cause the FDD to be moved to the divert position whenever there is a loss of signal from the meter or when the flow rate is below a preset minimum. This function may be provided in combination with the high flow alarm or as a separate device.
- E5.4.5 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. The time delay shall be tested by the regulatory agency and shall be sealed.
- E5.4.6 The flow transmitter, high flow alarm, low flow alarm and time delay device shall all be provided with a simple means of sealing, so that the settings cannot be changed or manipulated without breaking the seal.
- E5.4.7 The MBTS pump with either a fixed speed drive or equipped with an electrical variable speed drive shall be included.
- E5.4.8 Flow Control Valve or Check Valve: A normally closed, air operated, flow control valve shall be included as the flow controlling device in MBTS systems where the MBTS pump is operated with either a fixed speed drive or with an electrical variable speed drive except that:
- E5.4.8.1 A check valve shall be included in place of the flow control valve in MBTS systems where the MBTS pump is the flow-controlling device using an electrical variable speed drive.
- E5.4.8.2 If a normally open Flow-Control Valve is utilized, a check valve shall also be included immediately upstream of the Flow-Control Valve.
- E6 Legal Holding Tube**
- E6.1 The holding tube, including its inlet and outlet connections, shall be constructed of sanitary piping and fittings that conform to 3-A Sanitary Standards for Fittings Used on Milk and Milk Products Equipment and Used on Sanitary Lines Conducting Milk and Milk Products, Number 63-, and if intended to be mechanically cleaned, it shall conform to the 3-A Accepted Practices for Permanently Installed Sanitary Product -Pipelines and Cleaning Systems Used in Milk Products Processing Plants, Number 605-. All sanitary metal tubing shall conform to the 3-A Sanitary Standards for Polished Metal Tubing for Dairy Products, Number 33-.
- E6.2 The holding tube shall be designed to provide for the continuous holding of every particle of milk or milk product, for at least the minimum required holding time.
- E6.3 The holding tube shall be so designed that the simultaneous temperature difference between the hottest and coldest product in any cross-section of flow at any time during the holding period will not be greater than 1° F (0.5° C), and the average velocity through the holding tube shall not be less than 1.0 ft per sec (305 mm per sec).
- E6.4 The holding tube shall be so designed that no portion between the inlet and the FDD temperature sensor is heated. Optionally, it may be shielded, covered or enclosed to reduce heat loss as long as the holding tube is accessible for inspection.
- E6.5 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 designed so that sections of pipeline cannot be left out, resulting in a holding time less than the legal minimum.
- E6.6 The holding tube shall be designed to have a continuously upward slope, in the direction of flow, of not less than 1/4 in. per ft (20.8 mm per m) from its beginning to the connection at the inlet of the FDD. For HHST systems, only that section of the holding tube that has a continuously upward slope shall be used in determining the holding tube length.
- E6.7 Supports for holding tubes shall be provided so as to maintain all parts of the holding tube in a fixed position free from any movement laterally or vertically.
- E6.8 The holding tube shall be provided with fittings for installing an indicating thermometer and the temperature sensor of the STLR at the outlet end. When the conductivity test is to be used to determine holding time, provision shall be made for the temporary installation of a conductivity test electrode at the inlet end. The indicating thermometer connection may be used for the other conductivity test electrode.
- E6.9 For HTST systems, the STLR temperature sensor connection shall not be more than 18.0 in. (457 mm) upstream from the inlet of the FDD. The indicating thermometer sensor shall be located as close as practical to the STLR temperature sensor and shall measure the temperature of the same body of product.

- E6.10 For HHST systems, the STLR temperature sensor may be located either at the end of the holding tube or at the beginning of the holding tube if the holding tube is insulated to prevent heat loss.
- E7 Flow-Diversion Device (FDD)**
- E7.1 The FDD shall be so designed that, when in the diverted-flow position, product cannot pass into the forward-flow pipeline. To make certain of this, the device shall meet the following requirements:
- E7.1.1 The FDD shall include means that will automatically cause diversion of the product flow when the product leaving the holding tube is at sub-legal temperature. (See F3.5)
- E7.1.2 The FDD shall move from the forward-flow position to the diverted-flow position in not more than 1 sec after power loss or cut-out during descending temperatures in all systems, and when flow is below the minimum set point (alarm point) or above the legal maximum in a MBTS system.
- E7.1.3 A leak escape shall be provided on the forward-flow side of the valve seat. However, when back pressure is exerted on the forward-flow side of the valve seat, while the product flow is being diverted, the leak escape shall 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 port of a single stem valve shall be designed and the valve so installed as to drain all leakage to the outside. The leak escape shall be designed with one or more openings, with a total effective open area equivalent to at least 5/32 in. (3.99 mm) diameter.
- E7.1.3.1 The leak escape port of a single stem valve shall be designed and the valve so installed as to drain all leakage to the outside. The leak escape shall be designed with one or more openings, with a total effective open area equivalent to at least 5/32 in. (3.99 mm) diameter.
- E7.1.3.2 The leak escape port of a dual stem FDD shall be equal to or greater than the size of the inlet and shall conform to the requirements of Section F7.3.
- E7.1.4 The closure of the forward-flow seat shall be sufficiently tight so that leakage does not occur past it, as evidenced when the forward-flow line is disconnected; and in order that proper seating shall not be disturbed, the length of the connecting rod shall not be adjustable by the user.
- E7.1.5 It shall be impossible to tighten the stem packing of the single stem valve to such an extent as to prevent the valve from assuming the fully diverted-flow position.
- E7.2 The FDD shall include means that will automatically de-energize or valve out all applicable flow-promoting devices as required in F3.5 and F13.1.
- E7.3 The FDD shall provide means for automatically returning the product to forward-flow when the product has been restored to the required minimum legal temperature and flow rate. (See E5.4.5)
- E7.4 The FDD shall provide means that will automatically cause diversion of the product flow in case of actuating power failure.
- E7.5 The Inspect/Process/CIP mode selector switch and a manual divert button/switch is required for a dual-stem FDD and shall be located on the main control panel or on a FDD sub-panel.
- E7.6 The FDD shall assume the fully diverted-flow position within 1.0 sec when the manual divert is activated with the pasteurizer operating in forward-flow at the maximum flow rate on the most viscous product for which the system is designed.
- E8 Safety Thermal Limit Recorder (STLR)**
- E8.1 The STLR, with its temperature sensor located in accordance with E6.8 shall meet the following requirements:
- E8.2 Case shall be moisture-proof (under operating conditions encountered in pasteurization plants) unless installed in a protected area.
- E8.3 Chart range shall have a span not less than 30.0° F (17.0° C) including the temperature at which diversion is set, plus and minus 12.0° F (7.0° C).
- E8.4 Temperature accuracy shall be 1.0° F (0.5° C) plus or minus through a range of 5.0° F (3.0° C) above and below the diversion temperature.
- E8.5 All STLR clocks shall be electrically operated.
- E8.6 Temperature represented by smallest temperature-scale division shall be 1.0° F (0.5° C) over the specified chart range.
- E8.7 Spacing of 1.0° F (0.5° C) scale division shall be not less than 0.0625 of an in. (1.59 mm) apart at the diversion temperature, plus or minus 1.0° F (0.5° C); Provided, that temperature scale divisions of 1.0° F (0.5° C) spaced not less than

- 0.040 in. (1 mm) apart are permitted when the ink line is thin enough to be easily distinguished from the printed line, graduated in the required time-scale divisions. (See E8.8 and E8.9)
- E8.8 Time represented by smallest time-scale division shall be not more than 15.0 min chord or straight line.
- E8.9 Equivalent 15.0 min chord or straight-line length shall be not less than 1/4 in. (6.0 mm) through a range of 1.0° F (0.5° C) above and below the diversion temperature.
- E8.10 Provision for adjusting (mechanically or electronically) the recorded temperature to agree with the reference thermometer shall be provided. Adjustment shall be easily accessible and simple to accomplish.
- E8.11 Pen and chart paper shall be designed to give a continuous line not over 0.025 in. (0.64 mm) wide when in proper adjustment. The chart-marking device shall be easy to maintain.
- E8.12 Temperature sensor shall be protected against damage at temperatures up to 220.0° F (105.0° C) for HTST pasteurizer systems and to 300.0° F (149.0° C) for HHST pasteurizer systems.
- E8.12.1 The temperature sensing element shall be encased in appropriate material, and constructed in such a way that the final assembly is in accordance with 3-A Sanitary Standards for Sensors and Sensor Fittings and Connections Used on Milk and Milk Products Equipment No. 74-. Split-ferrule type sensing element connections shall not be utilized in mechanically cleaned systems.
- E8.13 Chart-speed for a circular chart shall be not more than one revolution in 12.0 hr and shall be graduated for a maximum record of 12.0 hr. Strip type charts may show a continuous recording for a 24.0 hr period. When a recorder uses a microprocessor or a computer to regulate the speed of the chart drive motor, the controls or method of set-up for this recorder shall be equipped with a locking, sealable switch that prevents accidental or unauthorized changes in chart rotation or speed when placed in the "Run" or sealable position.
- E8.14 The STLR shall be provided with an additional pen-arm or other devices for recording upon the outer edge of the chart the full record of the time during which the FDD is in the forward-flow and the diverted-flow positions. The temperature and diversion recording device shall be synchronized on the same chart time divisions. A multiple diversion STLR, if used, shall be provided with a third device to record on the chart the diversion temperature setting.
- E8.14.1 STLR multiple diversion cut-out or multiple hold time control can be accomplished by either of the following ways:
- E8.14.1.1 A multiple diversion STLR may be used to divert product at the proper temperature. Such an instrument shall be capable of adjustment and be sealed at different diversion temperatures. The selection of the proper diversion temperature shall be by positioning an electrical switch that may also be used for other interlocking purposes. In case of power failure, the diversion point shall automatically revert to the highest temperature and the FDD shall automatically assume the diverted-flow position.
- E8.14.1.2 Separate STLRs can be used, each set and sealed to divert at the proper temperature. The separate STLRs are wired to the FDD and electrically interlocked so that only one STLR operates the FDD at any one time. In case of power failure, the instrument with the higher diversion temperature shall operate the FDD.
- E8.14.1.3 Holding Time Control: If different holding times are required, the electrical switch which seals the proper diversion temperature is also used to supply power to the proper circuit governing the speed of the timing system. Such control circuits may be for two speed motors or for high flow alarm switches on meter based timing systems.
- E8.14.1.4 For HHST systems, auxiliary temperature sensing element(s) shall be included as components of the STLR system. All temperature sensing elements shall be designed for rapid response and adjustment mechanisms shall be sealable.
- E8.15 The control mechanism for setting the temperatures at which forward-flow and diverted-flow occur shall be provided with a simple means of sealing, so that it cannot be changed or manipulated without breaking the seal.
- E8.16 Thermometric response for HTST pasteurizer systems shall be determined with the STLR temperature sensor at room temperature and then immersed in a well stirred water bath (or can) at 7.0° F (4.0° C) above the desired cut-in temperature. The interval between the

moment when the recording thermometer reads 12.0° F (7.0° C) below the cut-in temperature and the moment of cut-in shall not be more than 5.0 sec. When digital thermometer displays are required for testing, the display shall change at a rate that can be noted during the thermometric lag test.

E8.17 The cut-in and cut-out response shall be independent of the temperature-recording pen-arm movement.

E9 Temperature Controller

E9.1 Each HTST and HHST pasteurizer system shall be equipped with a dependable automatic temperature control system designed so that the product temperature(s) can be accurately maintained.

E10 Indicating Thermometers

E10.1 Hot product thermometer(s) are required. One hot product thermometer conforming to the criteria of this section is required for all HTST and HHST pasteurizer systems. A second hot product thermometer is required for HTST and HHST pasteurizer systems when the timing pump is located as provided for in H1.2. Thermometers may be mercury actuated or digital, provided they meet the following criteria:

E10.1.1 Mercury actuated thermometers shall be direct reading, and be contained in a corrosion resistant case which protects against breakage and permits easy observation of the column and scale. Magnification of the column shall be to an apparent width of not less than 0.0625 in. (1.59 mm). The filling above the mercury shall be nitrogen or equally suitable gas.

E10.1.2 Digital thermometers shall be designed to meet the following:

E10.1.2.1 There shall be no more than 0.5°F (0.2° C) variation of the displayed temperature over a 3.0 month time period on a pasteurizer system when compared to a temperature reference which has at least a secondary traceability to the National Institute of Standards and Technology.

E10.1.2.2 The device shall have self-diagnostic circuitry, which provides constant monitoring of all sensing, input, and conditioning circuits. The diagnostic circuitry shall be capable of detecting “open” circuits, “short” circuits, poor connections, and faulty components. Upon detection of failure of any component, the device shall be blank, become unreadable or display

diagnostic error message.

E10.1.2.3 The electromagnetic compatibility of the device for this use shall be documented and available to the regulatory control authority. The device shall be tested to determine the effects of electro-static discharge, power fluctuation, conductive emission and susceptibility, and radiated emission and susceptibility. The device shall comply with the requirements for performance level characteristics of industrial devices. Protocols for these tests shall be in accordance with the requirements of the PMO and/or the regulatory control authority.

E10.1.2.4 The effect of exposure to specific environmental conditions shall be documented. The device shall be tested to determine the effects of low and high temperatures, thermal shock, humidity, physical shock, and salt fog. Protocols for these tests shall be developed by vendors with FDA concurrence.

E10.1.2.5 The probe and the display case shall be constructed so they may be sealed by a regulatory control authority.

E10.1.2.6 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 the appropriate Appendix of the PMO.

E10.1.2.7 The device shall be tested as a unit from the sensing probe through the final output or display.

E10.1.3 The scale shall have a span not less than 25.0° F (14.0° C) including the pasteurizing temperature, plus and minus 5.0° F (3.0° C) graduated in 0.5° F (0.25° C) divisions with not more than 8.0° F per in. of scale (4.0° C per 25.0 mm), and be protected against damage at 220.0° F (105.0° C) for HTST pasteurizer systems or 300.0° F (149.0° C) for HHST pasteurizer systems. Digital thermometer readout shall be displayed in units of temperature with at least 0.1°F (0.05°C) resolution.

E10.1.4 Accuracy shall be plus or minus 0.5° F (0.25° C) or better throughout the specified scale range.

E10.1.5 Stem fittings, shall be pressure-tight against the inside wall of the fittings with no threads exposed to product. The distance from the under side of the ferrule to the top of the sensitive portion of the bulb shall be such that the sensitive portion is positioned within the product flow path.

E10.1.6 For mercury actuated thermometers, the bulb shall be made of glass having a viscosity of at least $10^{14.6}$ poises at 914.0° F (490.0° C) and at least $10^{13.4}$ poises at 968.0° F (520.0° C) or equally suitable thermometric glass.

E10.1.7 The temperature sensing element shall be encased in appropriate material, and constructed in such a way that the final assembly is in accordance with 3-A Sanitary Standards for Sensors and Sensor Fittings and Connections Used on Milk and Milk Products Equipment No. 74-. Split-ferrule type sensing element connections shall not be utilized in mechanically cleaned systems.

E10.2 Cold product thermometer(s), if provided:

E10.2.1 Thermometers may be mercury actuated or digital, provided they meet the following criteria:

E10.2.2 Scale range shall be 30.0° F to 100.0° F (-1° C to 38.0° C), with extension on either side permitted. The thermometer(s) shall be protected against damage at temperatures up to 220.0° F (105.0° C) for HTST pasteurizer systems or to 300.0° F (149.0° C) for HHST pasteurizer systems and shall be graduated in 1.0° F (0.5° C) divisions, with not more than 22.0 divisions per 25.4 mm (1.0 in) of scale. Digital thermometer displays shall provide 1.0° F (0.5° C) resolution within the specified scale range.

E10.2.3 Accuracy shall be plus or minus 1° F (0.5° C) or better throughout the specified scale range.

E10.2.4 Alternate type thermometer(s) for cold product that conform to the above specifications shall be acceptable.

E11 Heating Medium System

E11.1 The heating medium system shall be any means, such as hot water, steam, electricity or regeneration, used to transfer heat to the product, provided it is applied in such a manner so as not to contaminate the product. (See E9 regarding required means of controlling the temperature.)

E12 **Cooling Medium System** (when a cooling section is included.)

E12.1 Water, brine, or non-toxic freezing point depressant

solutions, from safe sources, and direct expansion refrigeration may be used to transfer heat from the product, provided it is applied in such a manner so as not to contaminate the product.

E12.2 The cooling medium system, including the cooling medium supply storage tank, if provided, shall be designed to prevent contamination of the medium.

E12.3 The cooling medium system and the cooling section of the equipment shall be designed so that the pressure of the product in the product passages during operation is at least 2 psig (13.72 kPa) greater than the pressure of the cooling medium in the cooling medium passages. The control mechanism to satisfy this requirement shall be demonstrable to the regulatory authority.

E12.4 If the temperature of the cooling system is lower than the freezing temperature of the product, a means shall be provided which will automatically:

E12.4.1 Prevent freezing of the product, or

E12.4.2 Divert liquid product to the raw product constant level tank or to waste if freezing occurs.

E12.4.3 Such means shall not adversely affect the proper pressure relationship in the regenerator(s).

E13 Raw Product Booster Pump

E13.1 When a raw product booster pump is used, it shall be a centrifugal pump.

E13.2 The motor, casing and impeller of the booster pump shall be identified, and such records thereof maintained as directed by the regulatory control authority.

E13.3 A variable frequency speed control may be used for the booster pump motor, provided it is installed in conformance with Sections F13.2 through F13.2.3 and only Method E13.3.2 may be used to control the booster pump.

E14 Raw Product Booster Pump Control

E14.1 An automatic raw product booster pump control shall be provided that will not allow the raw product booster pump to operate unless the pressure in the pasteurized product side of a product to product regenerator is greater by at least 2 psig (13.72 kPa) than the pressure in the raw product side of a product to product regenerator, except that:

E14.1.1 In HHST systems, the raw product booster pump shall be permitted to run at all times provided that it is installed in compliance with Section F2.9.

E14.2 Means shall be provided for sealing the raw product booster pump control so that the settings cannot be changed without breaking the seal.

E14.3 Pressure gauge(s) shall be provided at the inlet of the raw regenerator and at the outlet of the pasteurized regenerator to permit determination of the relative pressure at any time except that, an indicating differential pressure controller satisfying E14.1 also fulfills this requirement.

F INSTALLATION

All component equipment, or optional component equipment, with product contact surfaces, shall be connected to each other with sanitary pipelines and fittings and shall be properly installed so as not to have any adverse effects on the required time, temperature, flow, and pressure relationships of the HTST or HHST pasteurizer system. Such parts and equipment shall be installed to facilitate easy access for cleaning, maintenance and inspection. The installation of all Component Equipment or Optional Equipment for which there are 3-A Sanitary Standard or 3-A Accepted Practices shall conform to the applicable 3-A Sanitary Standards or 3-A Accepted Practices.

F1 Raw Product Constant Level Tank

F1.1 The tank outlet shall be connected to the raw product inlet of the regenerative or heating section, or when a raw product booster pump is used, the tank outlet shall be connected to the inlet of this pump.

F1.2 When product to product regeneration is applied, the tank shall be installed so that its overflow level is lower than the bottom of the raw regenerator.

F1.3 The constant level tank or surge tank shall conform to the applicable provisions of E2 through E3.5 and shall be sized so the average product residence time is 4.0 min or less and the generation of foam is minimized. Except that if the average product

residence time in the tank is greater than 4 min, the product in the tank shall be held below 45.0° F (7.0° C) or above 145.0° F (63.0° C), or the tank shall be cleaned and sanitized at least every 4.0 hr.

F2 Regenerator Equipment

F2.1 When product to product regeneration is applied, and if the pressure of the product in the pasteurized product passages in the HTST pasteurizer system drops to within 2 psig (13.72 kPa) of the pressure of the product in the raw product passages, the booster pump shall stop.

F2.2 When product to product regeneration is applied, the pasteurized product, between its outlet from the regenerator and the nearest point downstream open to the atmosphere, shall rise to a vertical elevation of at least 12 in. (305 mm) 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. An effective vacuum breaker of sanitary design shall be considered as being an opening to the atmosphere. The vacuum breaker shall be installed downstream of the regenerator prior to any valve or device capable of being fully closed. The vacuum breaker shall be accessible.

F2.3 Suitable equipment (positive displacement pump, normally closed flow control valve or check valve) shall be installed between the outlet of the raw product regenerator and the inlet to the holding tube to prevent back flow of raw product to the regenerator when flow of raw product to the regenerator stops.

F2.4 All raw product in the regenerator(s) shall drain freely to the raw product constant level tank, or to waste when the raw product pump(s) is shut down, and the raw product pipeline is disconnected at the regenerator outlet. For split regenerators, all raw product sections shall drain freely to the constant level tank, or to waste, when the raw product pump(s) is shut down, and the raw product pipeline is disconnected at the lowest connection point(s) of the regenerators.

F2.5 Raw Product Regenerator Bypass

F2.5.1 The raw product may bypass the regenerator during startup when the raw product booster pump is not in operation or during processing to modify product temperatures. The bypass system permits cold product to be drawn directly to the timing pump or system from the

raw product constant level tank. After conditions of F11.2, F11.2.1, F11.2.2, and F11.2.3 are established, the booster pump may start to operate feeding raw product to the regenerator. The bypass pipeline may be manually or automatically controlled by a valve. Entrapment of product in the bypass pipeline during periods when the booster pump is in operation shall be precluded by close-coupled bypass connections, or by design of the manually or automatically controlled valve which will permit flow of product through the bypass pipeline, or by other equally effective means. The function of the regenerator pressure controller system shall not be defeated through use of this bypass.

F2.6 The processor shall have a current diagram available showing the plate and port arrangement in the correct operating sequence, and with the correct location of drain holes.

F2.7 Indirect Regenerators Above Atmospheric Pressure

When the pasteurized product is above atmospheric pressure, the product-to-heat transfer medium-to-product regenerator shall be constructed, installed, and operated such that the pasteurized product in the regenerator will be automatically under greater pressure than the heat-transfer-medium in the pasteurized product side of the regenerator. (High pressure systems shall be evaluated on an individual basis by the regulatory authority.)

F2.7.1 A differential pressure controller or recorder/controller shall be used to monitor pressures of the pasteurized product and the heat transfer medium. One pressure sensor shall be installed at the pasteurized product outlet of the regenerator and another pressure sensor shall be installed at the heat-transfer-medium inlet of the pasteurized product side of the regenerator.

F2.7.1.1 When this type of product-to-heat transfer medium-to-product regenerator is applied in HHST systems, this instrument shall divert the FDD whenever the lowest pressure of the pasteurized product in the regenerator fails to exceed the highest pressure of the heat-transfer-medium in the pasteurized product side of the regenerator by at least 2 psig (13.72 kPa). Forward flow of product shall be automatically prevented, and will not start again, until all product contact surfaces between the holding tube and the FDD have been held, continuously and simultaneously at or above the required pasteurization temperature for at least the required pasteurization time. The heat-transfer-medium pump shall be wired so that it cannot operate unless the timing device is in operation.

F2.7.1.2 When this type product-to-heat transfer medium-to-product regenerator is applied in HTST systems, the instrument shall stop the heat transfer medium pump whenever the lowest pressure of the pasteurized product in the regenerator fails to exceed the highest pressure of the heat transfer medium in the pasteurized product side of the regenerator by at least 2 psig (13.72 kPa), and further that the pasteurized product shall rise to a point at least 12 in. (305 mm) higher than the highest heat transfer medium in the system and the heat transfer medium supply is stopped and the heat transfer medium passages shall be vented to atmosphere. If a product vacuum breaker is in use, the venting of the heat transfer medium passages shall be at an elevation below that of the product vacuum breaker.

F2.8 Indirect Regenerators Below Atmospheric Pressure

Product-to-heat transfer medium-to-product regenerators, when the pasteurized product is below atmospheric pressure, shall be constructed, installed, and operated such that the heat-transfer-medium side of the regenerator, in the raw product section, will automatically be under greater pressure than the raw product side at all times.

F2.8.1 The heat-transfer water shall be a safe water and the heat-transfer water shall be in a covered tank which is open to the atmosphere at an elevation higher, by at least 12 in. (30.5 cm), than any raw milk level downstream from the constant-level tank. The heat-transfer water between its outlet from the regenerator and the nearest point downstream open to the atmosphere shall rise to a vertical elevation of at least 12 inches (30.5 centimeters) above the raw milk in the system and shall be open to the atmosphere at this or a higher elevation.

F2.8.2 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.

F2.8.3 The overflow of the constant level raw milk tank shall always be lower than the lowest milk level in the raw milk section of the regenerator. The regenerator shall be designed and installed so that all raw milk shall drain freely back to the upstream supply tank when the raw milk pumps are shut down and the raw milk line is disconnected from the regenerator outlet.

F2.8.4 No pump shall be located between the raw milk inlet to the regenerator and the raw milk supply tank, unless it is designed and installed to operate only when water is flowing through the heat-transfer section of the regenerator and when the pressure of the heat-transfer water is higher than the pressure of the raw milk. This may be accomplished by wiring the booster pump so that it cannot operate unless;

F2.8.4.1 The heat-transfer water pump is in operation and;

F2.8.4.2 The heat-transfer water pressure exceeds, by at least 2 psig (13.72 kpa), the raw milk pressure in the regenerator. Pressure gauges shall be installed at the raw product inlet and the heat-transfer water outlet of the regenerator. Except that an indicating differential pressure controller satisfying E14.1 also fulfills this requirement.

F2.9 In HHST pasteurizer systems with the FDD located downstream from the regenerator and/or cooler section and when 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, the controller shall be interlocked with the FDD. (Refer Section F5.6). The raw product booster pump may be permitted to run at all times, provided the timing pump is in operation.

F3 **Timing Pump or Timing System**

F3.1 The timing pump driving motor and starter shall be interwired with all components as prescribed in F5 and the timing pump or system shall be installed upstream of the holding tube, except as provided for in Section H1.2.

F3.2 Timing pumps and homogenizers, when used as timing pumps, shall not have bypass pipelines 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.

F3.3 **Other Flow Promoting Devices**

All other flow-promoting devices such as auxiliary pumps, separators, clarifiers and homogenizers, shall be properly interwired with the timing device so that they may only run and produce flow through the system when the FDD is in the fully diverted or the fully forward-flow position when in the product run mode as provided in F3.5.1.

F3.3.1 Separators or clarifiers that run continuously or continue to run after their power is shut off shall be automatically valved out of the system with fail-safe

valves so that they are incapable of producing flow during this period.

F3.3.2 Booster pumps shall be interwired with the timing pump and with the differential pressure controller.

F3.4 The individual components of the MBTS shall be installed in the system as follows:

F3.4.1 The pump shall be located downstream from the raw milk regenerator section if a regenerator is used.

F3.4.2 The magnetic flow meter shall be placed downstream from the pump. There shall be no intervening flow-promoting components between the pump and the FDD.

F3.4.3 Both the pump and the magnetic flow meter shall be located upstream from the holding tube.

F3.4.4 When a pump with an electronic variable speed drive is used in a MBTS, a sanitary product check valve or normally closed air-to-open valve shall be installed downstream of the raw product regenerator outlet and upstream of the holding tube to prevent positive pressure in the raw milk side of the regenerator whenever a power failure or shut down occurs.

F3.4.5 When a pump with a single speed drive is used in a MBTS, a normally closed air operated flow control valve shall be installed downstream of the meter and upstream of the holding tube.

F3.4.6 Flow through the magnetic meter and the holding tube shall be controlled to permit testing of the high-flow and low-flow/loss of signal alarm settings.

F3.4.7 Acceptable flow promoting devices for MBTS include:

- (a) Fixed speed pump with flow control valve.
- (b) Pump controlled by a variable speed drive.

F3.4.8 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 pump and the FDD.

F3.4.9 The magnetic flow meter shall be so installed that the product has contact with both electrodes at all times when there is flow through the system. This is most easily accomplished by mounting the flow tube of the magnetic flow meter in a vertical position with the direction of



- flow from the bottom to the top. However, horizontal mounting is acceptable when other precautions are taken to assure that both electrodes are in contact with product. The meter shall not be mounted on a high horizontal line which may be only partially full and thereby trap air.
- F3.4.10 The magnetic flow meter shall be piped in such a manner that at least ten times the meter flow tube diameter of straight, unobstructed pipeline exists upstream and downstream from the center of the meter before any elbow or change in direction takes place.
- F3.5 The timing pump and other flow-promoting devices not valved out of the system shall be interwired with the FDD and the STLR so they cannot run at sub-legal temperatures, unless the FDD is in the fully diverted position.
- F3.5.1 If interwiring of the timing pump is required as specified under F3.5 and H1.3, a time delay relay may be installed in the electrical circuit to the timing pump, so that during the normal transit time of the FDD (1 sec or less from forward to diverted-flow), the timing pump motor will remain running. The time delay relay shall provide a delay of not more than 1 sec. If the timing pump motor stops, it shall not restart automatically. It shall not be possible to restart the timing pump motor at sub-legal temperature, unless the FDD is in its fully diverted position. The time delay may be of the fixed time or adjustable time type. If the time delay relay is adjustable, means of sealing the unit shall be provided.
- F3.6 When a product to product regenerator is used with these systems, it usually is necessary to by pass the regenerator during start up and when the FDD is in the diverted flow position. There shall be no dead ends in the bypass pipeline.
- F3.7 All required public health controls shall be tested by the regulatory control authority at the frequency specified in the PMO. Where adjustment or changes can be made to these devices such as, variable or fixed capacity driving mechanisms or controls affecting flow rate, cut-in or cut-out temperature, appropriate seals shall be applied so that changes cannot be made without breaking the seals.
- F4 Holding Tube**
- F4.1 The holding tube supports shall be installed and adjusted to maintain all parts of the holding tube in a fixed position, and to maintain the minimum upward slope, as prescribed in E.6.6.
- F4.2 No part of the holding tube shall be higher than the inlet connection to the FDD.
- F4.3 Piping from the outlet of the heater to the beginning of the holding tube with less than 1/4 in. per foot (20.8 mm per m) continuously upward slope shall not be considered part of the holding tube.
- F4.4 A fitting for the timing electrode fitting is required to be installed in all systems, except HHST systems, at the inlet of the holding tube.
- F4.5 HHST Pasteurizers shall use holding times which are determined by calculated pumping rates. The holding tube shall be of sufficient length to prevent the fastest flowing product particles from traversing the holding tube in less than the required holding time. Since laminar flow can occur in the holding tube during pasteurization, holding tube lengths shall be calculated as twice the length required to hold the average flow for the time standard.
- F4.5.1 A pressure limit instrument/pressure controller shall be provided and shall be interwired so that the FDD will move to the divert position if the product pressure in the holding tube falls below a prescribed value. A means for sealing the controller shall be provided, so settings cannot be changed without breaking the seal. See Section F15 Steam Injection for additional requirements.
- F4.5.1.1 For operating temperatures between 191°F (89°C) and 212°F (100°C), the instrument shall be set at 10psig (69kPa).
- F4.5.1.2 For operating temperatures above 212.0°F (100.0°C), the instrument shall be set at a pressure 10psig (69kPa) above the boiling pressure of the product at its maximum temperature in the holding tube. (Note: If this pressure is too low, the resultant vaporization in the holding tube will substantially reduce residence times.)
- F4.5.1.3 The pressure limit instrument/pressure controller is not required when the equipment operates with product in forward flow with greater than 75 psig (518 kPa) in the holding tube.

F5 Flow-Diversion Device (FDD)

F5.1 Except as provided for in H1.3.3.1, H1.3.3.2 and F5.3.2, the FDD shall be so interwired with the STLR that when the product at the STLR temperature sensor is at sublegal temperature the FDD will automatically assume the diverted position. The FDD shall be actuated by the same temperature sensor that actuates the STLR.

F5.2 When MBTS is used the FDD shall be so interwired that when the flow rate is below the low flow alarm setting or, loss of signal alarm or, above the high flow alarm setting, the FDD shall automatically assume the diverted-flow position.

F5.3 The following additional criteria shall apply to dual stem Flow Diversion Devices.

F5.3.1 When the mode selector switch is moved from the "Process" to "Inspect" position, the FDD shall be prevented from assuming the forward-flow position until the timing pump and all other flow promoting devices have stopped. Separators and clarifiers shall be automatically valved out of the system. The time delay shall be set and sealed at a time that is greater than the longest run-down time of these flow-promoting devices which are not automatically valved out of the system.

F5.3.2 During mechanical cleaning, the FDD may assume the forward-flow position or be cycled at sub-legal temperature. If the system is designed so the FDD may assume the forward-flow position and the timing pump and other flow-promoting devices may run during mechanical cleaning at sub-legal temperatures, an additional time delay relay is required. This time delay shall hold the FDD in the diverted-flow position for at least 10.0 min after the FDD mode switch has been moved to the "CIP" position. Any flow-promoting device which may produce pressure in the raw regenerator during mechanical cleaning shall not run for at least 10 min after the FDD mode switch has been moved to the "CIP" position or, in the case of separators and clarifiers upstream of the FDD, shall be automatically valved out of the system during this 10 min period and the valves shall be controlled by the same time delay as the FDD. The 10.0 min time delay shall be set and sealed.

F5.3.3 If the area between the divert and leak detect valve seats is not self draining when the FDD is in the diverted position, a delay of at least one second and not more than two seconds is required between the movement of the divert and leak detect valves when the FDD assumes the forward flow position except that:

F5.3.3.1 The delay may be longer than two seconds in MBTS, or,

F5.3.3.2 The delay may be longer than two seconds if the holding time in diverted flow through an unrestricted divert valve line is longer than the required pasteurization time as specified in Definition B1 of this Practice, or,

F5.3.3.3 No time delay is required in HHST pasteurization systems in which the FDD is located down stream from the inlet of the pasteurized regenerator and in which all forward flow product contact surfaces of the FDD are sanitized (or sterilized) before processing.

F5.4 Reference Section F7 for sanitary pipes and fittings related to FDD interconnection.

F5.5 All electrical and pneumatic (between valve solenoid and FDD actuator) connections to the FDD shall be of a permanent type. (Quick disconnect or quick couplers are not acceptable)

F5.6 After a flow diversion in HHST systems, forward-flow is automatically prevented 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 for the product being pasteurized.

F6 Indicating Thermometer(s)

F6.1 Indicating Thermometer(s) - Hot Product: One thermometer shall be installed in the fitting at the outlet of the holding tube, as described in E6.8 and E6.9 except as provided for in Section H1.3.7.

F6.2 Indicating Thermometer(s) - Cold Product: If provided, this thermometer(s) shall be installed in the pipeline from the outlet of the cooling section.

F7 Connecting Sanitary Pipes and Fittings

F7.1 Sanitary pipelines connecting all components of the HTST or HHST pasteurizer systems shall be without dead-ends, except for openings on sanitary fittings which shall be close coupled.

F7.2 A recirculation valve(s) may be provided in the pasteurized product discharge pipeline as close as possible to the pasteurizer for recirculating pasteurized product, rinse water, cleaning solution, or sanitizing solution. The valve(s) shall be downstream from the opening to the



- atmosphere required in F2.2 If a recirculation valve(s) is used, a separate self-draining sanitary pipeline may be provided from the recirculation valve(s) directly to the raw product constant level tank-that is designed to preclude back siphonage. (See E3.5)
- F7.3 Sanitary pipelines shall be provided from the FDD to the raw product constant level tank, or to waste. If the diverted-flow and leak detect pipelines returns to the raw product constant level tank, they shall enter the top of the tank or side of the tank at a distance at least equal to two times the diameter of the largest inlet, above the maximum over-flow level of the raw product constant level tank and shall be self-draining.
- F7.3.1 The diverted-flow pipeline shall be free of restrictions or valves unless such restrictions or valves are so designed that stoppage of the diversion pipeline cannot occur. If necessary to lengthen the holding time during diverted-flow, an identifiable sanitary self-draining restrictor may be installed in a vertical portion of the diverted-flow pipeline.
- F7.3.2 The leak detect pipeline shall be free of restrictions and shall be self-draining, with no reductions in size from the valve inlet. If the leak detect pipeline returns to the raw product constant level tank, it shall incorporate a line-size sight glass in a vertical portion of the line to show evidence of leakage.
- F7.3.2.1 Sight and/or light windows and sight indicator openings, when provided, shall be in accordance with 3-A Sanitary Standards for Sight and/or Light Windows and Sight Indicators in Contact with Milk and Milk Products, Number 65-.
- F7.4 When a homogenizer of larger capacity than timing pump, is used in conjunction with a timing pump, it shall include an unrestricted, open, recirculation pipeline to connect the outlet pipeline from the homogenizer to its inlet pipeline. The recirculation pipeline shall 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 pipeline to the inlet pipeline, may be used in the recirculating pipeline provided it is of the type which provides a cross-sectional area at least as large as the recirculating pipeline, and be of the nonrestrictive type.
- F7.5 Connections to the pasteurizer heat exchanger(s) shall meet the applicable provisions of the 3-A Sanitary Standards for Sanitary Fittings for Milk & Milk Products No. 63-.
- F7.6 During processing, pipelines and equipment used to contain or conduct product shall be effectively separated from tanks or pipelines containing cleaning, and/or sanitizing solutions. This can be accomplished by:
- F7.6.1 Physically disconnecting all connection points between tanks or pipelines containing cleaning and/or sanitizing solutions from pipelines and equipment used to contain or conduct product or,
- F7.6.2 Separation of all connection points between such pipelines 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:
- F7.6.2.1 The opening to the atmosphere (vent) is equal to the largest pipeline feeding the valve(s).
- F7.6.2.2 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 properly seated in the blocked position.
- F7.6.2.3 These valves (or valve seats in the case of single bodied double seat valves) are part of an automatic fail-safe 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 cleaning the pipelines containing this valve arrangement. Testing criteria shall be available for these valves or systems.
- F7.6.2.4 The system does not have any manual overrides.
- F7.6.2.5 Controls for the fail-safe system are secured as directed by the regulatory agency in order to prevent unauthorized changes.
- F7.6.2.6 The vent is not cleaned until product has been removed or isolated.
- F7.6.3 In HHST systems, an instrumented steam block may be used between product and chemical circuits in lieu of F7.6.1 provided it is designed, interwired, and operated to effectively prevent a less than one valve separation in the case of leakage of either steam block to valve.
- F7.7 When a sanitary bypass pipeline is installed,

from the regenerator inlet to achieve proper separating temperature or proper exiting temperature of the pasteurized product, all components used in this pipeline shall be of sanitary design and no dead ends are allowed. The function of the regenerator pressure controller system and the vacuum breaker shall not be defeated through use of such pipeline.

F8 Heating Medium System

F8.1 When the heating medium system is not integral with other components of the pasteurizer, it may be installed in other than the product processing room.

F8.2 Sanitary piping is not required for connecting the heating medium system with the heating section of the pasteurizer. However, when a plate type heat exchanger is used, the piping shall not prevent opening the plates for inspection. The final connection shall be a sanitary fitting, except the stationary end may be a non-sanitary fitting.

F9 Cooling Medium System (When a cooling section is included.)

F9.1 The equipment used for re-cooling and recirculating the cooling medium shall be installed, whenever practical, in other than the product processing rooms.

F9.2 Sanitary piping is not required for connecting the cooling medium unit with the cooling section of the pasteurizer. However, when a plate type heat exchanger is used, the piping shall not prevent opening the plates for inspection. The final connection shall be a sanitary fitting, except the stationary end may be a non-sanitary fitting.

F9.3 Where recirculated cooling medium is used, it shall be properly protected from contamination.

F9.4 When recirculated cooling medium is in use and recirculating and if product pressure in product passages drops to within 2 psig (13.72 kPa) of the cooling medium pressure in the cooling medium passages, the cooling medium supply shall be stopped or diverted and the cooling medium passages vented to atmosphere. If a product vacuum breaker is in use, the venting of the cooling medium passages shall be at an elevation below that of the product vacuum breaker.

F10 Control Panel

F10.1 The control panel, if used, shall be supported so vibration is minimized and located to minimize temperature and moisture extremes, and convenient for operation and testing. (Convenient visual access

is required.)

F11 Raw Product Booster Pump Controls

F11.1 The raw product booster pump shall be permanently wired so that it cannot operate unless:

F11.1.1 The timing pump is in operation.

F11.1.2 The FDD is in forward-flow position.

F11.1.3 The raw product booster pump control shall not allow the raw product booster pump to operate unless the pressure in the pasteurized product side of a product to product regenerator is greater by at least 2 psig (13.72 kPa) than the pressure in the raw product side of a product to product regenerator. If the pasteurized product outlet is at the bottom of the plate heat exchanger, the 2 psig (13.72 kPa) shall be increased by an amount equal to the gravity head of product in the regenerator.

F11.2 Regenerator Pressure Sensing Methods

F11.2.1 A sanitary, sealable, adjustable, differential pressure controller of approved manufacture and designed to measure simultaneously the raw product booster pump discharge pressure and the pasteurized product regenerator outlet pressure. Set the differential between the two indicators to conform to the requirements of F11.1.3 and seal.

F11.3 When a two-speed booster pump is installed to provide higher pressures and flow for mechanical cleaning, the high-speed starter shall be wired through the FDD Mode Switch so that the pump will operate at the high speed only with the switch in CIP position (See F5.3.2). This pump shall not start for at least 10 minutes with FDD mode switch in the CIP position.

F12 Homogenizers

F12.1 When a stuffing pump is utilized in conjunction with a homogenizer it shall be inter-wired to run only when the homogenizer is running in the process mode, except that the stuffing pump may run at all times during the CIP mode.

F12.2 When the homogenizer is not used as a timing pump, it shall be a nonflow-promoting device and installed in such a manner that it cannot apply negative pressure at the forward-flow port of the FDD nor decrease the holding time of the product within the holding tube below the legal minimum. See F7.4



F12.2.1 When products are to be processed that do not require homogenization, a bypass pipeline may be installed with valving such that both the bypass and the homogenizer may not be connected at the same time. This may be accomplished with three-way plug valves, pinned such that an open path does not exist unless both valves are either in the homogenizer or the bypass position, or valved with suitable, fail-safe valves that accomplish the same objective. When used as a homogenizer a recirculation line is required.

F13 Separator and/or Clarifier

F13.1 When separator(s) and/or clarifier(s) are used in the HTST or HHST pasteurizer system, they shall be located to provide adequate access for cleaning and inspection and shall be installed and operated in such a manner that they will not adversely cause a change in 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 safeguard.

F13.2 The separator and/or clarifier may have the driving motor wired independently of the timing pump and FDD so that when the timing pump is stopped the separator and/or clarifier may continue to run. (See F13.4 through F13.7).

F13.3 Product to product regenerators requiring a pump to feed the separator and/or clarifier shall conform to requirements of Section F2 for the connection between the pasteurized product regenerator and any pump.

F13.4 A separator and/or clarifier when located on the raw side of the system shall automatically valve out and its stuffing pump shall de-energize when:

F13.4.1 The timing pump is de-energized, or,

F13.4.2 The dual stem FDD is in the inspect position, or

F13.4.3 During the first ten minutes of a required ten minute delay in CIP mode and during any period of diverted flow, or

F13.4.4 The pressure in any regenerator section is out of compliance with legal pressure requirements.

F13.5 A separator and/or clarifier shall not be located between the timing pump and the FDD.

F13.6 A separator and/or clarifier may be located downstream of the FDD if the following criteria are applied:

F13.6.1 An opening to the atmosphere is located between the FDD and the inlet to the separator and/or clarifier.

F13.6.2 All pasteurized product rises to at least 12.0 inches (305mm) higher than the highest raw milk in the system and is open to atmosphere at that point between the outlet of any pasteurized side regenerator and the inlet of the separator and/or clarifier.

F13.6.3 A separator and/or clarifier located down stream of the FDD shall automatically valve out of the system, and its stuffing pump shall de-energize when:

F13.6.3.1 The dual stem FDD is in the required 10.0 min. delay in CIP mode, or

F13.6.3.2 the FDD in the divert position, or

F13.6.3.3 the timing pump is de-energized, or

F13.6.3.4 the temperature is below the required pasteurization temperature and the FDD is not in the fully diverted position.

F13.7 The following criteria apply to an installation where a separator and/or clarifier shall be valved out.

F13.7.1 A valve shall be located to isolate the product supply line to the separator and/or clarifier, and

F13.7.2 a valve(s) shall be located to prevent all flow exiting the separator and/or clarifier from being returned to the pasteurization system down stream of the separator and/or clarifier, and

F13.7.3 the valves required to isolate the separator and/or clarifier out of the system to conform to the two criteria in Sections F13.7.1 and F13.7.2 shall actuate to the isolation position upon loss of air pressure or power.

F13.7.4 Any separator and/or clarifier stuffing pumps shall be de-energized when the condition requiring isolation exists.

F13.8 Either pasteurized cream or pasteurized skim milk from the separator may be re-introduced to the HTST or HHST pasteurizer, at a point beyond the FDD.

F13.9 If cream is discharged to a cream constant level tank, the criteria of section F1.3 shall apply.

F13.10 Where feasible, desludging separators and/or

clarifiers shall be located in a separate room or in such a manner as to minimize contamination from pathogen aerosols.

F14 **Flavor Control Equipment or Vacuum Treatment Equipment**

F14.1 Flavor control equipment, which includes vacuum and steam-vacuum treatment system, may be installed and operated in conjunction with HTST or HHST pasteurizer systems provided that such equipment shall not:

F14.1.1 Influence the proper pressure relationships within the regenerator;

F14.1.2 reduce the holding time below the required legal holding time;

F14.1.3 Interfere with the detection or the stoppage of, the forward flow of sub-legally heated product;

F14.1.4 contaminate the product with toxic substances or foreign material through the use of sub-standard steam or steam distribution systems;

F14.1.5 adulterate the product with added water when such addition is not permitted.

F14.2 All vacuum equipment shall conform to the following applicable provisions:

F14.2.1 When vacuum equipment is located downstream from the FDD, automatic means shall be provided to prevent negative pressure between the forward-flow port of the FDD and the inlet to the vacuum chamber. A vacuum breaker, and automatic shut-off valve downstream from the vacuum breaker shall be installed in the pipeline between the FDD and the inlet to the vacuum chamber. The effectiveness of such an installation shall be evaluated by disconnecting the pipeline from the forward-flow port while the pasteurizer is operating in diverted-flow, and with the vacuum equipment in operation, checking the pipeline for negative pressure.

F14.2.2 When vacuum equipment is located downstream from the FDD, means shall be provided to prevent the lowering of the pasteurized product pressure in the regenerator during diverted-flow or shutdown. An automatic shut-off valve, and a vacuum breaker downstream from the automatic shut off valve, shall be installed between the vacuum chamber and the regenerator. The vacuum breaker shall always be installed immediately upstream from the pasteurized product inlet to the regenerator, and at a minimum elevation of 12.0 in. (304.8 mm) above any raw milk in the system. The effectiveness of such an

installation shall be evaluated by disconnecting the pipeline to the inlet of the pasteurized product side of the regenerator while the pasteurizer is operating in diverted-flow and, with the vacuum equipment in operation, checking the pipeline for negative pressure.

F14.2.3 When vacuum equipment is located downstream from the FDD, the holding time shall be tested with the timing pump operating at maximum capacity, and the vacuum equipment operating at maximum attainable vacuum.

F14.2.4 Vacuum equipment shall use an indirect, closed-type condenser.

F15 **Steam Used In Contact With Product**

F15.1 Steam used in contact with product shall meet applicable provisions of the 3-A Accepted Practices for Producing Steam of Culinary Quality, Number 609-.

F15.2 When culinary steam is introduced into the 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. Such means shall include 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 shut-off valve installed in the culinary steam pipeline, each wired through the FDD so as to stop the introduction of steam when the FDD moves into diverted-flow position.

F15.3 When culinary steam is introduced directly into the product, automatic means shall be provided to maintain a proper temperature differential between incoming and outgoing product to preclude product dilution, when such dilution is not permitted the following apply:

F15.3.1 An automatic ratio controller which senses the temperature of the product prior to the addition of steam and also either in the vacuum chamber or at its exit and automatically adjusts the operating vacuum in the vacuum chamber so as to assure the removal of all water added in the form of steam, or other systems which will assure no dilution.

F15.3.2 The proper temperature differential between the incoming and outgoing products shall be determined for each HTST or HHST installation by means of total solids determination on product prior to the introduction of steam and after exit from the vacuum chamber and such differential set on the ratio controller. An air-



operated pressure switch, installed in the air control pipeline between the ratio controller and the vacuum regulator, or other automatic means, shall stop the introduction of steam into the product when the vacuum in the vacuum chamber is insufficient to prevent product dilution.

- F15.4 If product is heated by direct steam injection, a differential pressure limit controller across the injector shall be used to provide adequate isolation of the injection chamber. The instrument shall have a differential pressure controller so that the FDD will move to the divert position if the pressure drop across the injector falls below 10 psig (69 kPa).

F16 Strainers

- F16.1 When a strainer is used in conjunction with the HTST or HHST pasteurizer system, the strainer shall be placed upstream from the final heater, and be located to provide adequate access for cleaning and inspection of the housing.

F17 Auxiliary Pump

- F17.1 Auxiliary pump(s) used in the HTST or HHST pasteurizing system, shall be installed and operated in such a way that will not:

F17.1.1 influence the proper pressure relationship within the regenerator, or

F17.1.2 reduce the holding time below the required minimum, or

F17.1.3 cause flow through the holding tube at sub-legal temperatures unless the FDD is in the fully diverted position except as provided by F5.3.2.

F17.2 In the HTST or HHST pasteurizer system where an auxiliary, recirculating pump is installed in the system to obtain a greater velocity through a heater(s) than that which would be produced by the timing pump, a sanitary circulating pipeline between the outlet of the heater and the inlet of the recirculating pump shall be provided.

F17.2.1 When a recirculated heater is used in a MBTS, it may be installed either upstream or downstream of the centrifugal timing pump without special product flow considerations provided that it is installed upstream of the flow control valve. If the recirculated heater is installed downstream of the flow meter and flow control valve, the recirculation line shall be of the same or larger diameter than the inlet pipeline to the circulating pump.

F17.2.2 When a recirculated heater is used with a positive displacement timing pump, it may be installed

either upstream or downstream of the timing pump, but the recirculation line shall be of the same size or larger than the inlet pipeline to the circulating pump.

F18 Electric Wiring

- F18.1 All electric wiring interconnection shall be in permanent conduit or wire duct (except that rubber covered cable may be used for final connections) and installed in accordance with the local electrical code, with no electrical connections to defeat the purpose of any provision of these 3-A Accepted Practices.

F19 Checking and Testing

- F19.1 Prior to the final regulatory testing, completed installations shall be thoroughly checked and tested by a qualified representative of the manufacturer, their distributor, or the processor to determine that the installation meets all provisions of these 3-A Accepted Practices.

F19.1.1 The HTST or HHST System shall be made to function within the requirements of these 3-A Accepted Practices. Tests shall be made, in accordance with the methods prescribed in Appendix I, Pasteurization Equipment and Controls - Tests found in the PMO, using the most current revisions (other tests may be required that are not referenced).

G RECOMMENDED PUBLIC HEALTH CONTROL TESTS

G1 All applicable tests referenced in the PMO shall be performed as described therein (other tests may be required that are not referenced).

G2 Cooling Media Pressure Inspection

G2.1 Upon installation and at least semi-annually thereafter, all cooling media pressure monitoring and control equipment, including flow-control and stop valves, shall be inspected to assure operation is in compliance with the requirements of Sections E12.3 and F9.4. A record of the inspection results shall be maintained.

G3 Leak detection in all plate and tubular heat exchange surfaces shall be performed at least once every 12 months, and a record of inspection results maintained. (See Appendix K, Section 8.2 for examples of acceptable methods).

G4 Details on informational forms, provided at the

end of this practice, shall be maintained and presented to the regulatory control authority upon request. If required, seals shall be on hand ready for installation upon completion of checking and testing by the regulatory control authority. Equipment shall be sealed by the regulatory control authority or sealed in his/her presence.

- G4.1 A qualified tester is one who has received appropriate instruction on HTST or HHST pasteurizer systems, and has made or supervised two actual complete installations that have been approved and sealed by a regulatory control authority.
- G4.2 In an emergency, checking and testing by the qualified representative may be at the same time as the regulatory control authority checking and testing.
- G5 Notice of the approximate time an installation will be ready for checking and testing by the regulatory control authority shall be given to the regulatory control authority in writing by the processor at the time application is made, or at least seven (7) days prior to the time the unit will be ready for checking and testing by the regulatory control authority.
- G5.1 In case there is a delay affecting the designated time for regulatory control authority checking and testing, the regulatory control authority shall be notified immediately.
- G5.2 In case the regulatory control authority is unable to keep a designated testing date, the regulatory control authority should notify the processor immediately upon receipt of the notice.

H SPECIAL CONSIDERATIONS FOR SPRAY DRYER AND EVAPORATOR APPLICATIONS

- H1 **Special Considerations For Spray Dryers**
For some HTST pasteurizer systems, which are integral with spray dryer systems, it is necessary to have special considerations and exceptions to insure proper mutual operation of both the HTST pasteurizer and spray dryer systems without compromising the intent of these practices.
- H1.1 **Timing Pump and Flow-Diversion Device**
- H1.2 When the HTST pasteurizer is to be used to re-pasteurize a concentrated milk product for drying in a process in which the product pressure required for drying is at least 300 psig (2068 kPa), the timing pump may be located downstream from the FDD provided all other applicable requirements of these practices are met. In this application the timing

pump shall be a high pressure pump of the plunger type.

H1.3 Flow Diversion Device

- H1.3.1 When the timing pump is to be located as provided for in H1.2, the FDD shall have an auxiliary temperature sensor-controller and a time delay relay to accomplish the requirements of F5.1.
- H1.3.1.1 The auxiliary temperature sensor-controller and/or the time delay relay do not have to be in the same case with the STLR but they shall conform to the applicable provisions of section E8.1.
- H1.3.2 The auxiliary temperature sensor-controller shall have a control mechanism for setting the temperature at which forward-flow can occur and a means of indicating when the product temperature at the temperature sensor of the auxiliary temperature sensor-controller is at or above the temperature at which the control mechanism is set. The means of indicating may be a pilot light or other suitable means.
- H1.3.3 The FDD shall be actuated by the auxiliary temperature sensor-controller and the time delay relay as required in H.1.3 as well as by the temperature sensor that actuates the product temperature recorder as required in F.5.1.
- H1.3.3.1 Except as provided for in H1.3.3.3, the STLR, the auxiliary temperature sensor-controller and the time delay relay are to be so interwired that the FDD (1) will assume the diverted-flow position when the product temperature is below legal minimum and (2) will assume the forward-flow position only when the product temperature has reached minimum legal temperature for at least legal holding time. The interwiring shall be such that when the FDD is in the forward-flow position, the auxiliary temperature sensor-controller will not cause the FDD to move to the diverted-flow position when the temperature of the product at its temperature sensor is sub-legal.
- H1.3.3.2 If the FDD and/or STLR has a manual means of causing the FDD to assume the diverted-flow position, the STLR and the auxiliary temperature sensor-controller are to be so interwired that after the FDD has assumed the diverted-flow position due to operation of the manual means, the FDD will not assume the forward-flow position until the product temperature at both temperature sensors is at or above legal temperature for at least legal



holding time.

H1.3.3.3 During mechanical cleaning, the FDD may assume the forward-flow position or be recycled at sub-legal temperature. If the system is designed so that the FDD may assume the forward-flow position and the timing pump and other flow-promoting devices may run during mechanical cleaning at sub-legal temperatures, an additional time delay relay is required. This time delay relay shall hold the FDD in the diverted-flow position for at least 10 min after the FDD mode switch has been moved to the CIP position. The 10 min time delay shall be set and sealed.

H1.3.4 The auxiliary temperature sensor-controller and the time delay relay shall be provided with a simple means of sealing that will prevent, unless the seal is broken, the changing or manipulating of (1) the control mechanism for setting the temperature at which forward-flow can occur and (2) the mechanism for setting the length of time delay.

H1.3.5 The temperature accuracy of the auxiliary temperature sensor-controller shall be that required for the STLR in E.8.4.

H1.3.6 The thermometric response of the auxiliary temperature sensor-controller shall be that required for the STLR in E.8.16.

H1.3.7 The temperature sensor of the auxiliary temperature sensor-controller and the second hot product indicating thermometer, as required in Section E.10.1 shall be installed in a fitting located in the product constant level tank outlet line between the tank outlet connection and the first connection downstream.

H1.3.8 An automatic means shall be provided to prevent negative pressure at the downstream side of the forward-flow port of the FDD during diverted-flow. The automatic means shall be one of the following or other acceptable means:

H1.3.8.1 An FDD incorporating two valves (one a divert valve and the other a leak escape valve) with the leak escape opening having a total effective area at least as great as the area of the forward flow opening. The leak escape opening of the leak escape valve shall be provided with a discharge pipeline which shall discharge to either (1) the atmosphere and be protected from back siphonage of vapors or liquids or (2) the product constant level tank, in which case the pipeline shall be installed in accordance with F7.3.2.

H1.3.8.2 An automatic shut off valve, downstream from an effective vacuum breaker of sanitary construction

having enough air admitting capacity to prevent negative pressure, which shall automatically assume the stop position when the FDD is caused to divert.

H1.4 Safe Water

H1.4.1 A safe water pipeline, when connected to a product pipeline in which the product may be under vacuum, shall be installed in conformance with local plumbing codes for water flowing into a vacuum and shall have a sanitary check valve adjacent to its connection to the product pipeline to prevent back flow of product into the safe water pipeline.

H1.5 Auxiliary Pump

H1.5.1 An auxiliary pump is required when the timing pump is to be located as provided in Section H1.2, in order that there will be product recirculation during diverted-flow and to assure positive product pressure at the timing pump inlet during forward-flow. If the auxiliary pump is of greater capacity than the timing pump it becomes a recirculating pump and a sanitary recirculating line between the outlet of the heater and the inlet of the recirculating pump shall be provided. The product pressure at the inlet of the FDD shall be less than the maximum product pressure at which the FDD will move from the forward-flow position to the diverted flow position. This may be accomplished by one of the following:

H1.5.1.1 Use of a recirculating pump having a maximum output pressure of less than the maximum product pressure at which the FDD will move from the forward-flow position to the diverted-flow position.

H1.5.1.2 Installation of a pressure control valve in the recirculating line which is set and sealed at a pressure less than the maximum product pressure at which the FDD will move from the forward-flow position to the diverted flow position. This valve, if used, shall be designed and controlled so that it cannot be completely closed or allow the pressure to increase to where it interferes with the correct operation of the FDD.

H1.5.1.3 Altering or rebuilding the FDD so that the maximum product pressure at which it will move from the forward-flow position to the diverted-flow position is greater than the maximum output pressure of the recirculating pump.

H2 Special Considerations For HTST Systems Used With Evaporators and Employing Product to Product or Product to Heat Transfer Medium to Product Regeneration Systems

Those HTST pasteurizer systems which are integral with evaporator systems and employ product-to-product or product-to-heat transfer media to product regeneration systems shall be considered differently in order to insure proper operation of both the HTST pasteurizer and evaporator together without compromising the intent of these practices.

APPENDIX

I APPLICATION TO INSTALL

- I1 A manufacturer, distributor or processor desiring to install an approved HTST or HHST pasteurizer system should first make application on a suitable form, as prescribed by the local regulatory control authority, or, in the absence of a required form, on a form as suggested herein (FORM 1) and include a flow diagram. The manufacturer/supplier should provide the applicant with two completed copies of FORM 1, and the two copies of the flow diagram. Application should be submitted to the regulatory control authority by the applicant, on suitable forms, at least 15 days prior to the start of any installation. Approval or advice as to necessary changes should be made to the applicant promptly.
- I1.1 In an emergency the time interval above may be waived only by the regulatory control authority.
- I2 Changes in an existing system, affecting capacity, timing, or arrangement, should be submitted by the processor on a form as specified in 1.1 above. It is recommended that all milk control authorities adopt an APPLICATION TO INSTALL form including the data provided for in FORM 1. A REPORT OF INSTALLATION form, similar to FORM 2, is recommended for use in reporting the check-testing data prescribed in F19.1.

J INTERFACING PROGRAMMABLE LOGIC CONTROLLERS AND COMPUTERS TO HTST AND HHST PASTEURIZER SYSTEMS

- J1 Conventional hard-wired operating controls and instrumentation may be effectively interfaced with micro-processor based systems. The almost universal application of the dual-stem FDD(s) and its associated Inspect-Process-CIP mode selector switch makes it possible to interface all legal controls to a microprocessor based system in a manner which assures compliance with all public health requirements.
- J1.1 When computers or programmable logic controllers are used with these systems, they must be installed in such a manner that no public health controls are controlled by, or circumvented by, the computer or programmable logic controller during the product run operations except as allowed in the PMO and current FDA coded memoranda addressing this topic.⁸
- J2 **Micro-Processor Control**
- J2.1 Micro-Processor controlled outputs should not circumvent any function of the legal controls when the FDD mode switch is in the Process position.
- J2.2 Micro-processor control of system components including the booster pump, timing pump, and FDD(s) may be implemented with the FDD mode switch at the CIP position after the 10 min time delay.
- J2.3 Other components including regenerator bypass (startup) valve(s), pasteurized product regenerator back-pressure valves, discharge valves and recycle (bypass) valves, hot water set controls, raw product constant level tank controls, cold milk temperature controls, MBTS product flow controls and heating and cooling medium controls may be micro-processor controlled under all operating conditions.
- J2.4 Control outputs via the approved wiring to the booster pump, timing pump, FDD(s) and all devices required to be interlocked to these primary components may be used as inputs to the micro-processor for use in implementing desired control sequences.
- J2.5 Input hardware used in accordance with J2.4 must be incapable of functioning as an output, thus circumventing legal-wired logic.