APPENDIX I. PASTEURIZATION EQUIPMENT AND CONTROLS--TESTS

I. TESTING APPARATUS SPECIFICATIONS

TEST THERMOMETER

Type: Mercury-actuated; readily cleanable; plain front, enameled back; length 305 millimeters (12 inches); immersion point to be etched on stem; mercury to stand in contraction chamber at 0°C (32°F).

Scale Range: At least 7°C (12°F) below and 7°C (12°F) above the pasteurization temperature at which the operating thermometer is used, with extensions of scale on either side permitted; protected against damage at 149°C (300°F).

Temperature Represented by Smallest Scale Division: 0.1°C (0.2°F).

Number of Degrees per 25 Millimeters (Inch) of Scale: Not more than 4 Celsius degrees or not more than 6 Fahrenheit degrees.

Accuracy: Within 0.1°C (0.2°F), plus or minus, throughout specified scale range. The accuracy shall be checked against a thermometer which has been tested by the National Institute of Standards and Technology.

Bulb: Corning normal or equally suitable thermometric glass.

Case: Suitable to provide protection during transit and periods when not in use.

GENERAL PURPOSE THERMOMETER

Type: Pocket type

Scale Range: 1°C (30°F) to 100°C (212°F), with extension on either side permitted. Protected against damage at 105°C (220°F).

Temperature Represented by Smallest Scale Division: l°C (2°F).

Accuracy: Within 1°C (2°F), plus or minus, throughout the specified scale range. Checked periodically against a known accurate thermometer.

In the case of mercury actuated general purpose thermometers, the following additional specifications shall apply:

Magnification of Mercury Column: To apparent width of not less than 1.6 millimeter (0.0625 of an inch).

Number of Degrees per Inch of Scale: Not more than 29 Celsius degrees or not more than 52 Fahrenheit degrees.

Case: Metal, provided with a fountain pen clip.

Bulb: Corning normal or equally suitable thermometric glass.

ELECTRICAL CONDUCTIVITY MEASURING DEVICES

Type Manual or automatic.

Conductivity: Capable of detecting change produced by the addition of 10 ppm of sodium chloride, in water of 100 ppm of hardness.

Electrodes: Standard.

Automatic Instruments: Electric clock, time divisions not over 0.2 of a second.

STOPWATCH

Type: Open face, indicating fractional seconds.

Accuracy: Accurate to 0.2 of a second.

Hands: Sweep hand (if applicable), one complete turn every 60 seconds or less.

Scale: Divisions of not over 0.2 of a second.

Crown: Depression of crown or push button starts, stops and resets to zero.

II. TEST PROCEDURES

Equipment and field tests to be performed by the regulatory agency are listed and suitably referenced below. The results of tests shall be recorded on suitable forms (See Appendix M) and filed as the regulatory agency shall direct.

TEST 1
INDICATING THERMOMETERS--
TEMPERATURE ACCURACY

Reference: Item 16p(E).

Application: To all indicating thermometers used for measurement of product temperature during pasteurization or aseptic processing, including airspace thermometers.

Frequency: Upon installation and once each 3 months thereafter or whenever the thermometer has been replaced or the regulatory seal on a digital sensor or the digital control box has been broken.

Criteria: Within 0.25^{o} C (0.5^{o} F) for pasteurization and aseptic processing thermometers and 0.5^{o} C (1^{o} F) for airspace thermometers, plus or minus, in a specified scale range. Provided, that on batch pasteurizers used solely for 30-minute pasteurization of products at temperatures above 71° C (160° F), indicating thermometers shall be accurate to within 0.5° C (1° F) plus or minus.

Apparatus:

a. Test thermometer meeting specifications under Appendix I, Part 1.

b. Water or oil bath and agitator.

c. Suitable means of heating water or oil bath.

Method: Both thermometers exposed to a water or oil medium of uniform temperature. Indicating thermometer reading is compared to the reading of the test thermometer.

Procedure:

a. Prepare a quantity of water in a water bath, or a quantity of oil in an oil bath, or a quantity of other suitable heating media, by raising the temperature of the water, oil or other

suitable heating media to within a range of 2°C (3°F) of the appropriate pasteurization or airspace temperature, or aseptic processing temperature.

b. Stabilize the bath temperature and agitate water or oil bath rapidly.

c. Continue agitation. Insert indicating and test thermometers to indicated immersion point during the test.

d. Compare both thermometer readings at the temperature within the test range.

e. Repeat comparison of readings.

f. Record thermometer readings, and thermometer identification or location.

g. Install seals as appropriate on sensors and control boxes of digital thermometers.

Corrective Action: Do not run test if mercury column has been split or capillary tube is broken, as thermometer should be returned to the factory for repair. When the indicating thermometer differs from the test thermometer by more than 0.25°C (0.5°F) and the airspace thermometer by more than 0.5°C (1°F), the indicating thermometer should be adjusted to agree with the test thermometer. Retest the thermometer after adjustment.

TEST 2.
RECORDING THERMOMETERS--TEMPERATURE ACCURACY.

Reference: Item 16p(E).

Application: To all recording and recorder/controller thermometers used to record milk temperatures during pasteurization or aseptic processing.

Frequency: Upon installation, at least once each 3 months and whenever the recording pen-arm setting requires frequent adjustment, when sensing element has been replaced, or when a regulatory seal has been broken.

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

Apparatus: Pasteurizer or aseptic processor indicating thermometer previously tested against a known accurate thermometer, water baths or suitable vats or containers, agitator, suitable means of heating water baths and ice.

Note: When this test is performed on recorder/controllers, used with HHST pasteurization or aseptic processing systems operation at or above the boiling point of water, an oil bath shall be substituted for the processing (operating) temperature water mentioned in steps 1,4,5,6, and 7 as well as the boiling water mentioned in steps 2, 3 and 5. The temperature of the oil bath which is used in place of the boiling water shall be above the normal operating range but below the highest temperature division on the chart.

Method: The testing of a recording thermometer for temperature accuracy involves the determination of whether or not the temperature pen-arm will return to within 0.5°C (1°F), or 1° C (2° F) as provided above, of its previous setting, after exposure to high heat and melting ice .

Procedure:

a. Adjust the recording pen to read exactly as the previously tested indicating thermometer, in the temperature range for the process being used after a stabilization period of 5 minutes (two minutes for electronic recording thermometers) at a constant temperature. The bath shall be rapidly agitated throughout the stabilization period.

b. Prepare one water bath by heating to the boiling point and maintain temperature. Prepare a second container with melting ice. Place water baths within working distance of the recorder sensing element.

c. Immerse the sensing element of the recorder in boiling water for not less than 5 minutes (two minutes for electronic recording thermometers).

d. Remove the sensing element from the boiling water and immerse in water at a temperature within the testing range for the process being used. Allow a 5-minute (two minutes for electronic recording thermometers) stabilization period for both indicating and recording thermometers. Compare readings of the indicating and recording thermometers. The recorder reading should be within 0.5°C (1°F) or 1° C (2° F) as provided above, plus or minus, of the indicator thermometer reading.

e. Remove sensing element from the bath, at operating temperatures, and immerse in melting ice for not less than 5 minutes (two minutes for electronic recording thermometers).

f. Remove sensing element from the ice water and immerse in water at a temperature, within the testing range, for the process being used. Allow a 5-minute (two minutes for electronic recording thermometers) stabilization period for both indicating and recording thermometers. Compare readings of the indicating and recording thermometers. The recorder reading should be within 0.5°C (1°F), or 1° C (2° F) as provided above, plus or minus, of the indicator thermometer reading.

g. Re-seal regulatory controls as necessary and record the indicator and recording thermometer readings obtained at steps 1, 4, and 6.

Corrective Action: If the pen does not return to 0.5°C (1°F), or 1° C (2 F) as provided above, plus or minus, of indicating thermometer reading at steps 4 and 6, the re-cording thermometer should be repaired.

TEST 3.
RECORDING THERMOMETERS--
TIME ACCURACY

Reference: Item 16p(E).

Application: To all recording and recorder/controller thermometers used to record time of pasteurization or aseptic processing (including those used t record flow rate in magnetic flow meter based timing systems).

Frequency: Upon installation and at least once each 3 months thereafter, or whenever the seal of a programmable recorder/controller has been broken.

Criteria: The recorded time of pasteurization or aseptic processing shall not exceed the true elapsed time.

Apparatus:

a. A watch, graduated at intervals not to exceed 1 minute, and accurate to within 5 minutes in 24 hours.

b. A pair of dividers, or any other suitable device for measuring short distances.

Method: Comparison of the recorded time over a period of not less than 30 minutes with a watch of known accuracy. For recorders utilizing electric clocks, check the cycle on the face plate of clock with a known cycle; observe that the clock is in operating condition.

Procedure:

a. Determine if chart is appropriate to recorder. Insure that the recording pen is aligned with the time arc of the chart at both the center and the outside edge.

b. Inscribe reference mark at the pen point on the recorder chart and record the time.

c. At the end of 30 minutes by the watch, inscribe a second reference mark at the pen point position on the chart.

d. Determine the distance between the two reference marks and compare the distance with the time-scale divisions on the record chart at the same temperature.

e. For electric clocks, remove face plate, compare cycle specification on face plate with the current cycle utilized.

f. Re-seal regulatory controls as necessary and enter finding on chart and initial and record results.

Corrective Action: If recorded time is incorrect, the clock should be adjusted or repaired.

TEST 4.
RECORDING THERMOMETERS--CHECK AGAINST INDICATING THERMOMETERS

Reference: Item 16p(D).

Application: To all recording and recording/controller thermometers used to record product temperatures during pasteurization or aseptic processing.

Frequency: At least once each 3 months by regulatory agency; daily by plant operator.

Criteria: Recording thermometer shall not read higher than corresponding indicating thermometer.

Apparatus: No supplementary materials required.

Method: This test requires only that the reading of the recording thermometer be compared with that of the indicating thermometer at a time when both are exposed to a stabilized pasteurization or aseptic processing temperature.

Procedure:

a. While the indicating and recording thermometers are stabilized at the same acceptable pasteurization or aseptic processing temperature, read indicating thermometer.

b. Immediately inscribe on the recording thermometer chart a line intersecting the recorded temperature arc at the pen location, record on the chart the indicating thermometer temperature and initial.

c. Record the indicating and thermometer readings.

Corrective Action: If recording thermometer reads higher than indicating thermometer, the pen should be adjusted by the operator.

TEST 5. FLOW-DIVERSION DEVICE-- PROPER ASSEMBLY AND FUNCTION

Reference: Item 16p(E).

Application: Test 5 (parts 1 through 9) does not apply to aseptic processing divert systems, valves or other acceptable controls which may be used in place of a flow-diversion device. Parts 1 to 4 and 6 to 8 apply to all flow-diversion devices used with continuous-flow pasteurizers parts 5 and 9 apply only flow-diversion devices used with HTST pasteurizers.

Frequency: Upon installation and at least once each 3 months thereafter, or when a regulatory seal has been broken.

Criteria: The flow-diversion device shall function correctly in operating situations and shall de-energize the metering pump and all other flow promoting devices capable of causing flow through the holding tube in the event of malfunction or incorrect assembly.

5.1 LEAKAGE PAST VALVE SEAT(S)

Apparatus: For single stem flow-diversion devices, suitable tools for the disassembly of flow-diversion device and sanitary piping. None for dual stem flow-diversion devices.

Method: Observe the valve seat(s) of the flow-diversion device for leakage.

Procedure.—
With the system operating with water, place the flow-diversion device in diverted-flow position:

In the case of single stem flow-diversion devices disconnect the forward flow piping and observe the valve seat for leakage. Check leak escape ports to see if they are open.

In the case of dual stem flow-diversion devices, observe the leak detect line discharge or sight glass for leakage.

Corrective Action: If leakage is noted, device must be dismantled and defective gaskets replaced or other suitable repairs made.

5.2 OPERATION OF VALVE STEM(S)

Apparatus: Suitable tools for tightening the packing nut on the stem(s).

Method: Observe flow-diversion device valve stem(s) for ease of movement.

Procedure.—
When a stem packing nut is used, tighten stem packing nut as much as possible. Operate system at maximum normal operating pressure and place device in forward and diverted flow several times. Note freedom of action of valve stem.

Corrective Action: If valve action is sluggish, suitable adjustment or repair shall be made to permit stem to act freely in

all positions, with packing nut, when used fully tightened.

5.3 DEVICE ASSEMBLY--SINGLE STEM DEVICE

Apparatus: Sanitary fitting wrench.

Method: During diverted flow, by temperature, observe function of metering pump and all other flow promoting devices capable of causing flow through the holding tube when flow-diversion device is improperly assembled.

Procedure:

a. With system in operation below the required process temperature, unscrew by one-half turn, the 13H hex nut which holds the top of the valve to the valve body. This should de-energize the metering pump and all other flow promoting devices capable of causing flow through the holding tube. This test should be run with no piping connected to the forward flow port of the device since there can be sufficient force from the piping to keep the forward flow port tightly clamped even though the hex nut is loosened. Re-tighten the 13H hex nut.

b. With the HTST system in operation below the required process temperature, remove the connecting key located at the base of the valve stem. The metering pump and all other flow promoting devices capable of causing flow through the holding tube should be de-energized.

c. Re-seal regulatory controls as necessary and attempt to restart the metering pump and each flow promoting device capable of causing flow through the holding tube. None of these flow promoting devices should start or operate.

Corrective Action: If any flow promoting device fails to respond as indicated, immediate checks of the device assembly and wiring are required to locate and correct the cause.

5.4 DEVICE ASSEMBLY, DUAL STEM DEVICE

NOTE: The test procedure presented in this section is typical of tests accepted by FDA for various specific types of flow-diversion devices. Testing details which may vary are provided in individual flow-diversion device operators manuals which have been reviewed by FDA and which are specified by part # in FDA identical memorandums. In each of these FDA accepted test methods if the words "metering pump" or "timing Pump" are used they shall be understood to mean "metering pump and all other flow promoting devices capable of causing flow through the holding tube".

Apparatus: None

Method: Observe function of metering pump and all other flow promoting devices capable of causing flow through the holding tube when flow-diversion device is improperly assembled.

Procedure:

a. With the device in diverted-flow, by temperature, when the flow-diversion device is properly assembled.

b. Move the device to the forward-flow position and disconnect stem from actuator.

c. Move the device to the diverted-flow position and turn on the metering pump and all other flow

promoting devices capable of causing flow through the holding tube. The metering pump and each of the other flow promoting devices must be de-energized and must not run. If any pump starts momentarily and then stops, it may indicate improper wiring of the one second time delay as allowed in 16p.B.2.b.10. Separators must be effectively valved out of the system.

d. Reassemble the device by moving it to the forward-flow position and reconnecting the stem to the actuator.

e. Re-seal regulatory controls as necessary and repeat the procedure for the other actuator.

Corrective Action: If any of the flow promoting devices fail to respond as indicated, an immediate check of the device assembly and wiring is required to locate and correct the cause.

5.5 MANUAL DIVERSION (when booster pump is installed in the HTST system)

Apparatus: None.

Method: Observe the response of the system to manual diversion.

Procedure:

a. With the HTST system in operation and the flow-diversion device in the forward-flow position, press the manual diversion button. This should (a) cause the valve to assume the divert position, and (b) de-energize the booster pump. The pressure differential between raw and pasteurized milk in the regenerator should be maintained.

b. Operate the HTST system in forward flow and activate the manual divert button until the raw pressure reaches zero (0) psi. Deactivate the manual divert button and observe the raw milk and pasteurized milk pressures. The pressure differential between raw and pasteurized milk in the regenerator should be maintained. Re-seal regulatory controls as necessary.

Corrective Action: If the above described actions do not occur when procedures a and b are performed, or the necessary pressure differential between raw and pasteurized milk is not maintained, the assembly and wiring of the HTST system must be immediately reviewed and the indicated deficiencies corrected or proper adjustments made.

5.6 RESPONSE TIME

Apparatus: Temperature bath, stopwatch. The stopwatch should be used to determine that the response time interval does not exceed 1 second.

Method: Determine the elapsed time between the instant of the activation of the control mechanism at cut-out temperature on declining temperature and the instant the flow-diversion device takes the fully diverted-flow position.

Procedure:

a. With the water or oil bath at a temperature above cut-out temperature, allow the water or oil to cool gradually. At the moment the cut-out mechanism is activated, start the watch and the moment the flow-diversion device takes the fully-diverted position, stop the watch.

b. Re-seal regulatory controls as necessary and record results.

Corrective Action: Should response time exceed 1 second, immediate corrective action must be taken.

5.7 TIME DELAY INTERLOCK WITH METERING PUMP.

Application: To dual stem flow-diversion devices with a manual forward-flow switch.

Apparatus: None.

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

Procedure: With the system running in forward flow, move the control switch to the "Inspect" position and observe that the following events automatically occur in sequence:

a. The device immediately moves to the diverted-flow position and the metering pump and all other flow promoting devices capable of causing flow through the holding tube are turned off or in the case of separators, are effectively valved out of the system

b. The device remains in the diverted-flow position while the metering pump and all other flow promoting devices capable of causing flow through the holding tube are running down or in the case of a separator, valving out.

c. After the metering pump stops turning, and all other flow promoting devices capable of causing flow through the holding tube have also stopped, or in the case of separators, have been effectively valved out of the system, the device assumes the forward-flow position.

d. Repeat the above procedure by moving the control switch to the cleaned-in-place (CIP) position.

e. Record test results and seal the control enclosure.

Corrective Action: If the above sequence of events does not occur, either a timer adjustment or wiring change is required.

5.8 CIP TIME DELAY RELAY

Application: To all continuous flow pasteurizer systems in which it is desired to run the timing pump and/or other flow promoting devices during the CIP cycle without the controls required during product processing.

Criteria: When the mode switch on the flow-diversion device is moved from process product to CIP, the flow-diversion device shall move immediately to the diverted position and remain in the diverted position for at least 10 minutes, with all controls and safe guards required in product mode functioning, before starting its normal cycling in the CIP mode. In HTST systems, the booster pump shall be turned off during the 10 minute time delay.

Apparatus: Stopwatch.

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

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Procedure:

a. Operate pasteurizer in forward flow, with the mode switch on the flow-diversion device in the process product position, using water above pasteurization temperature. In systems which are equipped with magnetic flow meter based timing systems, operate the system, at a flow rate below the Flow Alarm set point and above the Loss-of-Signal Alarm set point.

b. Move the mode switch on the flow-diversion device to the CIP position. The flow-diversion device should move immediately to the diverted position. Start the stopwatch when the flow-diversion device moves to the diverted position. Check all controls and safeguards which are required to be in operation when the system is in product mode and in diverted flow. For example, in HTST systems, the booster pump must stop running. Separators located between regenerator sections or on the pasteurized side of the system must be effectively valved out and stuffer pumps for such separators must be de-energized.

c. Stop the stopwatch when the CIP timer times out. On most systems this is when the flow-diversion device moves to the forward position for its initial cycle in the CIP mode. At this time the system may be operated without the controls and safe guards normally required during product processing. For example, the booster pump may start at this time.

d. Record results for the office record.

e. Install and seal enclosure over the time delay relay.

Corrective Action: If the flow-diversion device does not remain in the diverted position for at least 10 minutes after the mode switch is moved from process product to CIP, increase the set point on the time delay relay and repeat this test procedure. All safe guards and controls which are required to be in operation when the system is in product mode and in diverted flow must be functional during this 10 minutes. If any of these required safeguards or controls are not functional during this 10 minutes, adjustments or repairs are needed. In HTST systems, if the booster pump runs at any time during the 10 minute delay, the booster pump wiring is in need of repair.

5.9 LEAK DETECT VALVE FLUSH - TIME DELAY

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

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

a. The minimum acceptable holding time in diverted flow can be achieved without the use of a restriction in the divert line, or

b. The timing system is magnetic flow meter based.

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

Apparatus: A stop watch.

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

Procedure:

a. Move the flow-diversion device from the diverted flow position to the forward flow position either by raising the temperature above the cut in set point or by operating the HTST pasteurizer above the cut in temperature in manual divert mode and releasing the manual divert.

b. When the divert valve begins to move to the forward flow position, start the watch.

c. When the detect valve begins to move to the forward flow position, stop the watch.

d. Record the elapsed time.

e. If the elapsed time is at or above one second and at or below five seconds, seal the time delay.

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

TEST 6.
LEAK PROTECTOR VALVE

Reference: Item 16p(E).

Application: To all batch (vat) pasteurizer outlet valves and to all batch (vat) pasteurizer inlet valves which are not disconnected and removed during holding, cooling and emptying periods.

Frequency: Upon installation and at least once each 3 months thereafter.

Criteria: No leakage of milk past the valve seat in any closed position.

Apparatus: No supplementary materials required.

Method: By observing when the piping is disconnected from the valve outlet whether or not leakage past the valve seat occurs when pressure is exerted against the upstream face of the valve.

Procedure:

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

(Caution: Care must be taken to avoid contamination of the valves or the piping.)

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

c. In the case of plug-type valves, turn the valve to the just-closed position, and examine the leakage into the valve outlet.

d. Reconnect the outlet piping.

e. Record identity of the valve, and findings, for the office record.

Corrective Action: If leakage past the valve seat should occur in any closed position, the valve plug should be re-ground, gaskets replaced, springs replaced or other necessary steps be taken to prevent leakage.

TEST 7.
INDICATING THERMOMETERS ON PIPELINES--
THERMOMETRIC RESPONSE

Reference: Item 16p(E).

Application: To all HTST indicating thermometers located on pipelines and used for determination of milk temperatures during pasteurization.

Frequency: Upon installation and once each 3 months thereafter, and whenever the seal on a digital thermometer has been broken.

Criteria: Four seconds under specified conditions.

Apparatus: Stopwatch, water bath, agitator, heat supply and indicating thermometer from pasteurizer.

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

Procedure:

a. Immerse indicating thermometer in water bath heated to a temperature at least 11°C (19°F) higher than minimum scale reading on the indicating thermometer. Bath temperature should be 4°C (7°F) higher than maximum required pasteurization temperature for which thermometer is used.

b. Immerse indicating thermometer in bucket of cold water for several seconds to cool it.

Note: Continuous agitation of water baths during the performance of steps c, d and e is required. Elapsed time between end of step a and beginning of step c, should not exceed 15 seconds, unless a constant temperature bath is used, so the hot water bath does not cool significantly.

c. Insert indicating thermometer in hot water bath to proper bulb immersion depth.

d. Start stopwatch when indicating thermometer reads 11°C (19°F) below bath temperature.

e. Stop stopwatch when indicating thermometer reads 4°C (7°F) below bath temperature.

f. Record thermometric response time for office record.

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

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

Corrective Action: If the response time should exceed 4 seconds, the thermometer should be replaced or returned for repair.

TEST 8.
RECORDER/CONTROLLER--
THERMOMETRIC RESPONSE

Reference: Item 16p(E).

Application: To all continuous-flow pasteurizers, except those in which the flow-diversion device is located at the end of the cooler section.

Frequency: Upon installation and at least once each 3 months thereafter.

Criteria: Five seconds, under specified conditions.

Apparatus: Previously tested indicating thermometer (on pasteurizers), stopwatch, water bath, agitator and heat supply.

Method: Measure the time interval between the instant when the recording thermometer reads 7°C (12°F) below the cut-in temperature and the moment of cut-in by the controller. This measurement is made when the sensing element is immersed in a rapidly agitated water bath maintained at 4°C (7°F) above the cut-in temperature.

Procedure:

a. Check and, if necessary, adjust the pen-arm setting of the recording thermometer in the proper reference to agree with the indicating thermometer reading at pasteurization temperature.

b. Determine the cut-in temperature of controller (Test 10), either while in normal operation or by using a water bath.

c. Remove sensing element and allow to cool to room temperature.

d. Heat water bath to 4°C (7°F) above the cut-in temperature while vigorously agitating bath to insure uniform temperature.

e. Immerse recorder/controller bulb in bath. Continue agitation during steps f. and g. below.

f. Start stopwatch when the recording thermometer reaches a temperature of 7°C (12°F) below the cut-in temperature.

g. Stop stopwatch when the controller cuts in.

h. Re-seal regulatory controls as necessary and record thermometric response time for office record.

Corrective Action: If the response time should exceed 5 seconds, the recorder/controller should be repaired.

TEST 9.
REGENERATOR PRESSURE CONTROLS

Reference: Item 16p(E).

9.1 PRESSURE SWITCHES: - Used to control operation of booster pumps.

Application: To all pressure switches controlling the operations of booster

pumps on HTST pasteurizer systems employing regenerators.

Frequency: Upon installation, each 3 months thereafter, after any change in the booster pump or the switch circuit and/or whenever the pressure switch seal is broken.

Criteria: The booster pump shall not operate unless there is at least a 6.9 kPa (1-pound) pressure differential on the pasteurized milk side of the regenerator.

Apparatus: Sanitary pressure gauge and pneumatic testing device, for checking and adjusting pressure switch settings.

A simple inexpensive pneumatic testing device may be made from a discarded 50 millimeter (2 inch) - 7BX sanitary tee, with two additional 13H nuts, one of which is provided with a 16A cap, drilled and tapped for a 13 millimeters (½ inch) galvanized iron nipple for the air connection. A hose connection is made to a compressed air source in the plant by means of a snap-on fitting. The air pressure can be controlled by an inexpensive pressure reducing valve (range [0-60] psi) followed by a 13 millimeters (½ inch) globe type bleeder valve connected into the side outlet of a 13 millimeters (½ inch) tee installed between the pressure reducing valve and the testing device. The pressure switch to be tested is disconnected from the pasteurizer and connected to another of the outlets of the sanitary tee, and the pressure gauge is connected to the third outlet of the sanitary tee. By careful manipulation of the air pressure reducing valve and the air bleeder valve, the air pressure in the testing device may be regulated slowly and precisely. (In operating the device, care should be taken to avoid exposing the pressure switch and the sanitary pressure gauge to excessive pressure which might damage them. This can be done by first closing off the air pressure regulating valve and opening fully the bleeder valve; these may then be manipulated slowly to bring the air pressure in the testing device within the desired range.) A test light of proper voltage can be placed in series with the pressure switch contact and in parallel with the electrical load (booster pump starter) so the actuation point may be readily determined.

Method: Check and make adjustment of pressure switch so as to prevent the operation of the booster pump unless the pressure of the pasteurized milk side of the regenerator is greater by at least 6.9 kPa (1 psi) than any pressure that may be generated on the raw side.

Procedure:

a. Determine maximum pressure of the booster pump.

(1) Install sanitary pressure gauge in tee at discharge of booster pump.

(2) Operate the pasteurizer with water with the flow-diversion device in forward-flow position, the metering pump operating at minimum speed possible and the booster pump operating at its rated speed. If vacuum equipment is located between the raw outlet from the regenerator and the metering pump, it should be bypassed while this determination is made.

(3) Note maximum pressure indicated by pressure gauge under these conditions.

b. Check and set the pressure switch.

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

(2) Remove the seal and cover to expose adjustment mechanism on pressure switch.

(3) Operate the testing device and determine the pressure gauge reading at the cut-in point of the pressure switch which will light the test lamp. (If the switch is short circuited, the lamp will be lighted before air pressure is applied.)

(4) The cut-in point should be adjusted, if necessary, so as to occur at a pressure gauge reading at least 6.9 kPa (1 psi) greater than the maximum booster pump operating pressure, as determined under section a. of this method. Where adjustment is necessary, refer to the manufacturer's instructions for adjusting procedures. After adjustment, recheck actuation point and readjust if necessary.

(5) Replace cover, seal the pressure switch and restore sensing element to original location.

(6) Record test the maximum booster pump pressure developed and the pressure switch setting for the office record.

9.2 DIFFERENTIAL PRESSURE CONTROLLER

Application: Part 2.1 applies to all differential pressure controllers used to control the operation of booster pumps on HTST and HHST systems, or used to control the operation of flow-diversion devices on HHST systems and aseptic processing systems, when no vacuum breaker is located downstream from the holding tube.
Part 2.2 Applies only to HTST systems.
Part 2.3 Applies to the testing of HHST systems in which the differential pressure controller is used to control the operation of the flow-diversion device. Test 2.3 also applies to aseptic processing systems in which the differential pressure controller is used to control the flow-diversion device, product divert system, product divert valve or other acceptable control system.

Frequency: Upon installation, each 3 months thereafter and whenever the differential pressure controller is adjusted or repaired.

Criteria: The booster pump shall not operate, or the pasteurizer shall not operate in forward flow, unless the product pressure in the pasteurized side of the regenerator is at least 6.9 kPa (1 psi) greater than the product pressure in the raw side of the regenerator. When the differential pressure controller is used to control the flow-diversion device on HHST or aseptic processing systems, and improper pressure occurs in the regenerator, the flow-diversion device shall move to the diverted-flow position and remain in diverted flow until proper pressures are re-established in the regenerator and all product-contact surfaces between the holding tube and flow-diversion device have been held at or above the required pasteurization or aseptic processing temperature, continuously and simultaneously for at least the required time.

Apparatus: A sanitary pressure gauge and a pneumatic testing device, described under PRESSURE SWITCHES (Test 9.1) above can be used for checking and adjusting the differential pressure switch setting.

Method: The differential pressure switch is checked and adjusted to prevent the operation of the booster pump, or prevent forward flow, unless the product pressure in the pasteurized, or aseptic, side of the regenerator is at least 6.9 kPa (1 psi)

greater than the pressure in the raw side of the regenerator.

9.2.1 CALIBRATION OF DIFFERENTIAL PRESSURE CONTROLLER PROBES

Procedure:

a. Loosen the process connection at both pressure sensors and wait for any liquid to drain through the loose connections. Both pointers, or digital displays, should be within 3.5 kPa (0.5 psi) of .0 kPa (0 psi). If not, adjust pointer(s), or digital display(s), to read 0 kPa (0 pounds psi).

b. Remove both sensors from the processor and mount them in a tee, either at the discharge of the booster pump, or connected to the pneumatic testing device. Note the separation between the two pointers or digital displays. The change in elevations of the sensors will have caused some change in the zero readings.

Turn on the booster pump switch and depress the test push button to operate the booster pump. If the pneumatic testing device is used in lieu of the booster pump, adjust air pressure to the normal operating pressure of the booster pump. Note that the pointer, or digital display reading separation is within 6.9 kPa (1 psi) of that observed before pressure was applied. If not, the instrument requires adjustment or repair.

c. Record the test results for the office record.

9.2.2 HTST-- INTERWIRING OF THE PRESSURE DIFFERENTIAL CONTROLLER WITH THE BOOSTER PUMP

Method: Determine if the booster pump stops when the pressure differential is not properly maintained in the regenerator.

Procedure:

a. Connect the pasteurized pressure sensor to a testing tee with the other end of the tee capped.

(Caution: If there is water in the HTST system, ensure that the recorder/controller probe and the pasteurized sensor ports are capped before the metering pump is turned on.)

b. Turn on the metering pump and the booster pump.

c. Place the recorder/controller probe in hot water which is above the cut-in temperature.

d. Turn up the air supply on tee to provide an adequate pressure differential to start the booster pump.

e. Decrease the air supply to the testing tee until the pressure is less than 14 kPa (2 psi) of the pressure on the raw milk pressure sensor. The booster pump should have stopped. Ensure that the flow-diversion device remains in the forward flow position and the metering pump continues to operate.

f. Reseal regulatory controls as necessary and record test results for the office record.

Corrective Action: If the booster pump fails to stop when the pressure

differential is not maintained, have the plant maintenance personnel determine and correct the cause.

9.2.3 HHST AND ASEPTIC PROCESSING -- INTERWIRING OF THE PRESSURE DIFFERENTIAL CONTROLLER WITH THE FLOW-DIVERSION DEVICE IN AN HHST SYSTEM OR AN ACCEPTABLE ALTERNATIVE DEVICE OR SYSTEM IN ASEPTIC PROCESSING EQUIPMENT

Application:

a. To all differential pressure controllers used to control the operation of flow-diversion devices on HHST systems when no vacuum breaker is located downstream from the holding tube,

and:

b. To all differential pressure controllers used to control the operation of flow-diversion devices, product divert systems, product divert valve(s) or other acceptable control systems used in aseptic processing equipment.

Apparatus: A sanitary pressure gauge and a pneumatic testing device, described under PRESSURE SWITCHES (Test 9.1) above can be used for checking and adjusting the differential pressure switch setting.

Method: The differential pressure switch is checked and adjusted to prevent forward flow, unless the product pressure in the pasteurized side of the regenerator is at least 6.9 kPa (1 psi) greater than the pressure in the raw product side of the regenerator. In the case of product to water to product regenerators protected on the pasteurized or aseptic side, the water side of the regenerator shall be considered to be the "raw product" for purposes of this test.

Procedure:

a. Wire the test lamp in series with the signal from the pressure differential switch to the flow-diversion device.

b. Calibrate the pressure switch and probes (using test 9.2.1).

c. 1. Adjust the pressure on the pressure switch sensors to their normal operating pressures (with the pasteurized, or aseptic pressure at least 14 kPa (2 psi) higher than the raw product pressure.

2. The test lamp should be lit. If the test light is not lit increase the pasteurized, or aseptic pressure (or lower the raw product pressure) until the test light is lit.

3. Gradually lower the pasteurized, or aseptic side (or raise the raw product pressure) until the test light turns off.

4. The test light should turn off when the pasteurized, or aseptic pressure is 14 kPa (2 psi) or more higher than the raw product pressure.

5. Note the differential pressure at the point the light turns off.

6. Gradually raise the pasteurized, or aseptic pressure (or lower the raw product pressure) until the test light turns on.

7. The test light not should turn on until the pasteurized, or aseptic pressure is greater than 14 kPa (2 psi) higher than the raw product pressure. Note the

differential pressure at the point the light turns off.

Note: This test may be completed using a pneumatic testing device capable of producing differential pressures on the probes. This device should be capable of being operated (and be operated) in a manner so as to duplicate the conditions described above.

d. Seal the instrument and record the test results for the office record.

9.3. ADDITIONAL HTST TESTS FOR BOOSTER PUMPS--

Application: To all booster pumps used for HTST systems.

Criteria: The booster pump shall be wired so it cannot operate if the flow-diversion device is in the diverted position or if the metering pump is not in operation.

Apparatus: A sanitary pressure gauge and pneumatic testing device as described in Test 9.1 and water with a heat source.

9.3.1 BOOSTER PUMPS-- INTERWIRED WITH FLOW-DIVERSION DEVICE.

Method: Determine if the booster pump stops by dropping the temperature and causing the flow-diversion device to divert.

Procedure:

a. Connect the pasteurized pressure sensor to a testing tee with the other end of the tee capped.

(Caution: If there is water in the HTST system, ensure that the recorder/controller probe and the pasteurized sensor ports are capped before the metering pump is turned on.)

b. Turn on the metering pump and the booster pump.

c. Place the recorder/controller probe in hot water which is above the cut-in temperature.

d. Turn up the air supply on tee to provide an adequate pressure differential to start the booster pump.

e. Remove the recorder/controller probe from the hot water.

f. When the flow-diversion device moves to the diverted flow position, the booster pump must stop. Ensure that the pressure differential remains adequate and the metering pump continues to operate.

g. Reseal regulatory controls as necessary and record the test results for office records.

Corrective Action: If the booster pump fails to stop when the flow-diversion device is in the diverted flow position, have the plant maintenance personnel check the wiring and correct the cause.

9.3.2 BOOSTER PUMPS-- INTERWIRED WITH THE METERING PUMP

Method: Determine if the booster pump stops when the metering pump is off.

Procedure:

a. Connect the pasteurized pressure sensor to a testing tee with the other end of the tee capped.

(Caution: If there is water in the HTST system, ensure that the recorder/controller probe and the pasteurized sensor ports are capped before the metering pump is turned on.)

b. Turn on the metering pump and the booster pump.

c. Place the recorder/controller probe in hot water which is above the cut-in temperature.

d. Turn up the air supply on tee to provide an adequate pressure differential to start the booster pump.

f. turn off the metering pump. The booster pump must stop. Ensure that the pressure differential remains adequate and the flow-diversion device remains in the forward flow position.

g. Reseal regulatory controls as necessary and record the test results for the office record.

Corrective Action: If the booster pump fails to stop when the metering pump has been turned off, have the plant maintenance personnel determine and correct the cause.

TEST 10.
MILK-FLOW CONTROLS--
MILK TEMPERATURE AT
CUT-IN AND CUT-OUT

References: Item 16p(B), 16p(E).
Milk-flow controls shall be tested for milk temperature at cut-in and cut-out by one of the following applicable tests at the frequency prescribed:

10.1 HTST PASTEURIZERS

Application: All recorder/controllers used in connection with HTST pasteurizers except those in which the flow-diversion device is located at the end of the cooler section.

Frequency: Upon installation and at least once each three months thereafter by the regulatory agency; daily by the plant operator, or when a regulatory seal has been broken.

Criteria: No forward flow until pasteurization temperature has been reached. Flow diverted before temperature drops below minimum pasteurization temperature.

Apparatus: No supplemental materials needed.

Method: By observing the actual temperature of the indicating thermometer at the instant forward flow starts (cut-in) and stops (cut-out).

Procedure:

a. Cut-in temperature.

(1) While milk or water is completely flooding the sensing element of the recorder/controller and the indicating thermometer, increase the heat gradually so as to raise the temperature of the water or milk at a rate not exceeding 0.5°C (1°F) every 30 seconds. If a water bath is used in place of water or milk flowing through the system, the water bath shall be adequately agitated during this test.

(2) Observe the indicating thermometer reading at the moment the forward flow starts (i.e., flow-diversion device moves). Observe that the frequency pen reading is synchronized with the recording pen on the same reference arc.

(3) Record the indicating thermometer reading on the recorder chart and initial. The regulatory agency shall record test findings.

b. Cut-out temperature.

(1) After the cut-in temperature has been determined, and while the milk or water is above the cut-in temperature, allow the water to cool slowly at a rate not exceeding (0.5°C) 1°F per 30 seconds. Observe the indicating thermometer reading at the instant forward flow stops.

(2) Re-seal regulatory controls as necessary and record the indicating thermometer reading on the recorder chart and initial.

Corrective Action: Should the reading be below the minimum pasteurization temperature, the cut-in and cut-out mechanism and/or the differential temperature mechanism should be adjusted to obtain proper cut-in and cut-out temperatures by repeated tests. When compliance is achieved, seal the controller mechanism.

10.2 HHST PASTEURIZERS AND ASEPTIC PROCESSING SYSTEMS USING INDIRECT HEATING

Application: All HHST pasteurizers and aseptic processing systems using indirect heating. When testing aseptic processing systems, the "product divert system"or "product divert valve" or "acceptable control system" may be substituted for the "flow-diversion device" when it is referenced in this test.

Frequency: Upon installation, and every 3 months thereafter; whenever the thermal controller seal is broken.

Criteria: The pasteurizer or aseptic processor shall not operate in forward flow unless pasteurization or aseptic processing temperature has been achieved. The product flow shall be diverted at a temperature no lower than the chosen pasteurization or aseptic processing standard.

Apparatus: No supplemental materials needed.

Method: The cut-in and cut-out temperatures are determined by observing the actual temperature in the constant temperature bath at which the two sensing elements signal for forward flow (cut-in) and diverted flow (cut-out).

Procedure:

a. Wire the test lamp in series with the control contacts of the sensing element (holding tube). Immerse this sensing element in the constant temperature bath. Raise the bath temperature at a rate not exceeding 0.5°C (1°F) every 30 seconds. Observe the temperature reading at the cut-in temperature. Record the temperature for the office record.

b. After the cut-in temperature has been determined and while the bath is above the cut-in temperature, allow the bath to cool slowly at a rate not exceeding 0.5°C (1°F) per 30 seconds. Observe the temperature reading on the controller when the test lamp goes out (cut-out temperature). Determine that the cut-out temperature on the thermal limit controller is equivalent to or greater than the chosen pasteurization or aseptic processing standard. Where adjustment is necessary, refer to the manufacturer's instructions. After adjustment, repeat the procedure above, and when the results are satisfactory, record the results for the office records.

c. Repeat the procedure for the other sensing element, (flow-diversion device). When proper cut-

out temperature has been verified for both sensing elements, seal the controller system.

10.3 HHST PASTEURIZERS AND ASEPTIC PROCESSING SYSTEMS USING DIRECT HEATING

Application: All HHST pasteurizers and aseptic processing systems using direct heating. When testing aseptic processing systems, the "product divert system" or "product divert valve" or "acceptable control system" may be substituted for the "flow-diversion device" when it is referenced in this test.

Frequency: Upon installation, every 3 months thereafter and whenever the thermal limit controller seal is broken.

Criteria: The pasteurizer or aseptic processor shall not operate in forward flow unless pasteurization or aseptic processing temperature has been achieved. The product flow shall be diverted at a temperature no lower than the chosen pasteurization or aseptic processing standard.

Apparatus: No supplemental materials needed.

Method: The cut-in and cut-out temperatures are determined by observing the actual temperature in the constant temperature bath at which each of the three sensing elements signals for forward flow (cut-in) and diverted flow (cut-out).

Procedure:

a. Wire the test lamp in series with the control contacts of the sensing element (the holding tube). Immerse this sensing element in the constant temperature bath. Raise the bath temperature at a rate not exceeding 0.5°C (1°F) every 30 seconds. Observe the temperature reading on the controller when the test lamp lights (cut-in temperature). Record the temperature for the office record.

b. After the cut-in temperature has been determined, and while the bath is above the cut-in temperature, allow the bath to cool slowly at a rate not exceeding 0.5°C (1°F) per 30 seconds. Observe the temperature reading on the controller when the test lamp goes out (cut-out temperature). Determine that the cut-out temperature, on the thermal limit controller, is equivalent to or greater than the chose pasteurization or aseptic processing standard. Where adjustment is necessary, refer to the manufacturer's instructions. After adjustment, repeat the procedure above and when the results are satisfactory, record the results for the office record.

c. Repeat the procedure for the other two sensing elements, i.e., the vacuum chamber and flow-diversion device. Rewire the test lamp in series with the control contacts from each sensing element, respectively. When proper cut-out temperatures have been verified for all three sensing elements, seal the controller system.

TEST 11. CONTINUOUS FLOW HOLDERS-- HOLDING TIME

Reference: Item 16p(B).

Continuous flow holders shall be tested for holding times by one of the applicable tests.

11.1 HTST PASTEURIZERS (except for magnetic flow meter systems)

Application: To all HTST pasteurizers employing a holding time of 15 seconds or longer.

Frequency: Upon installation, semiannually thereafter; whenever the seal on the speed setting is broken; any alteration is made affecting the holding time, the velocity of the flow (such as, replacement of pump, motor, belt, drive or driven pulleys, or decrease in number of HTST plates or the capacity of holding tube), or whenever a check of the capacity indicates a speedup.

Criteria: Every particle of milk shall be held for at least 15 seconds in both the forward- and diverted-flow positions.

Apparatus: Electrical conductivity measuring device, capable of detecting change in conductivity, equipped with standard electrodes; table salt (sodium chloride); 50 ml. syringe; stopwatch; and suitable container for salt solution.

Method: The holding time is determined by timing the interval for an added trace substance to pass through the holder. Although the time interval of the fastest particle of milk is desired, the conductivity test is made with water. The results found with water are converted to the milk flow time, by formulation, since a pump may not deliver the same amount of milk as it does water.

Procedure:

a. Examine the entire system to insure that all flow promoting equipment is operating at maximum capacity and all flow impeding equipment is so adjusted or bypassed as to provide the minimum of resistance to the flow. There shall be no leakage on the suction side of the timing pump.

b. Adjust variable speed pump to its maximum capacity (preferably with a new belt and full size impellers). Check homogenizers for seals, and/or gears or pulley identification. Check A. C. variable speed timing pump control boxes for seals.

c. Install one electrode at the inlet to the holder and the other electrode in the holder outlet. Close the circuit to the electrode located at the inlet to the holder.

d. Operate the pasteurizer, using water at pasteurization temperature, with the flow-diversion device in the forward-flow position.

e. Quickly inject 50 ml. of saturated sodium chloride solution into the holder inlet.

f. Start the stopwatch with the first movement of the indicator of a change in conductivity. Open the circuit to the inlet electrode and close the circuit to the electrode at the outlet of the holder.

g. Stop the stopwatch with the first movement of the indicator of a change in conductivity.

h. Record results.

i. Repeat the test six or more times, until six successive results are within 0.5 seconds of each other. The average of these six tests is the holding time for water in forward flow. When consistent readings cannot be obtained, purge the equipment, check instruments and connections and check for air leakage on the suction side. Repeat tests. Should consistent readings not be obtained, use the fastest time as the holding time for water.

j. Repeat steps d. through i. for the testing time on water in diverted flow.

k. With the pump at the same speed and equipment adjusted as in a. above, time the filling of a 38 liter (10-gallon) can with a measured weight of water, using the discharge outlet with the same head pressure as in normal operation. Average the time of several trials. (Since flow rates of the large capacity units make it very difficult to check by filling a 38 liter (10-gallon) can, it is suggested, that a calibrated tank of considerable size be used.)

l. For all gear type timing pumps, repeat procedure 'k' using milk.

For those homogenizers used as timing pumps repeat procedure 'k' using milk when the measured holding time for water is less than 120% of the legal holding time.

m. Compute the holding time for milk from one of the following formulas either by volume or by weight. Compute separately for forward flow and diverted flow. Re-seal regulatory controls as necessary.

BY VOLUME

The holding time for milk is equal to the holding time for water times quotient of the time it takes to deliver a volume of milk divided by the time it takes to deliver the same volume of water.

Tm = Tw(Vm/Vw)

In which: Tm = Adjusted product holding time for milk.

Tw = Holding time for water (the salt test results).

Vw = Time (usually in seconds) that it takes to pump a volume of water.

Vm = Time (usually in seconds) that it takes to pump the same volume of milk.

or

BY WEIGHT (Using specific gravity)

The holding time for milk is equal to the specific gravity of milk times the holding time for water times quotient of the time it takes to deliver a measured weight of milk divided by the time it takes to deliver the same weight of water.

Tm = 1.032xTw(Wm/Ww)

In which: 1.032 = the specific gravity of milk

Tm = Adjusted product holding time for milk.

Tw = Holding time for water (the salt test results).

Wm = Time (usually in seconds) that it takes to pump he a measured weight of milk.

Ww =Time (usually in seconds) that it takes to pump the same measured weight of water.

n. Record results for the office record.

Corrective Action: When the computed holding time for milk is less than that required, either in forward flow or diverted flow, the speed of the timing pump shall be reduced or an adjustment made in the holding tube and the timing test repeated until satisfactory holding time is achieved. Should an orifice be used, to correct the holding time in diverted flow, there should be no excessive pressure exerted on the underside of the valve seat of the flow-diversion device. Governors shall be sealed

on motors that do not provide a constant speed as provided in Item 16p(B)5b.

Application: To all high-temperature short-time pasteurizers with a Magnetic Flow Meter System, used in lieu of a metering pump.

Frequency: Upon installation, semiannually thereafter, whenever a seal on the Flow Alarm is broken, any alteration is made affecting the holding time, the velocity of the flow or the capacity of holding tube or whenever a check of the capacity indicates a speed up.

Criteria: Every particle of milk shall be held for at least a minimum holding time in both the forward and diverted flow positions.

Apparatus: Electrical conductivity measuring device, capable of detecting change in conductivity, equipped with standard electrodes, table salt (sodium chloride), 50-ml syringe, stopwatch and a suitable container for salt solution.

Method: The holding time is determined by timing the interval for an added trace substance to pass through the holder.

Procedure:

a. Examine the entire system to insure that all flow promoting equipment is operating at maximum capacity and all flow impeding equipment is so adjusted or bypassed as to provide the minimum resistance to the flow.

b. Adjust the set point on the Flow Alarm to its highest possible setting.

c. Adjust the set point on the Flow Controller to a flow rate estimated to yield an acceptable holding time.

d. Install one electrode at the inlet to the holder and the other electrode to the holder outlet. Close the circuit to the electrode located at the inlet to the holder.

e. Operate the pasteurizer, using water, above the pasteurization temperature, with the flow-diversion device in the forward flow position.

f. Quickly inject 50-ml of saturated sodium chloride solution into the holder inlet.

g. Start the stopwatch with the first movement of the indicator of a change in conductivity. Open the circuit to the inlet electrode and close the circuit to the electrode at the outlet of the holder.

h. Stop the stopwatch with the first movement of the indicator of a change in conductivity.

i. Record results.

j. Repeat the test six or more times, until six successive results are within 0.5 seconds of each other. The average of these six tests is the holding time for water in forward flow. When consistent readings cannot be obtained, purge the equipment, check instruments and connections and check for air leakage on the suction side of the pump, located at the raw product supply tank. Repeat tests. If six consecutive readings cannot be achieved within 0.5 seconds, in forward and diverted flow, the pasteurizing system is in need of repair.

k. With the Flow Controller at the same set point as in c. above, time the filling of a 38 liter (10-gallon) can with a measured volume of water using the discharge outlet, with the same head pressure as in normal operation. Average the time

of several trials. (Since flow rates of the large capacity units make it very difficult to check by filling a 38 liter (10-gallon) can, it is suggested that a calibrated tank of considerable size be used.)

l. Re-seal regulatory controls as necessary and record this result for the office record.

Corrective Action: When the computed holding time for milk is less than that required, either in forward flow or diverted flow, the set point on the Flow Controller shall be decreased, or adjustment made in the holding tube and the timing test repeated until a satisfactory holding time is achieved. Should an orifice be used to correct the holding time in diverted flow, there should be no excessive pressure exerted on the underside of the valve seat of the flow-diversion device.

11.2B CONTINUOUS FLOW HOLDERS--FLOW ALARM

Application: To all continuous flow pasteurization and aseptic processing systems using a Magnetic Flow Meter System to replace a metering pump. When testing aseptic processing systems, the "product divert system"or "product divert valve" or "acceptable control system" may be substituted for the "flow-diversion device" when it is referenced in this test.

Frequency: Upon installation, semiannually thereafter, whenever the seal on the Flow Alarm is broken, any alteration is made affecting the holding time, the velocity of the flow or the capacity of holding tube or whenever a check of the capacity indicates a speedup.

Criteria: When flow rate equals or exceeds the value at which the holding time was measured, the Flow Alarm shall cause the flow-diversion device to assume the diverted position, even though the temperature of the milk in the holding tube is above pasteurization or aseptic processing temperature.

Apparatus: None.

Method: Adjust the set point of the Flow Alarm so that flow is diverted when the flow rate equals or exceeds the value at which the holding time was measured or calculated (see parts 3 or 4 of this test).

Procedure:

a. Operate the pasteurizer or aseptic processing equipment in forward flow, at the flow rate at which holding time was measured, using water above the pasteurization or aseptic processing temperature.

b. Adjust set point on the Flow Alarm slowly downward until the frequency pen on the Recorder indicates that flow has been diverted. NOTE: when performing this test on systems which operate above the boiling point of water, be sure that the system is cooling is engaged to avoid the possibility of serious burns.

c. Observe that the flow-diversion device moved to the diverted position, while water passing through the holding tube remained above pasteurization or aseptic processing temperature.

d. Re-seal regulatory controls as necessary and record the set point of the Flow Alarm, the occurrence of flow-diversion and the temperature of the water in the holding tube, for the office record.

Corrective Action: If the flow-diversion device does not move to the

diverted position, when the frequency pen of the recorder indicates a diversion, a modification or repair of the control wiring is required.

11.2C CONTINUOUS FLOW HOLDERS--LOW FLOW/LOSS-OF-SIGNAL ALARM

Application: To all continuous flow pasteurization and aseptic processing systems using a Magnetic Flow Meter System to replace a metering pump. When testing aseptic processing systems, the "product divert system"or "product divert valve" or "acceptable control system" may be substituted for the "flow-diversion device" when it is referenced in this test.

Frequency: Upon installation, semiannually thereafter, whenever the seal on the Flow Alarm is broken, or any alteration is made affecting the holding time.

Criteria: Forward flow occurs only when flow rates are above the Loss-of-Signal Alarm set point.

Apparatus: None.

Method: By observing the actions of the frequency pens on the recorder and the position of the flow-diversion devise.

Procedure:

a. Operate the pasteurizer or aseptic processing equipment in forward flow, at a flow rate below the Flow Alarm set point and above the loss-of-signal alarm set point, using water.

b. Disrupt power to the magnetic flow meter or decrease the flow through the flow meter below the low flow alarm set point. Observe that the flow-diversion devise and both the safety thermal limit recorder frequency pen and the flow rate frequency pen assume the diverted flow position.

c. Re-seal regulatory controls as necessary and record results for the office record.

Corrective Action: If the valve does not divert or the pens do not move. Adjustment of low flow alarm or modification or repair of control wiring is required.

11.2D CONTINUOUS FLOW HOLDERS--FLOW OUT-IN AND CUT-OUT

Application: To all high-temperature short-time pasteurizers using a Magnetic Flow Meter System to replace a metering pump.

Frequency: Upon installation, semiannually thereafter, whenever the seal on the Flow Alarm is broken, any alteration is made affecting the holding time, the velocity of the flow or the capacity of holding tube, or whenever a check of the capacity indicates a speedup.

Criteria: Forward flow occurs only when flow rates are below the Flow Alarm set point and above the Loss-of-Signal Alarm set point.

Apparatus: None.

Method: By observing the recorder readings along with the action of the frequency pen on the recorder.

Procedure:

a. Operate the pasteurizer in forward flow, at a flow rate below the Flow Alarm set point and above the Loss-of-Signal Alarm set point, using water above pasteurization temperature.

b. Using the Flow Controller, increase flow rate slowly until the frequency pen on the recorder indicates a flow-diversion (flow cut-out point). The flow-diversion device will also assume the diverted position. Observe the reading of flow rate from the recorder, the instant flow cut-out occurs, as indicated by the frequency pen.

c. With the pasteurizer operating on water, above the pasteurization temperature, and with the flow-diversion device diverted because of excessive flow rate, slowly decrease flow rate until the frequency pen on the Flow Recorder indicates the start of a forward flow movement (flow cut-in point). Because of the time delay relay described in Test E, the flow-diversion device will not move immediately to the forward flow position. Observe the reading from the recorder, the instant flow cut-in occurs, as indicated by the frequency pen.

d. Re-seal regulatory controls as necessary and record results for the office record.

Corrective Action: If the cut-in or cut-out point occurs at a flow rate equal to or greater than the value at which holding time was measured, adjust the Flow Alarm to a lower set point and repeat the test.

11.2E CONTINUOUS FLOW HOLDERS--TIME DELAY RELAY

Application: To all high-temperature short-time pasteurizers using a Magnetic Flow Meter System to replace a metering pump.

Frequency: Upon installation, semiannually thereafter, whenever the seal on the Flow Alarm is broken, any alteration is made affecting the holding time, the velocity of the flow or the capacity of the holding tube, or whenever a check of the capacity indicates a speedup.

Criteria: Following the flow cut-in, as described in the test for flow cut-in and cut-out, forward flow shall not occur until all product in the holding tube has been held at or above pasteurization temperature for at least the minimum holding time.

Apparatus: Stopwatch.

Method: Set time delay equal to or greater than the minimum holding time.

Procedure:

a. Operate the pasteurizer in forward flow, at a flow rate below the Flow Alarm set point and above the Loss-of Signal Alarm set point, using water above pasteurization temperature.

b. Using the Flow Controller, increase flow rate slowly until the frequency pen on the Flow Recorder indicates a diversion movement and the flow-diversion device moves to the diverted position. There shall be no time delay between the movements of the frequency pen and the flow-diversion device.

c. With the pasteurizer operating on water, above the pasteurization temperature, with the flow-diversion device diverted because of excessive flow rate, slowly decrease flow rate.

d. Start the stopwatch the instant the frequency pen on the Flow Recorder indicates the start of a forward flow movement.

e. Stop the stopwatch the instant the flow-diversion device starts to move to the forward flow position.

f. Record results for the office record.

g. Install and seal enclosure over the time delay relay.

Corrective Action: If the time delay is less than the minimum holding time, increase the time setting on the time delay and repeat this test procedure.

11.3 CALCULATED HOLD FOR INDIRECT HEATING

Application: To all HHST pasteurizers using indirect heating.

Frequency: When installed, semiannually thereafter, whenever the seal on speed setting is broken, whenever any alteration is made affecting the holding time, the velocity of the flow, e.g., replacement of pump, motor, belt, driver or driven pulley, decrease in number of heat-exchange plates or the capacity of holding tube and whenever a check of the capacity indicates a speedup.

Criteria: Every particle of product shall be held for the minimum holding time in both the forward and diverted-flow positions.

Apparatus: No supplemental materials needed.

Method: Fully developed laminar flow is assumed and holding tube length is calculated. An experimental determination of pumping rate is required; this is accomplished by determining the time required for the pasteurizer to fill a vessel of known volume, converting these data by division to obtain flow rate in gallons per second and multiplying this value by the proper number in Table 12. of this paragraph to obtain the required length of the holding tube. Holding tube lengths for HHST pasteurizers with indirect heating for a pumping rate of 1 gallon/second are:

Table 13. Holding Tube Length--HHST Pasteurizers--Indirect Heating

	Tubing Size (inches)				
Holding Time (sec.)	1	1-1/2	2	2-1/2	3
	Holding Tube Length (inches)				
1.0	723.0	300.0	168.0	105.0	71.4
0.5	362.0	150.0	84.0	52.4	35.7
0.1	72.3	30.0	16.8	10.5	7.14
0.05	36.2	15.0	8.4	5.24	3.57
0.01	7.23	3.0	1.68	1.05	.714

Procedure:

a. Examine the entire system to ensure that all flow promoting equipment is operating at maximum capacity and all flow impeding equipment is so adjusted or bypassed to provide the minimum of resistance to the flow. This means that in-line filters must be removed, booster pumps must be in operation and vacuum equipment in the system must be operating at a maximum vacuum. Also, before the tests are begun, the pasteurizer should be operated at maximum flow for a sufficient time to purge air from the system (about 15 minutes) and pipe connections on the suction side of the metering pump should be made tight enough to exclude the entrance of air. With the pasteurizer operating with water, adjust the metering pump

to its maximum capacity, preferably with a new belt and full-size impellers.

b. Determine that no flow exists in the diverted line, and measure the time required to deliver a known volume of water at the forward-flow discharge line. Repeat the test at least once to determine that the measurements are consistent.

c. Repeat the steps in paragraphs a. and b. of this procedure in diverted flow by collecting the effluent at the discharge of the divert line.

d. Select the greatest flow rate (shortest delivery time for the known volume) and calculate the flow rate in gallons per second by dividing the known volume by the time required to collect he known volume. Multiply this value with the appropriate value in Table 13. to determine the required holding tube length.

e. Determine the number and type of fittings in the holding tube and convert these to equivalent lengths of straight pipe with the use of Table 14. of this paragraph. Determine the total length of the holding tube by adding the equivalent lengths of the fittings to the measured straight lengths of pipe. Record the number and type of fittings, the number and length of straight pipe and the holding tube configuration for the office record. If the temperature sensor is located at the beginning of the holding tube, the holding tube shall be protected against heat loss by material that is impervious to water. Re-seal regulatory controls as necessary.

Table 14. Centerline Distances of 3-A Fittings

3-A (inches) designation	Fitting size				
	1	1-1/2	2	2-1/2	3
	Centerline distance (inches)				
2C 90° bend	3.4	4.8	6.2	8.0	9.7
2CG 90° bend	3.1	4.5	5.8	7.6	9.3
2F 90° bend	3.4	4.8	6.2	8.0	9.7
2FG 90° bend	3.1	4.5	5.8	7.6	9.3
2E 90° bend	3.4	4.8	6.2	8.0	9.7
2EG 90° bend	3.2	4.6	6.0	7.7	9.4

Alternate procedure: For pasteurizers of large capacity, the method of measuring flow rate at the discharge of the pasteurizer is inconvenient, the following alternate test procedure may be used. Remove the divert line from the raw-product supply tank and turn off the product pump feeding the raw-product supply tank. Suspend a sanitary dip stick in the raw-product supply tank and operate the pasteurizer at maximum capacity. Record the time required for the water level to move between two graduations on the dip stick. The volume of water is calculated from the dimensions of the raw-product supply tank and the drop in water level. Flow rate is determined as follows: Divide the volume of

water removed from the raw-product supply tank by the time required to remove it.

Corrective Action: If the length of the holding tube is shorter than the calculated length, reseal the metering pump at a slower maximum speed, or lengthen the holding tube, or both, and repeat the above determination.

11.4 CALCULATED HOLD FOR DIRECT HEATING

Application: To all HHST pasteurizers using direct contact heating.

Frequency: When installed, semiannually thereafter, whenever the seal on the speed setting is broken, whenever any alteration is made affecting the holding time, the velocity of the flow, e.g., replacement of pump, motor, belt, driver or driven pulley, or decrease in the number of heat exchange plates, or the capacity of the holding tube and whenever a check of the capacity indicates a speedup.

Apparatus: No supplemental materials needed.

Criteria: Every particle of product shall be held for the minimum holding time in both forward- and diverted-flow positions.

Method: Fully developed laminar flow and a temperature increase by steam injection of 67°C (120°F) are assumed, the temperature-time standard is chosen by the processor and the required holding tube length is calculated from an experimental determination of pumping rate.

Procedure.—

a. Examine the entire system to ensure that all flow promoting equipment is operating at a maximum capacity and all flow impeding equipment is so adjusted or bypassed as to provide the minimum resistance to the flow. Remove in-line filters, make certain booster pumps are operating and that vacuum equipment in the system is operating at maximum vacuum. Also, before the tests are begun, operate the pasteurizer at maximum flow for a sufficient time to purge the air from the system (about 15 minutes) and tighten pipe connections on the suction side of the metering pump to exclude entrance of air. With the pasteurizer operating on water, adjust the metering pump to its maximum capacity. Determine that no flow exists in the diverted line, and measure the time required to deliver a known volume of water at the discharge of the pasteurizer in forward flow. Repeat the test at least twice to determine that the measurements are consistent.

b. Repeat the last step (a. above) in diverted flow by collecting the effluent at the discharge of the divert line. Select the greatest flow rate, the shortest delivery time for the known volume and calculate the flow rate in gallons per second, by dividing the tube lengths for direct contact heating pasteurizers with a pumping rate of 1 gallon/second are:

Table 15. Holding Tube Length, HHST Pasteurizers, Direct Heating

Tubing Size (inches)					
Holding time (sec.)	1	1-1/2	2	2-1/2	3
	Holding tube length (inches)				
1	810.0	336.0	188.0	118.0	80.0
0.5	405.0	168.0	94.0	59.0	40.0
0.1	81.0	33.6	18.8	11.8	8.0
0.05	40.5	16.8	9.40	5.90	4.0
0.01	8.10	3.36	1.88	1.18	0.8

c. Determine the number and type of fittings in the holding tube, and convert these to equivalent lengths of straight pipe with the use of Table 14. Determine the total length of the holding tube by adding the equivalent lengths of the fittings to the measured lengths of straight pipe. If the actual holding tube length is equivalent to or greater than the required holding tube length, record the number and type of fittings, the number and length of straight pipes and the holding tube configuration, for the office record. Make sure that the holding tube slopes upward at least 6.35 millimeters (0.25 inch) per foot. The holding tube shall also be protected against heat loss with insulation that is impervious to water if the temperature sensor is located at the beginning of the holding tube. Re-seal regulatory controls as necessary.

Alternate procedure: For pasteurizers of large capacity, the method of measuring flow rate at the discharge of the pasteurizer is inconvenient and the following alternate test procedure may be used. Remove the divert line from the raw product supply tank and turn off the product pump feeding the raw-product supply tank. Suspend a sanitary dip stick in the raw-product supply tank and operate the pasteurizer at maximum capacity. Record the time required for the water level to move between two graduations on the dip stick. Calculate the volume of water from the dimensions of the raw-product supply tank and the drop in water level. Determine flow rate as follows: Divide the volume of water, in gallons, removed from the raw-product supply tank by the time, in seconds, required to remove it. Then use Table 15. to calculate the required holding tube length.

Corrective Action: If the length of the holding tube is shorter than the calculated length, reseal the metering pump at a slower maximum speed, or lengthen the holding tube, or both, and repeat the procedure.

11.5 HOLDING TIME-- STEAM INFUSERS WITH STEAM POP OFF VALVE AND VACUUM CHAMBER ORIFICE USED IN PLACE OF A TIMING PUMP--

Application: To all HHST pasteurizers using direct steam infusion heating and using a steam pop off valve and a vacuum chamber orifice in place of a timing pump.

Frequency: Upon installation, and every 3 months thereafter, or when a regulatory seal has been broken.

Apparatus: No supplemental materials needed.

Criteria: Every particle of product shall be held for the minimum holding time in both forward- and diverted-flow positions.

The following controls are required:

a. The steam infuser shell or feed line shall be equipped with a pressure relief pop-off valve. This pressure relief valve shall be located and sized so that the total pressure inside the infuser can never exceed the set point on this pressure relief valve.

b An orifice or restriction, permanently installed in a noticeable fitting, shall be placed in the holding tube just prior to the vacuum chamber. The opening in the orifice or restriction, shall be sized to insure a minimum product residence time at least as long as that specified in the chosen HHST standard.

c. The size of the opening in the orifice or restriction and the setting of the steam pressure relief valve shall be determined by trial and error. Once an appropriate maximum flow rate has been determined and a legal minimum holding time has been calculated, both the restriction or orifice and the steam pressure setting on the pressure relief valve shall be sealed so that neither can be changed.

d. The state regulatory authority shall keep records of the orifice or restriction size. They shall also keep records of the location, size, setting and manufacturer of the pressure relief valve.

Procedure:

a. Examine the entire system to ensure that all flow promoting equipment is operating at a maximum capacity and all flow impeding equipment is so adjusted or bypassed as to provide the minimum resistance to the flow.

b. The steam pressure in the infuser shall be raised to a level just below the pressure relief point on the pop off valve.

c. Any back-pressure valves or other variable restrictions in the holding tube shall be normally placed into the fully open position.

d. All air bleeds to the vacuum chamber shall be closed so that the chamber will be operating under maximum vacuum.

e. Before the tests are begun, operate the pasteurizer at maximum flow for a sufficient time to purge the air from the system (about 15 minutes) and tighten pipe connections on the suction side of the metering pump to exclude entrance of air.

f. Determine that no flow exists in the diverted line, and measure the time required to deliver a known volume of water at the discharge of the pasteurizer in forward flow.

g. Repeat the test at least twice to determine that the measurements are consistent.

h. Repeat the last step (a. through e. above) in diverted flow by collecting the effluent at the discharge of the divert line.

i. Select the greatest flow rate, the shortest delivery time for the known volume and calculate the flow rate in gallons per second, by dividing the known volume by the time required to collect the known volume.

j. Multiply this value, gallons per second, with the appropriate value in Table 15, to determine the required holding tube length.

k. Holding tube lengths for direct contact heating pasteurizers with a pumping rate of 1 gallon/second are specified in Table 13.

l. Determine the number and type of fittings in the holding tube, and convert these to equivalent lengths of straight pipe with the use of Table 14. Determine the total length of the holding tube by adding the equivalent lengths of the fittings to the measured lengths of straight pipe.

m. Make sure that the holding tube slopes upward at least 6.35 millimeters (0.25 inch) per foot.

n. The holding tube shall also be protected against heat loss with insulation that is impervious to water if the temperature sensor is located at the beginning of the holding tube.

o. If the actual holding tube length is equivalent to or greater than the required holding tube length, record the number and type of fittings, the number and length of straight pipes and the holding tube configuration, for the office record. Re-seal regulatory controls as necessary.

Corrective Action: If the length of the holding tube is shorter than the calculated length, lengthen the holding tube and repeat the above determination.

TEST 12.
THERMAL LIMIT CONTROLLER FOR CONTROL-SEQUENCE LOGIC

References: Items 16p(B), 16p(E).

Thermal limit controllers used with HHST and aseptic processing systems that have the flow-diversion device located downstream from the regenerator and/or cooler shall be tested by one of the following applicable tests at the frequency specified.

12.1 HHST PASTEURIZATION AND ASEPTIC PROCESSING-- INDIRECT HEATING

Application: To all HHST pasteurizers and aseptic processing systems using indirect heating. When testing aseptic processing systems, the "product divert system"or "product divert valve" or "acceptable control system" may be substituted for the "flow-diversion device" when it is referenced in this test.

Frequency: Upon installation, and every 3 months thereafter, or when a regulatory seal has been broken.

Criteria: The pasteurizer, or aseptic processing equipment, shall not operate in forward flow until the product surfaces downstream from the holding tube have been sanitized, or in the case of aseptic processing equipment, sterilized. On start up, surfaces shall be exposed to fluid at pasteurization, or in the case of aseptic processing equipment, sterilizing temperature for at least the required pasteurization or sterilization time. If the product temperature falls below the pasteurization or sterilization standard in the holding tube, forward flow shall not be re-achieved until the product surfaces downstream from the holding tube have been re-sanitized, or in the case of aseptic processing equipment, re-sterilized.

Apparatus: A constant temperature bath of water, or oil, and the test lamp from the pneumatic testing device described in Test 9.1 can be used to check the control-sequence logic of the thermal limit controller.

Method: The control-sequence logic of the thermal limit controller is determined by monitoring the electric signal from the thermal limit controller during a series of immersions and removals of the two sensing elements from a bath heated above the cut-in temperature.

Procedure:

a. Heat a constant temperature water or oil bath a few degrees above the cut-in temperature on the thermal limit controller. Wire the test lamp in series with the signal from the thermal limit controller to the flow-diversion device. If some processors have time delays built into their control logic, in excess of that required for public health reasons, by pass these timers or account for their effect in delaying forward flow.

b. Immerse the sensing element of the flow-diversion device in the bath, which is above the cut-in temperature. The test lamp should remain unlighted, i.e., diverted flow. Leave the sensing element in the bath.

c. Immerse the sensing element from the holding tube in the bath. The test lamp should light up, i.e., forward flow after a minimum time delay of 1 second for continuous flow pasteurization systems. For aseptic processing systems no delay is required if the filed process includes a documented sterilization period.

d. Remove the sensing element of the flow-diversion device from the bath. The test lamp should remain lighted, i.e., forward flow.

e. Remove the holding tube sensing element from the bath. The test lamp should go out immediately, i.e., diverted flow.

f. Re-immerse the sensing element of the holding tube in the bath. The test lamp should remain unlighted, i.e., diverted flow. Re-seal regulatory controls as necessary.

Corrective Action: If the control-sequence logic of the thermal limit controller does not follow this pattern, the instrument shall be rewired to conform to this logic.

12.2 HHST PASTEURIZATION AND ASEPTIC PROCESSING-- DIRECT HEATING

Application: To all HHST pasteurizers and aseptic processing systems using direct contact heating. When testing aseptic processing systems, the "product divert system"or "product divert valve" or "acceptable control system" may be substituted for the "flow-diversion device" when it is referenced in this test.

Frequency: Upon installation and every 3 months thereafter, or when a regulatory seal has been broken.

Criteria: The pasteurizer, or aseptic processing equipment, shall not operate in forward flow until the product surfaces downstream from the holding tube have been sanitized, or in the case of aseptic processing equipment, sterilized. On start up, surfaces shall be exposed to fluid at pasteurization, or in the case of aseptic processing equipment, sterilizing

temperature for at least the required pasteurization or sterilization time. If the product temperature falls below the pasteurization or sterilization standard in the holding tube, forward flow shall not be reachieved until the product surfaces downstream from the holding tube have been re-sanitized, or in the case of aseptic processing equipment, re-sterilized.

Apparatus: A constant temperature bath of water, or oil, and the test lamp from the pneumatic testing device described in Test 9.1 can be used to check the control-sequence logic of the thermal limit controller.

Method: The control-sequence logic of the thermal limit controller is determined by monitoring the electric signal from the thermal limit controller during a series of immersions and removals of the three sensing elements from a bath heated above the cut-in temperature.

Procedure:

a. Heat a water or oil bath to a constant temperature, a few degrees above the cut-in temperature on the thermal limit controller. Wire the test lamp in series with the signal from the thermal limit controller to the flow-diversion device. If some processors have time delays built into their control logic, in excess of that required for public health reasons, bypass these timers or account for their effect in delaying forward flow. Before performing this test, make sure the pressure switches, which must be closed to achieve forward flow, have also been bypassed.

b. Immerse the sensing element from the flow-diversion device in the bath which is above the cut-in temperature. The test lamp should remain unlighted, i.e., diverted flow. Remove this sensing element from the bath.

c. Immerse the sensing element, from the vacuum chamber, in the bath. The test lamp should remain unlighted, i.e., diverted flow. Remove the sensing element from the bath.

d. Immerse two sensing elements, from the vacuum chamber and flow-diversion device, in the bath. The test lamp should remain unlighted, i.e., diverted flow. Leave the two sensing elements in the bath.

e. Immerse the third sensing element, from the holding tube, in the bath. The test lamp should light up, i.e., forward flow, after a minimum time delay of 1 second for continuous flow pasteurization systems. For aseptic processing systems no delay is required if the filed process includes a documented sterilization period.

f. Remove one sensing element, the flow-diversion device, from the bath. The test lamp should remain lighted, i.e., forward flow.

g. Remove another sensing element, the vacuum chamber, from the bath. The test lamp should remain lighted, i.e., forward flow.

h. Remove the last sensing element, the holding tube, from the bath. The test lamp should go out, i.e., diverted flow, immediately.

i. Re-immerse the sensing element, holding tube, in the bath. The test lamp should remain unlighted, i.e., diverted flow. Re-seal regulatory controls as necessary.

Corrective Action: If the control-sequence logic of the thermal limit con-

troller does not follow the pattern set out in the procedure section, the instrument shall be rewired to conform to this logic.

TEST 13. SETTING OF CONTROL SWITCHES FOR PRODUCT PRESSURE IN THE HOLDING TUBE

Reference: Item 16p(B).

Application: To all HHST pasteurizers and aseptic processing systems which are capable of operating with product in forward flow mode, with less than 518 kPa (75 psig) pressure in the holding tube. When testing aseptic processing systems, the "product divert system"or "product divert valve" or "acceptable control system" may be substituted for the "flow-diversion device" when it is referenced in this test.

Frequency: Upon installation, every 3 months thereafter, whenever the pressure switch seal is broken and whenever the operating temperature is changed.

Criteria: The pasteurizer or aseptic processor shall not operate in forward flow unless the product pressure in the holding tube is at least 69 kPa (10 psi) above the boiling pressure of the product.

Apparatus: A sanitary pressure gauge and a pneumatic testing device described in Test 9.1 can be used for checking and adjusting the pressure switch setting.

Method: The pressure switch is checked and adjusted so as to prevent forward flow unless the product pressure in the holding tube is at least 69 kPa (10 psi) above the boiling pressure of the product.

Procedure:

a. From Figure 45 determine the pressure switch setting necessary for the operating temperature (not the diversion temperature) being used in the process.

Install the sanitary pressure gauge, of known accuracy, and the pressure switch sensing element on the pneumatic testing device.

b. Remove the seal and cover to expose the adjustment mechanism on the pressure switch. Place the test lamp in series with the pressure switch contacts or use some other method to monitor the cut-in signal.

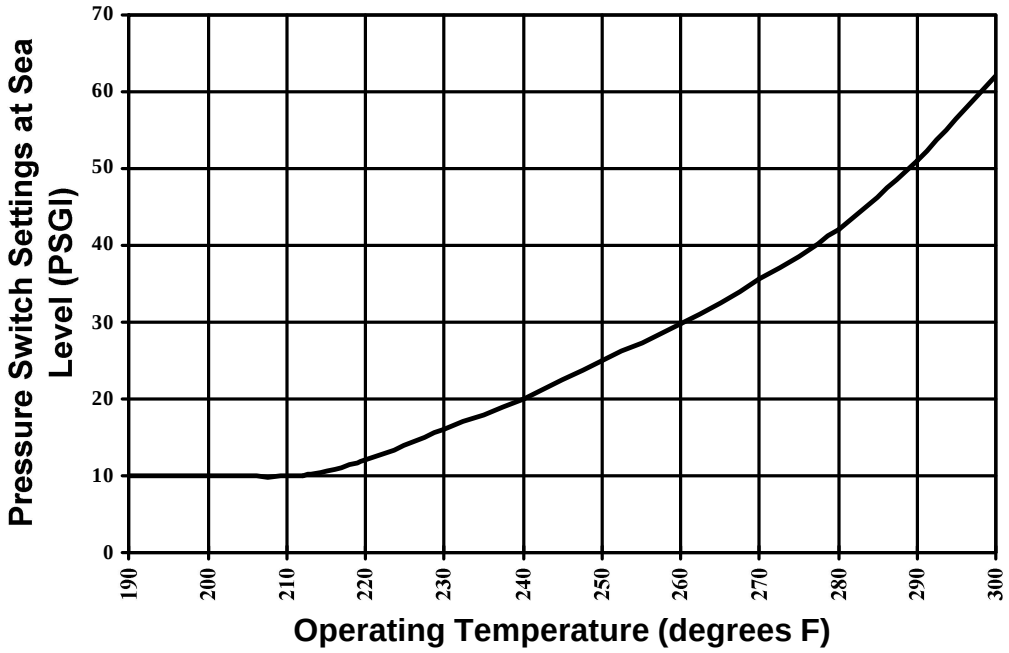
c. Apply air pressure to the sensing element and determine the pressure gauge reading at the cut-in point of the switch which sill light the test lamp. If the switch is short circuited, the lamp will be lit before air pressure is applied.

d. Determine that the cut-in pressure on the switch is equivalent to or greater than the required pressure from Figure 45. Where adjustment is necessary, refer to the manufacturer's instructions.

e. After adjustment, repeat the procedure.

f. When the results are satisfactory, seal the pressure switch setting and record the results for the office record.

For each operating temperature on HHST pasteurizers or aseptic processing systems using direct contact heating, the product pressure switch setting is as follows:



This pressure setting shall be adjusted upward by the difference between local normal atmospheric pressure and sea level.

Figure 45. Pressure Switch Setting

TEST 14. SETTING OF CONTROL SWITCHES FOR DIFFERENTIAL PRESSURE ACROSS THE INJECTOR

Application: To all HHST pasteurizers and aseptic processing systems using direct contact heating. When testing aseptic processing systems, the "product divert system"or "product divert valve" or "acceptable control system" may be substituted for the "flow-diversion device" when it is referenced in this test.

Frequency: Upon installation, every 3 months thereafter and whenever the differential pressure controller seal is broken.

Criteria: The pasteurizer or aseptic processor shall not operate in forward flow unless the product pressure drop across the injector is at least 69 kPa (10 psi).

Apparatus: A sanitary pressure gauge and a pneumatic testing device described in Test 9.1 can be used for checking and adjusting the differential pressure controller.

Method: Check the differential pressure switch and adjust it so as to prevent forward flow, unless the differential pressure across the injector is at least 69 kPa (10 psi).

Procedure:

a. Remove both pressure sensing elements from their original locations on the pasteurizer, or

aseptic processor. Install a sanitary pressure gauge of known accuracy and the pressure sensing element, that is installed prior to the steam injection, on the pneumatic testing device.

b. Leave the other pressure sensing element open to the atmosphere, but at the same height as the sensing element connected to the pneumatic testing device.

c. Wire the test lamp in series with the microswitch of the differential pressure controller or use the method provided by the instrument manufacturer to monitor the cut-in signal.

d. Apply air pressure to the sensing element and determine the pressure gauge reading at the cut-in point of the differential pressure switch that will light the test lamp.

e. Determine that the differential pressure cut-in on the controller is at least 69 kPa (10 psi).

f. After adjustment, repeat the procedure.

g. When the results are satisfactory, seal the instrument and record the results for the office record.

APPENDIX J. STANDARDS FOR THE FABRICATION OF SINGLE-SERVICE CONTAINERS AND CLOSURES FOR MILK AND MILK PRODUCTS

PREFACE

Single-service containers and closures have been used in the dairy industry for many years. Industry applied quality assurance controls for manufacturing and handling of the materials have made it possible for these products to reach the point of use in a sanitary condition free from toxic materials which may migrate into milk or milk products.

Within recent years, single-service container manufacturers have introduced new materials, equipment, and design concepts for these containers and closures. Evaluation of the industry's basic manufacturing and handling techniques and establishment of sanitation criteria assure that single-service containers and closures and the materials from which they are formed are safe and in compliance with bacteriological standards of Item 12p of the Grade "A" Pasteurized Milk Ordinance -- 1978 Recommendations of the United States Public Health Service / Food and Drug Administration (1999 Revision).

STANDARDS FOR THE FABRICATION OF SINGLE-SERVICE CONTAINERS AND CLOSURES FOR MILK AND MILK PRODUCTS

A. PURPOSE AND SCOPE

The use of these standards will insure the production of sanitary containers and closures for milk and milk products, as defined in the *Grade "A" Pasteurized Milk Ordinance*.

These standards shall apply to all blank fabricators, converters, printers, closure manufacturers, plastic laminators, sheet formers, blow molders, vacuum formers, plastic extruders, injection molders, preformers, manufacturers of valves, tubes, dispensing devices, sample containers and similar plants. These also apply to the installation, operation, cleaning, sanitization and maintenance of equipment used in compounding materials for the fabrication, production, handling and storage of single-service containers and closures.

Milk and food plants manufacturing and/or selling containers to other milk or milk products plants as defined in the *Grade "A" Pasteurized Milk Ordinance* shall meet all the requirements of these standards. These requirements shall not apply to paper mills or resin manufacturing plants.

Grade “A” milk and milk product plants as defined in the *Grade "A" Pasteurized Milk Ordinance* shall use single-service containers and closures from plants certified in the latest quarterly publication of the *Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers* (IMS List).

B. DEFINITIONS

The following definitions shall be employed in the application of these sanitation standards.

1. "Single-service container" shall mean any container having a milk or milk product-contact surface and used in the packaging,

handling or storage of Grade “A” milk and milk products which is intended for one use only.

2. "Closure" shall mean a cap, lid, seal, tube, valve, lidding material or other device in or on a container used for the purpose of enclosing or dispensing the contents.

3. "Paper stock" means any paper made from the following materials:

a. Paper and paperboard manufactured from clean, sanitary virgin chemical or mechanical pulp or from "broke and trim" of such paper and paperboard, provided they have been handled, treated and stored in a clean, sanitary manner, or reclaimed fiber using acceptable or approved protocol in compliance with Title 21 Code of Federal Regulation (CFR) 176.260.

b. Components meeting the requirements of the *Federal Food, Drug, and Cosmetic Act* as amended.

4. "Broke and trim" means paper and paperboard that have been discarded anywhere in the process of manufacture, such as on paper-making machines in the form of trim. This may also include unprinted trim from the converting process provided the trim has been handled, treated and transported in a clean, sanitary manner.

5. "Plastic molding, forming, extrusion, and laminating resins" means:

a. Resins or an intimate admixture of resins with other ingredients which meet the requirements of the *Federal Food, Drug, and Cosmetic Act* as amended and;

b. Plastic composed solely of clean cuttings or regrind, provided they have been handled and maintained in a sanitary manner.

This definition shall not preclude the use of recycled plastic material when it complies with a protocol which has been reviewed and accepted by the Food and Drug Administration.

6. "Regrind" means that clean plastic material which is trimmed from the container or closure, and imperfectly formed containers or closures which result from the manufacture of single-service containers and closures, provided it is handled in a clean, sanitary manner. This may be in its trimmed or molded form and ground in a suitable grinder within the plant. It shall not include any material, container or closure which comes from an unapproved source or whose source, chemical content and treatment is unknown, or which may have poisonous or deleterious material retained in the plastic which migrates to the food at levels exceeding regulatory levels. Regrind, when transported from one approved plant to another, will be shipped in suitable, clean, sealed, properly labeled containers. This definition shall not preclude the use of regrind plastic material when it complies with a protocol which has been reviewed and accepted by the FDA.

7. "Production scrap" means that material which remains from the manufacture of single-service containers or closures which has been handled or treated in such a manner that it does not comply with the definition for "broke and trim" or "regrind", but may be collected for recycling. It may contain material such as containers or trim that have fallen on the floor.

8. "Coatings" means any layer or covering which is applied to the product-contact surface.

9. "Product-contact surface" means those surfaces of the container or closure with which the product comes in contact.

10. "Nontoxic materials" means those materials which are free of substances which may render the milk injurious to health or which may adversely affect the flavor, odor, composition or bacteriological quality of the product and which meet the requirements of the *Federal Food, Drug, and Cosmetic Act* as amended.

11. "Metals" means those metals which are nontoxic, nonabsorbent and corrosion-resistant under conditions of intended use.

12. "Sanitization" is the application of any effective method or substance to a clean surface for the destruction of pathogens and of other microorganisms as far as is practicable. Such treatment shall not adversely affect the equipment, the milk or milk product, or the health of consumers. Chemical sanitizers shall meet the requirements contained in Part I of Appendix F of the *Grade "A" Pasteurized Milk Ordinance*.

13. "Single-service articles" means those articles which are constructed wholly, in part, or in combination from paper, paperboard, molded pulp, plastic, metals, coatings or similar materials which are intended by the manufacturer for one usage only.

14. "Preformed container" means a container in completed form ready for filling.

15. "Manufacturer" means any person or company in the business of manufacturing a single-service container or closure product which is capable for use by a milk plant for the packaging of a finished Grade "A" milk product.

16. "Component part" shall mean any item that by itself, does not perform any function, but when assembled with one or more component parts or closures, becomes a part of the single-service container or closure. These may include, but are not limited to blanks, sheeting, filling valve parts, tubes, dispensing devices and sampling containers. All material used for fabrication of a component part must meet the requirements of the *Federal Food, Drug, and Cosmetic Act* as amended .

17. "Sample set" means: for the rinse test, a minimum of four containers shall be tested. For the swab test a minimum of four 50 square centimeters areas of surface from separate containers shall be tested. In the case of containers or closures with a product-contact surface area smaller than 50 square centimeters, more than 4 containers or closures to equal at least 50 square centimeters times 4 will be required to be swabbed.

18. "Manufacturing Line" means a manufacturing process such as extrusion, blow-mould, etc.

C. BACTERIAL STANDARDS AND EXAMINATION OF SINGLE-SERVICE CONTAINERS AND CLOSURES

1. Paper stock shall meet the bacteriological standard of not more than 250 colonies per gram as determined by the disintegration test. The supplier of the paper stock shall certify that his/her paper stock was manufactured in compliance with this standard. This applies only to the paper stock prior to lamination.

2. Where a rinse test can be used, the residual microbial count shall not exceed 50

per container, except that in containers less than 100 ml, the count shall not exceed 10, or not over 50 colonies per 8 square inches (1 per square centimeter) of product-contact surface when the swab test is used, in 3 out of 4 samples taken at random on a given day. All single-service containers and closures shall be free of coliform organisms.

3. During any consecutive six months, at least four sample sets shall be collected in at least four separate months, except when three months show a month containing two sampling dates separated by at least 20 days, and analyzed at an official laboratory, commercial laboratory or industry laboratory approved by the state milk laboratory certifying agency specifically for the examinations required under these standards. See item 12p of the *Grade "A" Pasteurized Milk Ordinance* for sampling of containers and closures in pasteurization plants.

4. When a single-service container or closure is made from one or more component parts as defined in this document, only those final assembled products which may have product-contact surface(s)must be sampled and tested for compliance with Section "C".

Procedures for obtaining samples and for the laboratory examination of these products are contained in the latest edition of *Standard Methods for the Examination of Dairy Products* and shall be in substantial compliance with these methods. Such procedures and examinations shall be evaluated in accordance with the current revision of *The Evaluation of Milk Laboratories, 1985 Recommendations of the United States Public Health / Food and Drug Administration.* A list of approved laboratories may be found in *Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers* which is published quarterly by the Food and Drug Administration.

D. FABRICATION PLANT STANDARDS

Note: To be used in conjunction with form FD 2359c, "Manufacturing Plant Inspection Report -- Single-Service Containers".

1. FLOORS

a. The floor shall be smooth, impervious, and maintained in a state of good repair.

b. The joints between the walls and floor shall be tight, impervious and shall have coved or sealed joints.

c. Where floor drains are provided, they shall be properly trapped and floors sloped to drain.

2. WALLS AND CEILINGS

a. Walls and ceilings of fabricating areas shall have a smooth, cleanable, light-colored surface.

b. Walls and ceilings in fabricating and storage areas shall be kept in good repair.

3. DOORS AND WINDOWS

a. All outside openings shall be effectively protected against entry of insects, dust and airborne contamination.

b. All outer doors shall be tight and self-closing.

4. LIGHTING AND VENTILATION

a. All rooms shall be adequately lighted by either natural light, artificial light, or both. A minimum of 20 foot-candles should be maintained in fabricating areas and 5 foot-candles in storage areas. Packaging, sealing, wrapping, labeling and similar procedures are considered part of the fabricating area.

b. Ventilation shall be sufficient to prevent excessive odors and the formation of excessive water condensation.

c. The intake of all pressure ventilation systems in fabricating areas, whether they are positive or exhaust, shall be properly filtered.

5. SEPARATE ROOMS

a. All fabricating areas shall be separate from non-fabricating areas to protect against contamination. Provided, that if the entire plant meets all sanitation requirements and no source of cross contamination exists, separation between areas is not required.

b. All regrinding of plastic and the shredding, packaging or baling of paper trim shall be conducted in rooms separate from the fabricating room except that they may be conducted within a designated area of the fabricating room provided such operations are kept clean and free of dust.

6. TOILET FACILITIES - SEWAGE DISPOSAL

a. Disposal of sewage and other wastes shall be in a public sewage system or in a manner in compliance with state and local regulations.

b. All plumbing shall comply with the state and local plumbing regulations.

c. Toilet rooms shall have solid, self-closing doors and shall not open directly into fabricating areas.

d. The toilet room and fixtures shall be maintained in a clean and sanitary condition and in good repair.

e. Each toilet room shall be well lighted and adequately ventilated. Air ventilation ducts from toilet facilities shall vent to the outside.

f. Proper hand washing facilities shall be provided in toilet rooms.

g. All windows shall be effectively screened when open.

h. Signs shall be posted in all toilet rooms reminding employees to wash hands before returning to work.

i. Eating and/or storage of food is prohibited in toilet rooms.

7. WATER SUPPLY

a. The water supply, if from a public system, shall be approved as safe by the state agency responsible for water quality, and in the case of individual water systems, comply with at least the specifications outlined in Appendix D of the *Grade "A" Pasteurized Milk Ordinance***.**

b. There shall be no cross-connection between a safe water supply and any unsafe or questionable water supply or any source of pollution through which the safe water supply might become contaminated.

c. Samples for bacteriological testing of individual water supplies are taken upon the initial approval of the physical structure, each 12 months thereafter, and when any repair or alteration of the water supply system has been made. The examination of the sample shall be conducted in an officially designated laboratory.

8. HAND-WASHING FACILITIES

a. Hot and cold and/or warm running water, soap, air dryers or individual sanitary towels shall be convenient to all fabricating areas. Provided, that solvent or soft soap dispensers containing sanitizers may be used if water is not available. When individual sanitary towels are used, covered trash containers shall be provided.

b. Hand-washing facilities shall be kept clean.

9. PLANT CLEANLINESS

a. The floors, walls, ceilings, overhead beams, fixtures, pipes and ducts of production, storage, regrind, baling and compacting rooms shall be clean.

b. All production areas, warehouse, toilet, lunch and locker rooms shall be free of evidence of insects, rodents, and birds.

c. Machines and appurtenances shall be kept clean. Provided, that minor accumulations of paper, plastic or metal dust and other production soils incidental to normal fabricating operations do not violate this requirement.

10. LOCKER AND LUNCH ROOMS

a. Locker and lunch rooms shall be separate from plant operations and be equipped with self-closing doors.

b. Eating and/or storage of food is prohibited in fabricating and storage areas.

c. Locker and lunch rooms shall be kept in a clean and sanitary condition.

d. Cleanable refuse containers, properly labeled, shall be provided which are covered, impervious, leak-proof and readily accessible.

e. Proper hand washing facilities shall be convenient to locker rooms and lunchrooms.

f. Signs shall be posted reminding employees to wash their hands before returning to work.

11. DISPOSAL OF WASTES

a. All refuse and garbage shall be stored in covered, impervious and leak-proof containers. This requirement does not pertain to production scrap.

b. All waste containers shall be clearly labeled for their intended purpose and contents.

c. Where possible, garbage and assorted rubbish should be stored outside the building in covered, impervious, cleanable containers. If stored inside the building, it must be contained in similar receptacles, but in an area separate from fabricating areas.

12. PERSONAL CLEANLINESS

a. Hands shall be thoroughly washed before commencing plant functions and as often as may be required to remove soil and contamination, and before returning to work after visiting the toilet room or lunchroom.

b. All personnel shall wear clean outer garments and shall wear effective hair restraints, hair nets or caps.

c. No person affected with any disease in a communicable form, or while a carrier of such disease, and no person with an infected cut or lesion shall work in any processing area in any capacity where there is a likelihood of such person contaminating product or product-contact surfaces with pathogenic organisms.

d. The use of tobacco products is prohibited in fabricating, regrind and storage areas.

13. PROTECTION FROM CONTAMINATION

a. Upright, open formed containers and closures shall be protected from contamination by the use of overhead shields.

b. Whenever air under pressure is directed at resin or a product-contact surface, it shall be free of oil, dust, rust, excessive moisture, extraneous materials and odor and shall otherwise comply with the applicable requirements of Appendix H of the *Grade "A" Pasteurized Milk Ordinance.*

c. Air that is directed at product or product-contact surfaces by fans or blowers shall be filtered and shall otherwise comply with the applicable requirements of Appendix H of the *Grade "A" Pasteurized Milk Ordinance*.

d. Only pesticides approved for use in food plants and registered with the U.S. Environmental Protection Agency shall be used for insect and rodent control.

e. Pesticides shall be used in accordance with the manufacturer's directions and used so as to preclude the contamination of containers or closures.

14. STORAGE OF FINISHED PRODUCT AND MATERIAL IN PROCESS

a. Blanks, roll stock and all other single-service containers, closures and articles shall be stored in a manner to provide protection from contamination by use of pallets, slip sheets or other methods and away from any wall a sufficient distance to facilitate inspection, cleaning and pest control activities. Any roll stock having dirty or soiled outer turns and/or edges shall have sufficient turns discarded prior to use and edges trimmed to provide protection from contamination.

b. Single-service articles in process shall be protected from contamination by use of a single-service cover sheet or other protective device. This includes chip board, dividers, separators, bags and other items that can become contact surfaces.

c. Appropriate clean, dry storage facilities shall be provided for single-service containers, closures, paper for wrapping, adhesives, blanks and other production material to provide protection from splash, insects, dust, and other contamination.

d. Where containers and closures are pre-formed in plants other than the original fabricating facility:

1. Containers, blanks and closures shall be stored in the original cartons and sealed until used.

2. Partially used cartons of containers, blanks and closures shall be resealed until used.

e. Containers used for storage of resin, regrind, broke and trim, intended for reuse, shall be covered, clean, impervious and properly identified. Reuse of storage containers, such as gaylords, is permitted provided plastic liners are used.

f. In-process storage bins that touch the product-contact surface of containers or closures shall be constructed of cleanable, nonabsorbent material and kept clean.

15. FABRICATING, PROCESSING AND PACKAGING EQUIPMENT

The requirements of this section pertain to all equipment and processes used in the fabrication of containers and closures irrespective of the materials used and whether or not mentioned herein. Some of this equipment includes grinders, rollers, reamers and cutters, molders and fittings, extruders, silos, resin bins and hoppers, printing equipment, blanking equipment and sealing equipment.

a. Rolls, dies, belts, tables, mandrels, transfer tubing and all other contact surfaces shall be kept clean, sanitary and reasonably free of accumulation of paper, plastic or metal dust and other production soils. Equipment designed for milk plant use which is utilized for preforming containers shall be clean and sanitized prior to operation.

b. All materials in process for containers and closures shall be protected from contamination by condensate or drippage from overhead pipes or equipment components.

c. Makeshift devices such as tape, rope, twine, paperboards, etc., shall not be used. All fasteners, guides, hangers, supports and baffles shall be constructed of impervious, cleanable materials and kept in good repair.

d. Take-off tables and other container contact surfaces shall be constructed of cleanable material, kept clean and in good repair.

e. Waxing shall be performed so as to assure that containers or closures are completely coated and the wax shall be kept at a temperature of 140°F (60°C) or higher.

f. All grinders, shredders and similar equipment used for regrinding shall be installed above the floor or installed in such a manner that they are protected, so that floor sweepings and other contaminants cannot enter the grinder or shredder.

g. Storage tanks, silos, gaylords or bins used for plastic resins shall be so constructed to protect the resin from contamination. All air vents shall be filtered to prevent the entrance of dust or dirt. Air tubes used to conduct resin shall be supported above ground to prevent their becoming submerged in water. Air tubes used to convey resin shall have end caps, attached by chain or cable, that prevent contamination. This section also applies to all raw materials handled in like manner.

16. EQUIPMENT AND MATERIALS FOR CONSTRUCTION OF CONTAINERS AND CLOSURES

a. Single-service containers and closures for milk and milk products shall not be fabricated on equipment used for the manufacture of products made of non-food-grade materials unless such equipment has been thoroughly cleaned and/or purged of all non-food-grade material by a process that will not contaminate the food-grade material.

b. Only plastic sheeting and extrusions, plastic laminated paper, metal and paperboard blanks, or combinations thereof, from a manufacturing and/or fabricating plant conforming with these standards shall be used. Fabricating plants listed in the current IMS publication of "Certified Manufacturers of Single-service Containers and Closures for Milk and Milk Products" shall be considered in compliance with this item.

c. Only sanitary, nontoxic lubricants shall be used on container-closure contact surfaces. Excess lubricant shall be removed from surfaces close to shafts, rollers, bearing sleeves and mandrels. These lubricants shall be handled and stored in a manner that will prevent cross contamination with non-food-grade lubricants. Such storage areas shall be clean and adequately ventilated.

d. The manufacture of single-service containers and closures for milk and milk products shall be carried on in such a manner that there will be no cross contamination of raw material or regrind with non-food-grade materials.

e. Containers, resin and flashing on the floor and floor sweepings of production materials are prohibited from being reused. This shall not preclude the use of these materials when it cmplies with a protocol which has been reviewed and accepted by the FDA.

17. WAXES, ADHESIVES, SEALANTS AND INKS

a. Waxes, adhesives, sealants and inks used for containers and closures shall be handled and stored in a manner that will prevent cross contamination with similar non-food-grade materials. Such storage areas shall be clean and adequately ventilated.

b. Unused materials shall be covered and properly stored.

c. Waxes, adhesives, sealants and inks shall not impart odor or taste to the milk or milk products and shall not contaminate the product with microorganisms or toxic or injurious substances. All materials that are applied to the product-contact surface shall comply with the requirements of Parts 175 through 178 of Title 21 of the Code of Federal Regulations.

d. Transfer containers shall be kept clean and shall be properly identified and covered.

18. HANDLING OF CONTAINERS AND EQUIPMENT

Handling of fabricated containers, and container and closure-contact surfaces shall be kept to a minimum. Handlers shall sanitize their hands frequently or wear clean, single-use gloves.

19. WRAPPING AND SHIPPING

a. Blanks, closures, halves, nested or preformed containers and parts such as valves, hoses, tubes and other fittings shall

be properly packaged or containerized prior to shipping.

b. The outer package or containerized units shall protect the contents from dust and other contamination.

c. Transportation vehicles used to ship finished materials from the single-service container or closure plant or within the plant shall be clean and in good repair and shall not have been used for the transportation of garbage, waste or toxic materials.

d. Paperboard containers, wrappers, and dividers that contact the surface of the container or closure shall not be reused for this purpose.

e. All packaging materials that contact the product-contact surface of the container or closure shall comply with the requirements of Parts 175 through 178 of Title 21 of the *Code of Federal Regulations* and the bacteriological standards of Section "C" of this document, but the material does not have to be manufactured at a listed single-service plant.

20. IDENTIFICATION AND RECORDS

a. Outer wrappings shall be identified with the name and city of the plant where the contents are fabricated, except those manufactured in, and which are only for use in the same facility. In the cases where several plants are operated by one firm, the common firm name may be utilized, provided that the location of the plant at which the contents were fabricated is also shown either directly or by the FIPS numerical code on the outer wrapper.

b. Records of all required bacteriological tests of containers and closures shall be maintained at the plant of manufacture for two years and results shall be in compliance with Section C of these Standards.

c. The fabricating plant shall have on file information from suppliers of raw material, waxes, adhesives, sealants and inks indicating that the material complies with the requirements of Parts 175 through 178 of Title 21 of the *Code of Federal Regulation*.

d. The fabricating plant shall have on file information from the suppliers of packaging materials specified in Section 19e of these Standards indicating that the material complies with the requirements of Parts 175 through 178 of Title 21 of the *Code of Federal Regulation* and the bacteriological standards of Section "C" of this document.

e. Multi-plant corporations may have all required information at a central location as long as it can be transmitted to the site upon request.

21. SURROUNDINGS

a. Exterior surroundings shall be neat and clean and free from conditions which might attract or harbor flies, other insects and rodents.

b. Driveways, lanes and areas serving the plant vehicular traffic are graded, drained and free from pools of standing water.

Department of Health and Human Services Public Health Service Food and Drug Administration	**MANUFACTURING PLANT INSPECTION REPORT *(Single-Service Milk Containers)***	*Form Approved*
		Inspecting Agency

Name and Location of Plant:

1. BUILDINGS AND ROOMS:
Fabricating rooms separate from non-production areas……(a)_____
Regrinding conducted in separate Room(s).....(b) _____

2. FLOORS:
Smooth; impervious; in good repair; free of litter.....(a) _____
Joints between walls and floors tight(b) _____
Floor drains properly trapped.....(c) _____

3. WALLS AND CEILINGS:
In production areas- smooth, clean light, colored.....(a) _____
Overhead beams, fixtures, pipes, and ducts clean.....(b) _____

4. DOORS AND WINDOWS:
No openings into living quarters ...(a) _____
All outside openings protected against Entrance of insects, dust, and airborne contamination.....(b) _____

5. LIGHTING AND VENTILATION:
Adequate light in all rooms-20 foot candles in Production areas and 5 foot candles in storage areas.....(a) _____
Ventilation sufficient to prevent excessive \odors and condensation.....(b) _____

6. TOILET FACILITIES:
All plumbing complies with State and local plumbing codes .....(a) _____
Self-closing doors on toilet rooms(b) _____
Clean; in good repair.....(c) _____
Adequate light and ventilation.....(d) _____

7. WATER SUPPLY:
Safe: Sanitary quality; complies with bacteriological and construction Requirements .....(a) _____
No direct or indirect connection between safe and unsafe water.....(b) _____

8. HAND-WASHING FACILITIES:
Hot and cold or warm running water; soap; individual towels or air dryers provided.....(a) _____
Clean; convenient to fabricating areas and toilet facilities.....(b) _____

9. STORAGE OF MATERIALS AND FINISHED PRODUCTS:
Elevated off the floor and away from wall.....(a) _____
Stored in clean, dry place, protected from splash, insects, and dust.....(b) _____
Where containers and closures are formed in other than original converting facility, blanks stored in original cartons and sealed until used; partially used cartons resealed during storage.....(c) _____
Containers for reuse materials to be covered, clean and identified.....(d) _____

10. LOCKER AND LUNCHROOMS:
Separated from plant operations; clean; self-closing doors.....(a) _____
Covered, impervious trash containers provided.....(b) _____

11. DISPOSAL OF WASTES:
In public sewer or in sanitary manner; in compliance with State and local regulations.....(a) _____
Refuse properly stored in covered Containers.....(b) _____
Refuse containers properly identified.....(c) _____

12. INSECT AND RODENT CONTROL:
Plant interior free of evidence of insects and rodents.....(a) _____
Surroundings free of harborages and breeding areas.....(b) _____
Approved pesticides; safely used (c) _____

13. AIR UNDER PRESSURE:
Air under pressure in compliance (a) _____

14. PERSONNEL CLEANLINESS:
Clean hands.....(a) _____
Clean outer garments; hair restraints.....(b) _____
No person with inadequately treated wounds or lesions working in processing areas(c) _____

15. FABRICATING PROCESSING AND PACKAGING EQUIPMENT:
Contact surfaces clean.....(a) _____
Materials in process protected from contamination; overhead shields used(b) _____
Fasteners, guides, hangers, supports and baffles properly constructed; makeshift devices not Used.....(c) _____
Container contact surfaces properly constructed; in good repair.....(d) _____
Wax coating covers properly; proper wax temperature maintained.....(e) _____
Grinders, shredders and similar equipment properly installed; protected from contaminants.....(f) _____
Resin storage facilities properly constructed; air vents properly filtered; air tubes covered.....(g) _____

16. EQUIPMENT AND MATERIALS FOR CONSTRUCTION OF CONTAINERS AND CLOSURES :
Equipment thoroughly cleaned after use of non-food-grade materials .....(a) _____
Plastic sheeting, laminated paper, metal, and paperboard blanks from approved source.....(b) _____
Sanitary lubricants used on contact Surface .....(c) _____
Proper separation of raw and non-food-grade Materials .....(d) _____

17. WAXES, ADHESIVES, AND INKS :
Properly stored in covered containers(a) _____
Unused materials properly stored(b) _____
Nontoxic; impart no flavor or odor to Product.....(c)_____

18. HANDLING OF CONTAINERS AND EQUIPMENT :
Handling of product-contact surfaces Minimal .....(a) _____

19. WRAPPING AND SHIPPING :
Blanks, closures, halves, nested or preformed containers protected from contamination prior to use or shipping.....(a) _____
Packaged contents properly protected.....(b) _____
Transportation vehicles clean; in good Repair.....(c) _____
Paper board containers, wrappers and dividers not reused .....(d) _____

20. IDENTIFICATION AND RECORDS :
Individual containers or outer wrappings Identified.....(a) _____
Required bacteriological and chemical Tests on file.....(b) _____
All materials and components from approved source and records on file.....(c) _____

21. SURROUNDINGS:
Surroundings neat and clean; free from insect or rodent harborages .....(a) _____
Driveways and lanes graded, drained, free from standing water .....(b) _____

Remarks:

Date:	Sanitarian:

Note: This form has been developed to use with the *Grade "A" Pasteurized Milk Ordinance*, 1999 Recommendations of the U.S. Public Health Service/Food and Drug Administration

Form FDA 1359c

APPENDIX K. RESERVED FOR FUTURE USE.

APPENDIX L. STANDARDS OF IDENTITY FOR MILK AND MILK PRODUCTS AND *FEDERAL FOOD, DRUG, AND COSMETIC ACT*

The following definitions and standards of identity are contained in the *Code of Federal Regulations, Title 21* unless otherwise noted.

21 CFR 131.3 Cream.
21 CFR 131.110 Milk.
21 CFR 131.111 Acidified Milk.
21 CFR 131.112 Cultured Milk.
21 CFR 131.150 Heavy Cream.
21 CFR 131.155 Light Cream.
21 CFR 131.157 Light Whipping Cream.
21 CFR 131.160 Sour Cream.
21 CFR 131.162 Acidified Sour Cream.
21 CFR 131.170 Eggnog.
21 CFR 131.180 Half-and-Half.
21 CFR 131.200 Yogurt.
21 CFR 131.203 Lowfat Yogurt.
21 CFR 131.206 Nonfat Yogurt.
21 CFR 133.128 Cottage Cheese.
21 CFR 133.129 Dry Curd Cottage Cheese.

21 CFR 130.10
Requirements for Foods Named by Use of a Nutrient Content Claim and a Standardized Term.

Federal Food, Drug, and Cosmetic Act, as amended Sec. 402[342] Adulterated Food

Federal Food, Drug, and Cosmetic Act, as amended Sec. 403[343] Misbranded Food

1 CFR PART 110 - Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food

21 CFR PART 113 - Thermally Processed Foods Packaged In Hermetically Sealed Containers.

21 CFR 113.5
Current Good Manufacturing Practice.

21 CFR 113.10 Personnel.

21 CFR 113.40
Equipment and Procedures.

21 CFR 113.60 Containers.

21 CFR 113.83
Establishing Scheduled Processes.

21 CFR 113.89
Deviations in Processing, Venting, or Control of Critical Factors.

21 CFR 113.100
Processing and Production Records.

21 CFR 173.310
Boiler Water Additives.

21 CFR 101
Food Labeling

APPENDIX M. REPORTS AND RECORDS

The following field reports and office records have been developed for use with the current edition of the *Pasteurized Milk Ordinance.*

Department of Health and Human Services
Public Health Service
Food and Drug Administration

MILK PLANT INSPECTION REPORT

(Includes Receiving Stations, Transfer Stations, and Bulk Tank Cleaning Facilities)

Inspecting Agency

Name and Location of Plant:

POUNDS SOLD DAILY : Milk_____
Other Milk Products_____
Total_____
Permit No._____

Inspection of your plant today showed violations existing in the items checked below. You are further notified that this inspection sheet serves as notification of the intent to suspend your permit if the violations noted are not in compliance at the time of the next inspection. (See sections 3 and 5 of the *Grade "A" Pasteurized Milk Ordinance*.)

1. FLOORS:
Smooth; impervious; no pools; good repair; trapped drains..... (a)____
2. WALLS AND CEILINGS:
Smooth; washable; light-colored; good repair..... (a)____
3. DOORS AND WINDOWS: All outer openings effectively protected against entry of flies and rodents..... (a)____
Outer doors self-closing; screen doors open Outward..... (b)____
4. LIGHTING AND VENTILATION:
Adequate in all rooms..... (a)____
Well ventilated to preclude odors and condensation; filtered air with pressure systems..... (b)____
5. SEPARATE ROOMS:
Separate rooms as required; adequate size..... (a)____
No direct opening to barn or living quarters..... (b)____
Storage tanks properly vented..... (c)____
6. TOILET FACILITIES: Complies with local ordinances..... (a)____
No direct opening to processing rooms; self-closing doors..... (b)____
Clean; well-lighted and ventilated; proper facilities..... (c)____
Sewage and other liquid wastes disposed of in sanitary Manner..... (d)____
7. WATER SUPPLY:
Constructed and operated in accordance with Ordinance..... (a)____
No direct or indirect connection between safe and unsafe Water..... (b)____
Condensing water and vacuum water in compliance with Ordinance requirements..... (c)____
Complies with bacteriological Standards..... (d)____
8. HAND-WASHING FACILITIES:
Located and equipped as required; clean and in good repair; improper facilities not used..... (a)____
9. MILK PLANT CLEANLINESS: Neat; clean; no evidence of insects or rodents; trash properly handled..... (a)____
No unnecessary equipment..... (b)____
10. SANITARY PIPING: Smooth; impervious, corrosion-resistant, non-toxic, easily cleanable materials; good repair; accessible for inspection..... (a)____
Mechanically cleaned lines meet Ordinance specs..... (b)____
Pasteurized products conducted in sanitary piping, except as permitted by Ordinance..... (c)____
11. CONSTRUCTION AND REPAIR OF CONTAINERS AND EQUIPMENT:
Smooth, impervious, corrosion-resistant, non-toxic, easily cleanable materials; good repair; accessible for Inspection..... (a)____
Self-draining; strainers of approved design..... (b)____
Approved single-service articles; not reused..... (c)____
12. CLEANING AND SANITIZING OF CONTAINERS/ EQUIPMENT:
Containers, utensils, and equipment effectively cleaned..... (a)____
Mechanical cleaning requirements of Ordinance in Compliance; records complete..... (b)____
Approved sanitization process applied prior to use of product-contact surfaces..... (c)____
Required efficiency tests in compliance..... (d)____
Multi-use plastic containers in compliance..... (e) ____
Aseptic system sterilized..... (f) ____
13. STORAGE OF CLEANED CONTAINERS AND EQUIPMENT: Stored to assure drainage and protected from contamination..... (a)____
14. STORAGE OF SINGLE-SERVICE ARTICLES:
Received, stored and handled in a sanitary manner; paperboard containers not reused except as permitted by the Ordinance..... (a)____
15a. PROTECTION FROM CONTAMINATION: Operations conducted and located so as to preclude contamination of milk, milk products, ingredients, containers, equipment, and utensils..... (a) ____
Air and steam used to process products in compliance with Ordinance..... (b) ____
Approved pesticides, safely used..... (c) ____
15b. CROSS CONNECTIONS: No direct connections between pasteurized and raw milk or milk products..... (a) ____
Overflow, spilled and leaked products or ingredients discarded..... (b) ____
No direct connections between milk or milk products and cleaning and/or sanitizing solutions..... (c)____
16a. PASTEURIZATION-BATCH:
(1) INDICATING AND RECORDING THERMOMETERS:
Comply with Ordinance Specifications..... (a) ____
(2) TIME AND TEMPERATURE CONTROLS :
Adequate agitation throughout holding; agitator sufficiently submerged..... (a) ____
Each pasteurizer equipped with indicating and recording thermometer; bulb submerged..... (b) ____
Recording thermometer reads no higher than indicating thermometer..... (c) ____
Product held minimum pasteurization temperature continuously for 30 minutes, plus filling time if product preheated before entering vat, plus emptying time, if cooling is begun after opening outlet..... (d) ____
No product added after holding begun..... (e) ____
Airspace above product maintained at not less than 5.0 F higher than minimum required pasteurization temperature during holding..... (f) ____
Approved airspace thermometer; bulb not less than 1 inch above product level..... (g)____
Inlet and outlet valves and connections in compliance with Ordinance..... (h) ____
16b. PASTEURIZATION-HIGH TEMPERATURE:
(1) INDICATING AND RECORDING THERMOMETERS:
Comply with Ordinance specifications..... (a) ____
(2) TIME AND TEMPERATURE CONTROLS:
Flow-diversion device complies with Ordinance requirements..... (a) ____
Recorder controller complies with Ordinance requirements..... (b)____
Holding tube complies with Ordinance requirements..... (c) ____
Flow promoting devices comply with Ordinance requirements..... (d) ____
(3) ADULTERATION CONTROLS: Satisfactory means to prevent adulteration with added water..... (a) ____
16c. ASEPTIC PROCESSING:
(1) INDICATING AND RECORDING THERMOMETERS:
Comply with Ordinance Specifications..... (a) ____
(2) TIME AND TEMPERATURE CONTROLS:
Flow-diversion device complies with Ordinance requirements..... (a) ____
Recorder controller complies with Ordinance Requirements..... (b) ____
Holding tube complies with Ordinance requirements..... (c) ____
Flow promoting devices comply with Ordinance requirements..... (d) ____
(3) ADULTERATION CONTROLS:
Satisfactory means to prevent adulteration with added water..... (a) ____
16d. REGENERATIVE HEATING: Pasteurized or aseptic product in regenerator automatically under greater pressure than raw product in regenerator at all times..... (a) ____
Accurate pressure gauges installed as required; booster pump properly identified and installed..... (b) ____
Regenerator pressures meet Ordinance Requirements..... (c) ____
16e. RECORDING CHARTS:
Batch pasteurizer charts comply with applicable Ordinance Requirements..... (a) ____
HTST & HTST pasteurizer charts comply with applicable Ordinance Requirements..... (b) ____
Aseptic charts comply with applicable Ordinance Requirements..... (c) ____
17. COOLING OF MILK: Raw milk maintained at 45 F or less until processed..... (a)____
Pasteurized milk and milk products, except those to be cultured, cooled immediately to 45 F or less in approved equipment; all milk and milk products stored thereat until delivered..... (b) ____
Approved thermometer properly located in all refrigeration rooms and storage tanks..... (c) ____
Recirculated cooling water from safe source and properly protected; complies with bacteriological standards..... (d) ____
18. BOTTLING AND PACKAGING: Performed in a plant where contents finally pasteurized..... (a) ____
Performed in a sanitary manner by approved mechanical equipment..... (b) ___
Aseptic filling in compliance..... (c) ____
19. CAPPING: Capping and/or closing performed in sanitary manner by approved mechanical Equipment..... (a) ____
Imperfectly capped/closed products properly handled..... (b) ____
Caps and/or closures comply with Ordinance..... (c) ____
20. PERSONNEL CLEANLINESS: Hands washed clean before performing plant functions; rewashed when contaminated..... (a) ____
Clean outer garments and hair covering worn..... (b) ____
No use of tobacco in processing areas..... (c) ____
21. VEHICLES: Vehicles clean; constructed to protect milk..... (a) ____
No contaminating substances transported..... (b) ____
22. SURROUNDINGS: Neat and clean; free of pooled water, harborages, and breeding areas..... (a) ____
Tank unloading areas properly constructed..... (b) ____
Approved pesticides, used properly..... (c) ____

Remarks:

Date: Sanitarian:

1. A receiving station shall comply with Items 1 to 15, inclusive, and 17, 20, and 22. Separation requirements of item 5 do not apply.
2. A transfer station shall comply with Items 1, 4, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 20, 22 and as climatic and operating conditions require, applicable provisions of Items 2 and 3. In every case, overhead protection shall be required.
3. Facilities for the cleaning and sanitizing of bulk transport tanks shall comply with the same requirements for transfer stations.

NOTE – Item numbers correspond to required sanitation items for Grade "A" pasteurized milk in the *Grade "A" Pasteurized Milk Ordinance*.

FORM FDA 2359

Department of Health and Human Services
Public Health Service
Food and Drug Administration

DAIRY FARM INSPECTION REPORT

Inspecting Agency

NAME AND LOCATION OF DAIRY FARM

POUNDS SOLD DAILY:

PLANT:

PERMIT #:

Inspection of your farm today showed violations existing in the items checked below. You are further notified that this inspection sheet serves as notification of the intent to suspend your permit if the violations noted are not in compliance at the time of the next inspection. (See Sections 3 and 5 of the *Grade "A" Pasteurized Milk Ordinance*.

COWS

1. **Abnormal Milk** :
Cows secreting abnormal milk milked last or in separate equipment.....(a) _____
Abnormal milk properly handled and disposed of .....(b) _____
Proper care of abnormal milk handling Equipment .....(c) _____

MILKING BARN, STABLE, OR PARLOR

2. **Construction** :
Floors, gutters, and feed troughs of concrete or equally impervious materials; in good repair .....(a) _____
Walls and ceilings smooth, painted or finished adequately; in good repair; ceiling dust-tight .....(b) _____
Separate stalls or pens for horses, calves, and bulls no overcrowding .....(c) _____
Adequate natural and/or artificial light; well distributed.....(d) _____
Properly ventilated; .....(e) _____

3. **Cleanliness** :
Clean and free of litter .....(a) _____
No swine or fowl.....(b) _____

4. **Cowyard** :
Graded to drain; no pooled water or wastes .....(a) _____
Cowyard clean; cattle housing areas & manure packs properly maintained.....(b) _____
No swine.....(c) _____
Manure stored inaccessible to cows.....(d) _____

MILKHOUSE OR ROOM

5. **Construction and Facilities** :

Floors

Smooth; concrete or other impervious material; in good repair.....(a) _____
Graded to drain.....(b) _____
Drains trapped, if connected to sanitary system .....(c) _____

Walls and Ceilings

Approved material and finish .....(a) _____
Good repair (windows, doors, and hoseport included) .....(b) _____

Lighting and Ventilation

Adequate natural and/or artificial light; properly distributed.....(a) _____
Adequate ventilation.....(b) _____
Doors and windows closed during dusty weather.....(c) _____
Vents and lighting fixtures properly installed ...(d) _____

Miscellaneous Requirements

Used for milkhouse operations only; sufficient size.....(a) _____
No direct opening into living quarters or barn, except as permitted by Ordinance.....(b) _____
Liquid wastes properly disposed of.....(c) _____
Proper hoseport where required .....(d) _____
Acceptable surface under hoseport .....(e) _____
Suitable shelter for transport truck as required by this Ordinance .....(f) ____

Cleaning Facilities

Two-compartment wash and rinse vat of adequate size.....(a) _____
Suitable water heating facilities .....(b) _____
Water under pressure piped to milkhouse.....(c) _____

6. **Cleanliness :**
Floors, walls, windows, tables, and similar non-product-contact surfaces clean.....(a) _____
No trash, unnecessary articles, animals or fowl .....(b) _____

TOILET AND WATER SUPPLY

7. **Toilet :**
Provided; conveniently located.....(a) _____
Constructed and operated according to *Ordinance*.....(b) _____
No evidence of human wastes about premises..(c) _____
Toilet room in compliance with *Ordinance*..... (d) _____

8. **Water Supply :**
Constructed and operated according to *Ordinance*.....(a) _____
Complies with bacteriological standards..... (b) _____
No connection between safe and unsafe supplies; no improper submerged inlets;.....(c) _____

UTENSILS AND EQUIPMENT

9. **Construction :**
Smooth, impervious, nonabsorbent, safe materials; easily cleanable; .....(a) _____
In good repair; accessible for inspection..... (b) _____
Approved single-service articles; not reused.....(c) _____
Utensils and equipment of proper design ..... (d) _____
Approved mechanically cleaned milk pipeline system.....(e) _____

10. **Cleaning :**
Utensils and equipment clean.....(a) _____

11. **Sanitization :**
All multi-use containers and equipment subjected to approved sanitization process (See *Ordinance*)(a) _____

12. **Storage :**
All multi-use containers and equipment properly stored.....(a) _____
Stored to assure complete drainage, where applicable.....(b) _____
Single-service articles properly stored.....(c) _____

MILKING

13. **Flanks, Udders, and Teats :**
Milking done in barn, stable, or parlor.....(a) _____
Brushing completed before milking begun.....(b) _____
Flanks, bellies, udders, and tails of cows clean at time of milking; clipped when required.....(c) _____
Teats cleaned, treated with sanitizing solution and dry, prior to milking.....(d) _____
No wet hand milking.....(e) _____

TRANSFER AND PROTECTION OF MILK

14. **Protection From Contamination :**
No overcrowding.....(a) _____
Product and CIP circuits separated.....(b) _____
Improperly handled milk discarded.....(c) _____
Immediate removal of milk.....(d) _____
Milk and equipment properly protected.....(e) _____
Sanitized milk surfaces not exposed to Contamination .....(f) _____
Air under pressure of proper quality.....(g) _____

15. Drug and Chemical Control
Cleaners and sanitizers properly identified.....(a) _____
Drug administration equipment properly handled and stored.....(b) _____
Drugs properly labeled (name and address) and Stored.....(c) _____
Drugs properly labeled (directions for use, Cautionary statements, active ingredient).....(d) _____
Drugs properly used and stored to preclude Contamination of milk .....(e) _____

PERSONNEL

16. **Hand-Washing Facilities :**
Proper hand-washing facilities convenient to milking operations.....(a) _____
Wash and rinse vats not used as hand-washing facilities .....(b) _____

17. **Personnel Cleanliness :**
Hands washed clean and dried before milking, or performing milk house functions; rewashed when contaminated.....(a) _____
Clean outer garments worn.....(b) _____

COOLING

18. **Cooling :**
Milk cooled to 45 F or less within 2 hours after milking, except as permitted by *Ordinance*.....(a) _____
Recirculated cooling water from safe source and properly protected; complies with bacteriological standards .....(b) _____

PEST CONTROL

19. **Insect and Rodent Control :**
Fly breeding minimized by approved manure disposal methods (See *Ordinance*).....(a) _____
Manure packs properly maintained.....(b) _____
All milkhouse openings effectively screened or otherwise protected; doors tight and self-closing; screen doors open outward.....(c) _____
Milkhouse free of insects and rodents .....(d) _____
Approved pesticides; used properly.....(e) _____
Equipment and utensils not exposed to Pesticide contamination.....(f) _____
Surroundings neat and clean; free of harborages and breeding areas.....(g) _____
Feed storage not attraction for birds, Rodents or insects.....(h) _____

Remarks:

Date:

Sanitarian:

Note: Item numbers correspond to required sanitation items for Grade "A" raw milk for pasteurization in the *Grade "A" Pasteurized Milk Ordinance*.

FORM FDA 2359a

Department of Health and Human Services
Public Health Service / Food and Drug Administration

MILK PLANT EQUIPMENT TEST REPORT

TEST NO.		TEST	TEST FREQUENCY	TESTED (X or NA)	RESULTS OF TEST (SEE REVERSE FOR WORKING NOTES)
1.		Indicating thermometers (including air space): Temperature accuracy	3 months		
2.		Recording thermometers: Temperature accuracy	3 months		
3.		Recording thermometers: Time accuracy	3 months		
4.		Recording thermometers: Checked against indicating thermometer	3 months		Daily by operator
5.		Flow-diversion device: Proper assembly and function (HTST and HHST)			
	5.1	Leakage past valve seat(s)	3 months		
	5.2	Operation of valve stem(s)	3 months		
	5.3	Device assembly (micro-switch) single stem	3 months		
	5.4	Device assembly (micro-switches) dual stem	3 months		
	5.5	Manual diversion - Parts (A,B, and C) (HTST only)	3 months		
	5.6	Response Time	3 months		
	5.7	Time delay interlock (dual stem devices) (Inspect)	3 months		
	5.8	Time delay interlock (dual stem devices) (CIP)	3 months		
	5.9	Leak Detect flush time delay (HTST only as applicable)	3 months		
6.		Leak-protect valves: Leakage (Vats only)	3 months		
7.		Indicating thermometers in pipelines: Thermometric response (HTST only)	3 months		
8.		Recorder-Controller: Thermometric response (HTST only)	3 months		
9.		Regenerator Pressure Controls			
	9.1	Pressure Switches (HTST only)	3 months		
	9.2	Differential pressure controllers			
	9.2.1	Calibration	3 months		
	9.2.2	Interwiring Booster Pump (HTST only)	3 months		
	9.2.3	Interwiring FDD (HHST and Aseptic)	3 months		
	9.3	Additional Booster Pump interwiring (HTST only)			
	9.3.1	With FDD	3 months		
	9.3.2	With Metering Pump	3 months		
10.		Milk-flow controls: Cut-in and cut-out temperatures (10.1, 10.2, or 10.3)	3 months		Daily by operator (HTST)
11.		Timing System Controls			
	11.1	Holding time (HTST except magnetic flow meters)	6 months		Adjusted holding time if applicable
	11.2.a	Magnetic Flow Meters (HTST only)	6 months		
	11.2.b	Flow alarm (HTST, HHST, and Aseptic)	6 months		
	11.2.c	Loss of signal alarm (HTST, HHST, and Aseptic)	6 months		
	11.2.d	Flow cut-in/cut-out (HTST only)	6 months		
	11.2.e	Time delay (After divert) (HTST only)	6 months		
	11.3	HHST Indirect heating	6 months		
	11.4	HHST Direct Injection Heating	6 months		
	11.5	HHST Direct Infusion heating	6 months		
12.		Controller: Sequence logic (HHST and Aseptic) (12.1 or 12.2)	3 months		
13.		Product pressure-control switch setting (HHST and Aseptic)	3 months		
14.		Injector differential pressure (HHST and Aseptic) (Injection heating)	3 months		

Remarks

PLANT	IDENTITY OF EQUIPMENT	LOCATION	DATE	SANITARIAN

NOTE: This form is a supplement to the Milk Plant Inspection Report FDA 2359, and these tests are in addition to the equipment requirements for which compliance is determined by inspection. See Appendix I, *Grade "A" Pasteurized Milk Ordinance*.

FORM FDA 2359b

APPENDIX N. DRUG RESIDUE TESTING AND FARM SURVEILLANCE

I. INDUSTRY RESPONSIBILITIES

A. Monitoring and Surveillance.

Industry shall screen all bulk milk pickup tankers for beta lactam drug residues. Additionally, other drug residues shall be screened for by employing a random sampling program on bulk milk pickup tankers. The random bulk milk pickup tanker sampling program shall represent and include, during any consecutive six months, at least four (4) samples collected in at least four (4) separate months, except when three months show a month containing two sampling dates separated by at least 20 days. Samples collected under this random sampling program shall be analyzed as specified by FDA. (See M-a-75).

Bulk milk pickup tanker testing shall be completed prior to processing the milk. Industry samplers shall be evaluated according to the requirements specified in Section 6: The Examination of Milk and Milk Products. Bulk milk pickup tanker samples found to be positive for drug residues shall be retained as determined necessary by the regulatory agency. Industry shall also record all sample results and retain such records for a period of six months.

B. Reporting and Farm Traceback.

When a bulk milk pickup tanker is found to be positive for drug residues, the regulatory agency shall be immediately notified of the results and the ultimate disposition of the raw milk.

The producer samples from the bulk milk pickup tanker, found to be positive for drug residues, shall be individually tested to determine the farm of origin. The samples shall be tested as directed by the regulatory agency.

Further pickups of the violative individual producer shall be immediately discontinued, until such time, that subsequent tests are no longer positive for drug residues.

II. REGULATORY AGENCY RESPONSIBILITIES

A. Monitoring and Surveillance.

State regulatory agencies shall monitor industry surveillance activities by making unannounced, on-site inspections to collect samples from bulk milk pickup tankers and to review industry records of the random sampling program. A review shall include, but not be limited to, the following:

1. Is the program an appropriate routine monitoring program for the detection of drug residues? Is the program utilizing appropriate test methods?
2. Is each producer's milk represented in a testing program for drug residues and tested at the frequency prescribed in I. A. above for drug residues?
3. Is the program assuring timely notification to the appropriate regulatory agency of positive results, the ultimate disposition of the bulk milk pickup tanker milk and of the trace back to the farm of origin? Is farm pickup suspended until subsequent testing establishes the milk is no longer positive for drug residues?

The regulatory agency shall also perform routine sampling and testing for drug residues determined to be necessary as outlined in Section 6 and M-a-75.

B. Enforcement.

If testing reveals milk positive for drug residues, the milk shall be disposed of in a manner that removes it from the human or animal food chain, except where acceptably reconditioned under FDA compliance policy guidelines. The regulatory agency shall determine the producer responsible for the violation.

Suspension. – Any time milk is found to test positive for a drug residue, the regulatory agency shall immediately suspend the producer's Grade "A" permit or equally effective measures shall be taken to prevent the sale of milk containing drug residues.

Penalties.—Future pick-ups are prohibited until subsequent testing reveals the milk is free of drug residue. The penalty shall be for the value of all milk on the contaminated load plus any costs associated with the disposition of the contaminated load. The State Regulatory Authority may accept certification from the violative producer's milk marketing cooperative or purchaser of milk as satisfying the penalty requirements.

Reinstatement.—The Grade "A' producer permit may be reinstated, or other action taken, to allow sale of milk for human food, when a representative sample taken from the producer's milk, prior to commingling with any other milk, is no longer positive for drug residue.

Follow-Up.—Whenever a drug residue test is positive an investigation shall be made to determine the cause:

Farm inspection is completed by the regulatory agency or its agent to determine the cause of the residue and actions taken to prevent future violations including:

(a) On farm changes in procedures necessary to prevent future occurrences as recommended by the state regulatory agency.
(b) Discussion and education on the Drug Residue Avoidance Control measures outlined in Appendix C.

Permit Revocation: After a third violation in a 12 month period the regulatory agency shall initiate administrative procedures pursuant to revocation of the producer's Grade "A" permit under the authority of "Section 3, Permits", due to repeated violations.

Reinstatement: The producer permit may be reinstated, or other such similar action taken, to allow sale of milk for human food, when a representative sample taken from the producer's milk, prior to commingling with any other milk, is no longer positive for drug residue.

III. ESTABLISHED TOLERANCES AND/OR SAFE LEVELS OF DRUG RESIDUES

"Safe levels" are used by FDA as guides for prosecutorial discretion. They do not legalize residues found in milk that are below the safe level. In short, FDA uses the "safe levels" as prosecutional guidelines and in full consistency with CNI v. Young stating, in direct and unequivocal language, that the "safe levels" are not binding -- that they do not dictate any result, that they do not limit the agency's discretion in any way, and

that they do not protect milk producers (or milk) from court enforcement action.

"Safe levels" are not and cannot be transformed into tolerances that are established for animal drugs under section 512 (b) of the *Federal Food, Drug, and Cosmetic Act* as amended . "Safe levels" do not (1) bind the courts, the public (including milk producers), or the agency (including individual FDA employees), and (2) do not have the "force of law" of tolerances (or of binding rules).

Notification, changes or additions of "safe levels" will be transmitted via Memoranda of Information (M-I's).

IV. Approved Methods

AOAC First Action and AOAC Final Action methods are accepted in accordance with Section 6. Drug residue detection methods shall be evaluated at the safe level or tolerance. Regulatory action based on each test kit method may be delayed until the evaluation is completed and the method is found to be acceptable to FDA and complies with the provisions of Section 6.

One year after test(s) have been evaluated by FDA and accepted by the NCIMS for a particular drug or drug family, other unevaluated tests are not acceptable for screening milk. The acceptance of evaluated tests does not mandate any additional screening by industry with the evaluated method.

APPENDIX O. VITAMIN FORTIFICATION OF FLUID MILK PRODUCTS

PROCESS/METHODS OF VITAMIN ADDITION

Vitamin fortification can be accomplished by the addition of vitamins at many different points in the processing system, preferably after separation, including the pasteurizing vat (for vat pasteurization), to the HTST balance tank, or on a continuous basis into the pipeline after standardization and prior to pasteurization in accordance with the manufacturer's recommendations. Both batch addition and addition with metering pumps can be used. The batch procedure requires accurate measurement of the volume of milk to be fortified, accurate measurement of the vitamin concentrate, and proper mixing. When a vitamin metering pump(s) is used with an HTST unit or an HHST unit the pump(s) must be installed so as to be activated only when the unit is sending product forward. The addition of vitamins must be accomplished prior to pasteurization in accordance with the manufacturer's recommendations.

The problem of under fortification is often related to the point in the system where fortification takes place. Vitamins A and D are fat soluble and will gradually become more concentrated in the milk fat portion of the milk. Both oil and water base vitamins are susceptible to this migration problem.

If vitamins are added in the proper amount before separation and standardization, and the product is separated and standardized, then the low fat product will tend to be under fortified and the high fat product over fortified. Water soluble vitamin concentrates can minimize this problem if vitamins are added before separation. Processors who use this procedure should perform confirmatory assays to ensure proper fortification levels of each product.

Many HTST systems are now being used with in-line fat standardization which also makes possible switching without stopping from products being fortified with Vitamin D to those being fortified with both A and D. These systems require metered injection of the proper vitamins at a point after standardization and before pasteurization. Sanitary positive displacement pumps are available for this purpose.

There are two types available, one is a piston type positive displacement metering pump without valves. It is equipped with a micrometer, which allows accurate and reproducible amounts of vitamins to be added based on the rate of product flow through the system.

The other type metering pump also is a positive displacement or peristaltic pump which offers precise control. This is because volume can be controlled by the size of tubing used and pump speed. This is easy to clean because only the tube is in contact with the vitamin concentrates. These pumps also have a history of reproducibility and reliability. All metering pumps should be designed specifically to conform with this Ordinance as recommended by equipment employed in sanitary applications.

The recommended point for metered injection of vitamin concentrate is after separation and prior to homogenization. This allows the homogenization process to distribute the vitamins throughout the milk. A positive displacement metering pump and a check valve for in-line injection are recommended. The check valve will prevent contamination of the vitamin concentrate with milk.

When vitamin A, A & D or D concentrates are injected by metering pumps,

separate positive pressure pumps with separate delivery tubing and check valves are recommended. (See Figure 46 for an example of such an arrangement.) Pumps should be calibrated based on the product flow rate of the continuous pasteurization system. If flow rates change for different milk products, additional vitamin pumps may be needed. Adjusting calibration of vitamin metering pumps is not recommended without verifying the adjusted calibration is accurate. Calibration checks of vitamin metering pumps should be done on a routine basis.

Essential to proper results are the following:

(1) Management must be committed to proper fortification and concerned with both over and under levels.

(2) Design the system correctly for proper addition in which concentrate is added after standardization and before pasteurization.

(3) Written procedures and training should be provided to all employees responsible for vitamin fortification for each product to be fortified. These procedures should focus on product start up and product change over.

(4) Keep accurate records of vitamins used and products produced, checked daily against theoretical use. Care should be taken that adequate fortification of small run products like skim milk is not masked by much larger volumes of 2% or other partly skimmed milk products.

METERING PUMPS

(5) Use an accurate, sanitary, positive displacement metering pump with a scheduled cleaning procedure after use. For batch addition, use only accurate, calibrated measuring devices, such as plastic graduated cylinders, or pipettes. Measuring devices should be sized to the amount of concentrate added, i.e. if 8 ml. is added, a 10 ml. graduated cylinder would be appropriate. Measuring devices should be rinsed with the product being fortified to insure no residual concentrate is left.

(6) Use a check valve on the injection line to prevent milk from being pushed back into the line. This depends on pump displacement.

(7) Check meter calibration regularly including both the pump and the tubing by determining delivery rate accuracy. Use only properly calibrated tubing for peristaltic pump systems and replace tubing regularly.

(8) Storage vessels used for supplying vitamin concentrate to metering pumps should be emptied on a regular basis. A regular systematic cleaning and sanitizing schedule must be maintained for these vessels, pumps and tubing.

(9) Vitamin concentrates should be stored and held in accordance with the manufacturer's recommendations for maximum shelf life.

(10) Vitamin metering pumps should be interwired with the flow divert and recycle valves to prevent operation during divert and/or recycle flows.

(11) Check finished products regularly. Results should be reported in International Units (I.U.)/Quart. Because of the sensitivity and difficulty in performing these tests, it is necessary to procure the services of a competent laboratory, one that is familiar with the handling and testing of vitamin fortified dairy products.

(12) Care must be taken when reprocessing reclaimed product so vitamin A and/or D levels do not exceed the label claims by more than 150%.

GOOD MANUFACTURING PRACTICES

Good manufacturing practices require that the vitamin A & D levels not be less than 2000 International Units per quart of vitamin A and 400 International Units of vitamin D. Fluid dairy products are allowed not less than 100% and not more than 150% of required values or label claims to be in compliance with good manufacturing practices.

TESTING METHODS

Test methods used for the detection of vitamins A and/or D[3] shall be those acceptable the Food and Drug Administration or other official methodologies which give statistically equivalent results to the FDA methods. Vitamin analysis shall be conducted in a laboratory accredited by the Food and Drug Administration and acceptable to the regulatory agency.

TYPE OF CONCENTRATES AVAILABLE

A number of different types of concentrates are available. All contain vitamin D and/or vitamin A palmitate with a carrier consisting of any of the following: butter oil, corn oil, evaporated milk, non-fat dry milk, polysorbate 80, propylene glycol and glycerol monooleate. It is best to store all concentrates under refrigeration unless manufacturer directions indicate otherwise. To achieve adequate dispersion viscous concentrates should be brought to room temperature before addition.

NEED FOR ADDITION

Vitamin A is fat soluble, that is it will dissolve when mixed with fat and will not dissolve in water. For this reason Vitamin A is found in whole milk and to a lesser degree in low fat and absent in non-fat milk, unless these products are fortified.

Vitamin D is the major regulator of calcium absorption in the intestine. Fortification of fresh milk with Vitamin D, is acknowledged to have virtually eliminated rickets in milk drinking children. Since normal levels of Vitamin D are necessary for optimal calcium absorption in children, it is also known that these levels are required as one increases in age. It has been associated with reducing the incidence of osteoporosis in premenopausal women.

Vitamin A performs many functions. One is to enable the retina of the eye to respond to dim light. Deficiency of Vitamin A produces night blindness. Vitamin A is also involved in the ability of the eye to discern color.

Vitamin A and D can be a potential threat to public health if consumed at excessive levels. Over fortification with levels of Vitamin A over 6,000, and Vitamin D over 800 should be considered harmful; therefore it is necessary to accurately control the proper level of fortification.

PROBLEMS INVOLVED WITH FORTIFICATION

Milk and milk products which contain a large proportion of fat are relatively good dietary sources of Vitamin A, but as is the case with other natural foods, the Vitamin D content of unfortified milk is quite low. As with other milk components, Vitamin A & D levels are affected by breed, season, diet,

lactation and in the case of Vitamin D animal exposure to sunlight.

In general when lactating animals are transferred from pasture to winter rations in the fall, a decline in the Vitamin A & D levels can be expected in the raw milk. This occurs slowly through the winter season until the animals are once more on pasture in the spring. With proper selection of feed and diet concentrates this effect can be kept to a minimum. Natural levels of Vitamin A range from 400 I.U. in winter to 1200 I.U. in summer, and Vitamin D, 5 I.U. in winter to 40 I.U. in summer. These are approximate ranges to indicate possible seasonal variations. Because of seasonal and other variations in natural vitamin levels it is necessary to monitor the level of fortification to assure that levels are within good manufacturing practices.

Vitamin concentrate potency degrades with time. Concentrates should be stored in accordance with manufacturer's recommendation to maintain label potency. Vitamin concentrate potency should be verified by the vitamin supplier.

Vitamin D is very stable in homogenized whole milk and is not affected by pasteurization or other processing procedures. Vitamin D in fortified homogenized whole milk will remain constant with little or no loss of vitamin potency during long periods of proper storage. No loss of vitamin D will be experienced under normal shelf life periods.

Vitamin A and D fortified skim milk products are subject to decreases in vitamin A, because the vitamin is no longer protected by fat as it is in whole milk. In fluid skim or low fat milk, added vitamin A deteriorates gradually during normal storage of the milk at 4.4°C (40°F.) in the dark but is destroyed rapidly when the milk is exposed to sunlight in transparent glass bottles or translucent plastic containers. The photo destruction of added vitamin A is dependent on the intensity and wave length of light and milk source. The use of amber or brown glass bottles, pigmented plastic containers formulated with specific light barriers and colored paper cartons retard this destruction. Vitamin A losses in 2% milk from five dairy plants ranged from 8% to 31% when they were exposed to 200 foot candles of fluorescent light for 24 hours in opaque plastic containers. Use of pigmented containers or gold shields over fluorescent tubes practically eliminated these losses.

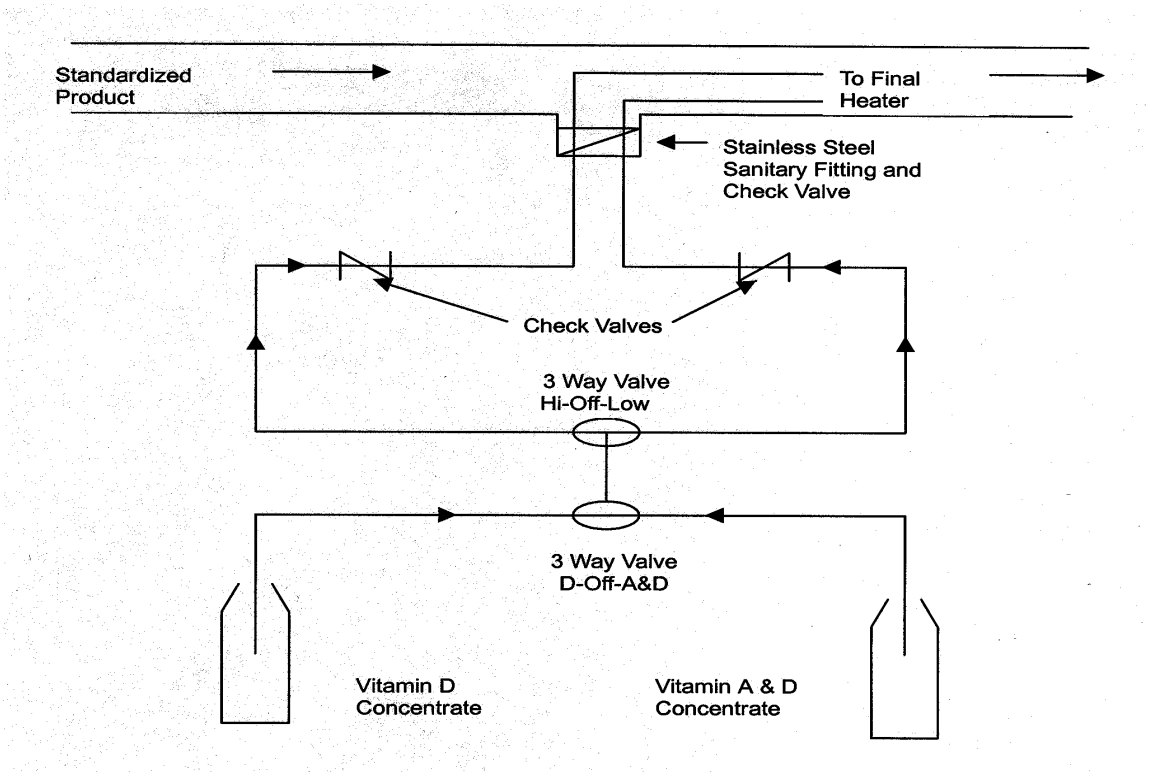


Figure 46. Vitamin Fortification

Problems associated with natural levels, loss of vitamin A during storage and the problems with the mechanical addition discussed in the following section of this guideline indicate the difficulty in providing a product that will have proper potency levels.

NOTE: Figure 46 details a two speed vitamin fortification installation using two pumps and two vitamin concentrate sources. This enables changing from different vitamin concentrates and different speed pumps via the adjustment of three-way valves.

Recommendations:

1. Use sanitary check valve(s) to separate milklines from vitamin concentrates.
2. Keep all milk contact surfaces of sanitary design that are easily cleanable and available for inspection.

APPENDIX P. PERFORMANCE-BASED DAIRY FARM INSPECTION SYSTEM

I. Preface

A performance-based inspection system is an option to traditional routine inspection frequency (at least once every 6 months) on Grade "A" dairy farms. This option provides states with a choice. For some states, inspecting every farm routinely twice a year may provide effective regulatory oversight and make efficient use of inspection resources. In other states, however, an optional system which determines routine farm inspection frequency based on producer milk quality and inspection performance may be more desirable, equally effective, and make the most efficient use of limited inspection resources. The overall inspection effort devoted to a performance-based farm inspection system may be more or less than the traditional inspection system which requires a routine inspection at least once every 6 months per farm.

II. Inspection Interval and Criteria

Dairy farms will be categorized at least every 3 months using the immediately previous 12 months farm inspection and milk quality data. The following criteria will be used to categorize farms into 4 inspection intervals as defined below.

<u>Minimum 1 year inspection interval (1 inspection each 12 months)</u>
(All criteria below must have been met for the previous 12 months).

1. All SPC ≤ 25,000
2. All SCC ≤ 500,000
3. No temperature violations
4. No drug residue violations
5. No "critical control point" violations observed during farm inspections

Dairy Farm inspection report items numbered:

- 10, 11-Cleaning and sanitizing of milk contact surfaces
- 15(c), (d) and (e)-Significant drug violations
- 18-Significant cooling violations

6. No violation which creates a substantial risk of adulteration or imminent health hazard
7. No more than 5 violations documented on any inspection sheet
8. No consecutive inspection violations on any inspection item.
9. No record of suspended permit, certification or license due to inspection, milk quality or drug residue deficiencies.
10. Bacteriologically safe water supply at time of categorization

NOTE: Farms in this category who are recategorized to a 6 month inspection interval for a single violation of one milk quality parameter (SPC > 25,000, SCC > 500,000 or temperature violation) may be recategorized to the 1 year inspection interval if all 10 criteria listed above are met for the next 6 months.

<u>Minimum 6 month inspection interval (1 inspection each 6 months)</u>
(All criteria below must have been met for the previous 12 months).

1. May have 1 or more SPC > 25,000
2. May have 1 or more SCC > 500,000
3. No more than 1 warning letter issued due to non-compliance of 2 out of 4 previous official sample results for SPC and SCC
4. No temperature violations
5. No drug residue violations
6. No "critical control point" violations observed during farm inspections

Dairy Farm inspection report items numbered:

- 10, 11-Cleaning and sanitizing of milk contact surfaces
- 15(c), (d) and (e)-Significant drug violations
- 18-Significant cooling violations

7. No violation which creates a substantial risk of adulteration or imminent health hazard
8. No more than 5 violations documented on any inspection sheet
9. No consecutive inspection violations on any inspection item.
10. No record of suspended permit, certification or license due to inspection, milk quality or drug residue deficiencies.
11. Bacteriologically safe water supply at time of categorization

NOTE: Farms meeting the criteria for 1 year or 6 month inspection intervals but with less than 12 months of farm inspection and milk quality history (i.e. new farms) will be assigned to 6 month inspection intervals.

<u>Minimum 4 month inspection interval (1 inspection each 4 months)</u>
(Any criteria below results in farm being placed into this inspection interval for 12 months from the next recategorization).

1. More than 1 warning letter issued due to non-compliance of 2 out of 4 previous official sample results for SPC and SCC
2. Farm conditions which caused the regulatory agency to take official regulatory action (i.e., warning letter, intent to suspend, reinspection etc.)
3. 1 drug residue violation
4. "Critical control point" violations observed during farm inspections

Dairy Farm inspection report items numbered:

- 10, 11-Cleaning and sanitizing of milk contact surfaces
- 15(c), (d) and (e)-Significant drug violations
- 18-Significant cooling violations

5. Violation which creates a substantial risk of adulteration or imminent health hazard
6. More than 5 violations on any inspection
7. Unsafe water supply at the time of categorization

<u>Minimum 3 month inspection interval (1 inspection each 3 months)</u>
(Any criteria below results in farm being placed into this inspection interval for 12 months from the next recategorization).

1. More than 1 drug residue violation
2. Any farm suspended from the market by the regulatory agency during the evaluation period (previous 12 months) for any reason other than drug residue violations.
3. More than 1 incident where violative farm conditions or milk quality parameters caused the regulatory agency to take official regulatory action (i.e., warning letter, intent to suspend, reinspection, etc.)

NOTE: The above guidelines for Grade "A" farm inspection intervals are not intended to prevent farm inspections at more frequent intervals if in the judgement of the inspection staff more frequent intervals are necessary.

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