APPENDIX H. PASTEURIZATION EQUIPMENT AND PROCEDURES

I. HTST PASTEURIZATION

OPERATION OF HTST SYSTEMS

HTST pasteurization has become important to the dairy industry because of the operating efficiencies which it affords. Properly operated, these units allow a high volume of production in a minimum of processing space.

The ability of HTST pasteurizers to assure a safe, finished product hinges on the reliability of the time-temperature-pressure relationships which must prevail whenever the system is in operation. It is important that the plant operator understand the HTST process in order to maintain proper surveillance over the equipment. The basic flow pattern is described below:

1. Cold raw milk, in a constant level supply tank, is drawn into the regenerator section of the HTST pasteurizer.

NOTE: Some operators prefer to bypass the regenerator when starting. Under this system, cold milk is drawn directly through the timing pump (step 3) and into the heater section. The remaining steps are performed without exception. This bypass arrangement facilitates and speeds up the starting operation. After forward flow is established at the flow-diversion device, the bypass, which may be manually or automatically controlled, is not used and the raw milk flows through the regenerator. A second start-up technique involves the use of sanitizing solution at 77 C (170 F). This is passed through the complete unit and followed immediately by milk. Dilution of the first milk does occur; however, care must be taken to prevent this from being packaged.

2. In the regenerator section, the cold raw milk is warmed by hot pasteurized milk flowing in a counter current direction on the opposite sides of thin stainless steel surfaces.

3. The raw milk, still under suction, passes through a positive displacement timing pump which delivers it under pressure through the rest of the HTST pasteurization system.

4. The raw milk is pumped through the heater section, where hot water or steam on opposite sides of thin stainless steel surfaces heats the milk to a temperature of at least 72^{o}C (161^{o}F).

5. The milk, at pasteurization temperature, and under pressure, flows through the holding tube where it is held for at least 15 seconds. (The maximum velocity of the milk through the holding tube is governed by the speed of the timing pump, the diameter and length of the holding tube and surface friction.)

6. After passing the sensing bulbs of an indicating thermometer and a recorder/controller, the milk passes into the flow-diversion device which automatically assumes a forward-flow position, if the milk passes the recorder/controller bulb at the preset cut-in temperature (i.e., 72^{o}C (161^{o}F).

7. Improperly heated milk flows through the diverted-flow line back to the raw milk constant level supply tank.

8. Properly heated milk flows through the forward-flow line to the pasteurized milk regenerator section where it serves to warm the cold raw milk and, in turn, is cooled.

9. The warm milk passes through the cooling section, where coolant, on the sides of thin stainless steel surfaces

opposite the pasteurized milk, reduces its temperature to 4°C (40°F) and below.

10. The cold pasteurized milk then passes to a storage tank or vat to await packaging.

HTST PASTEURIZERS EMPLOYING MILK-TO-MILK REGENERATORS WITH BOTH SIDES CLOSED TO THE ATMOSPHERE

Item 16, 2p(D) of Section 7 establishes standards for regenerators. These standards insure that the raw milk will always be under less pressure than pasteurized milk in order to prevent contamination of the pasteurized milk in the event flaws should develop in the metal or joints separating it from the raw milk. An explanation of regenerator specifications is given below.

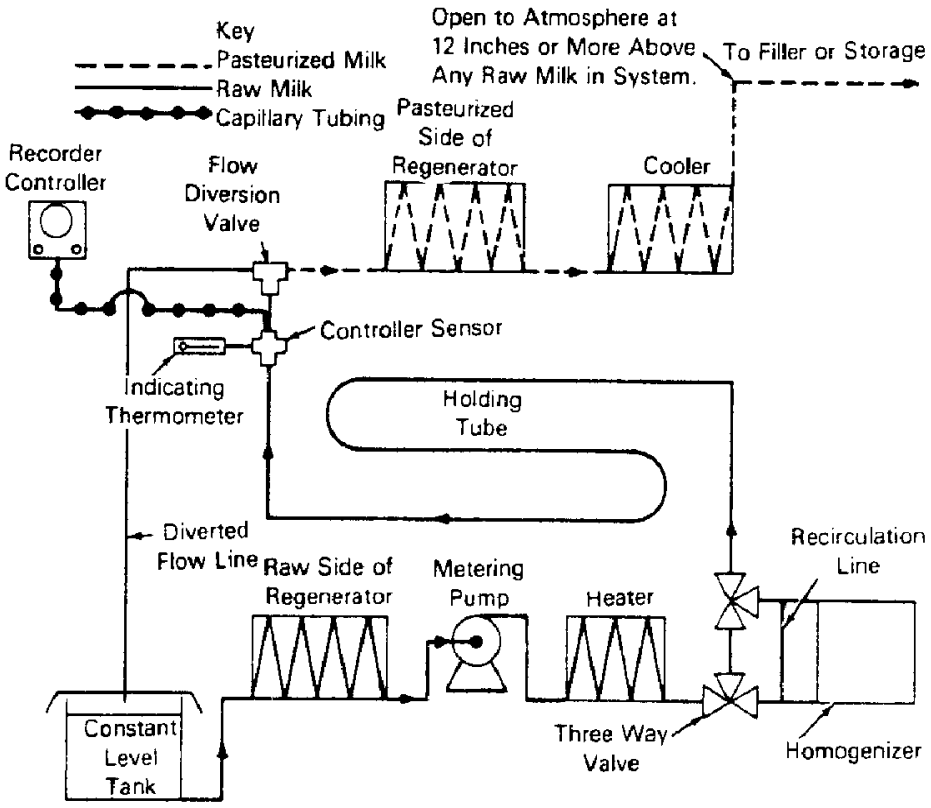

Figure 26. Milk-to-Milk Regeneration--Homogenizer Upstream from Holder

During normal operation (i.e., while the timing pump is operating), raw milk will be drawn through the regenerator at sub-atmospheric pressure. The pasteurized milk in the milk-to-milk regenerator will be above atmospheric pressure. The required pressure differential will be assured when there is no flow-promoting device downstream from the pasteurized milk side of the regenerator to draw the pasteurized milk through the regenerator, and the pasteurized milk downstream from the regenerator rises to at least 30 centimeters (1-foot elevation) above the highest raw milk level downstream from the constant-level tank, and is open to the atmosphere at this or a higher elevation, as required in Item 16, 2p(D)2.

During a shutdown (i.e., when the timing pump stops), the raw milk in the regenerator will be retained under suction, except as this suction may be gradually relieved by possible entrance of air drawn through the regenerator plate gaskets from the higher outside atmospheric pressure. With a free draining regenerator, as required under Item 16p(D)7, the raw milk level in the regenerator may drop slowly, depending on the tightness of the gaskets, ultimately falling below the level of the plates to the product level in the raw milk supply tank. However, under these conditions, as long as any raw milk remains in the regenerator, it will be at sub-atmospheric pressure.

During shutdown, the pasteurized milk in the regenerator is maintained at atmospheric pressure or above by meeting the elevation requirement of Item 16p(D)2. Pressure greater than atmospheric is maintained when the level of pasteurized milk is at or above the required elevation and loss of pressure, due to suction, is prevented by prohibiting a downstream pump.

Any backflow of milk through the flow-diversion device would lower the pasteurized milk level, during pump shut-downs, thus tending to reduce the pressure on the pasteurized milk side of the regenerator. A flow-diversion valve cannot be relied upon to prevent backflow in such instances, because during the first few minutes following a pump shutdown, the milk is still at a sufficiently high temperature to keep the diversion valve in the forward-flow position. Compliance with the provisions of Item 16p(D)2 and 3; however, will insure a proper pressure differential in the regenerator.

At the beginning of a run, from the time raw milk or water is drawn through the regenerator, until the pasteurized milk or water has risen to the elevation specified in Item 16p(D)2, the pasteurized milk side of the regenerator is at atmospheric pressure or higher. Even if the metering pump should stop during this period, the pressure on the pasteurized milk side of the regenerator will be greater than the sub-atmospheric pressure on the raw milk side. This will be assured by compliance with Item 16p(D)2 and 3, as long as any raw milk remains in the generator.

When a raw milk booster pump is incorporated into the HTST system, Item 16p(D)5 requires, in part, that automatic means shall be provided to assure, at all times, the required pressure differential between raw and pasteurized milk in the regenerator, before the booster pump can operate.

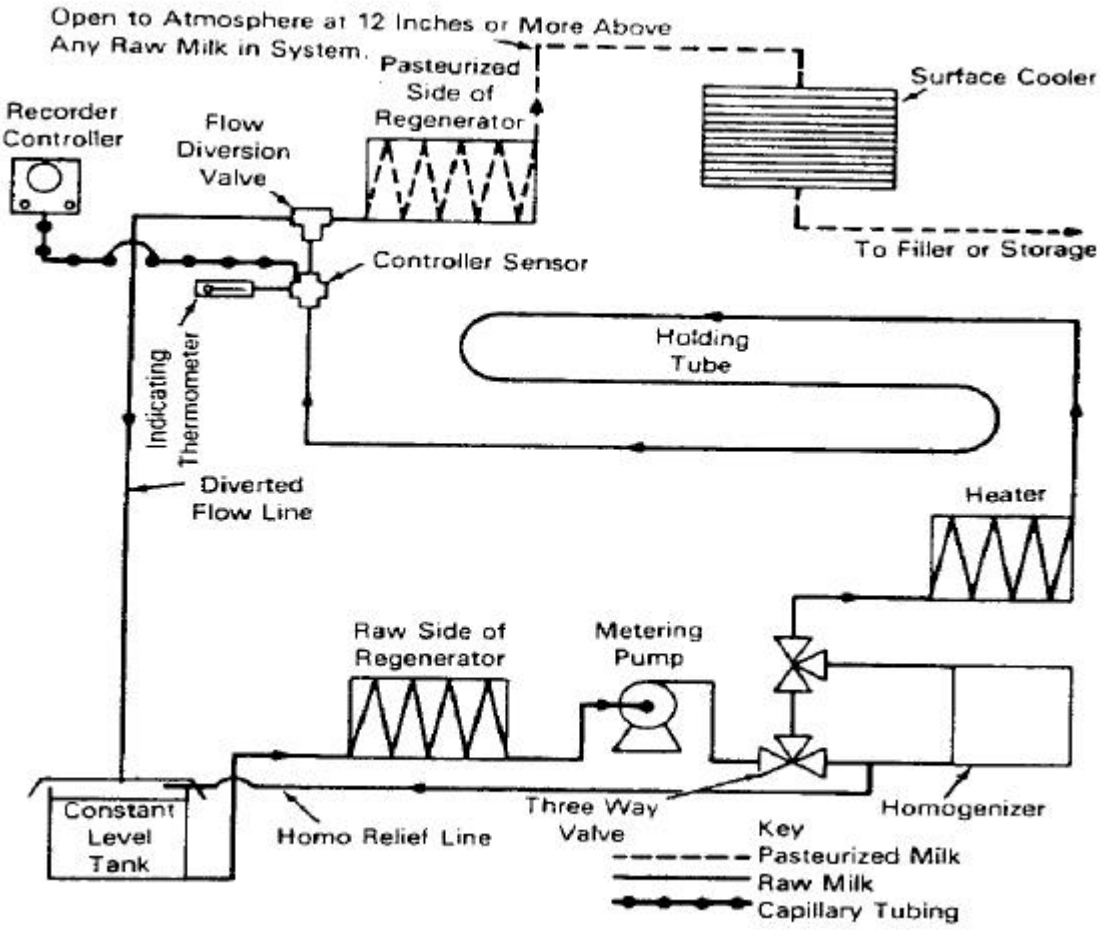

Figure 27. Milk-to-Milk Regeneration--Surface Cooler

THE USE OF SEPARATORS WITHIN HTST SYSTEMS

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

1. A separator may be located between the outlet of a raw regenerator and the timing pump or between raw regenerator sections if the separator is automatically valved out of the system, and separator stuffing pump(s) are de-energized, when:

a. The timing pump is not in operation;

or,

b. A dual stem FDD is in the inspect position;

or,

c. In a system with a dual stem FDD in which the separator is located between sections of a raw regenerator, during the first ten minutes of a required ten minute delay in CIP mode and during any period of diverted flow;

or,

d. The pressures in any raw regenerator sections, located after the

separator, are out of compliance with PMO pressure requirements.

(Note: the second section of a split raw side regenerator must freely drain back to the constant level tank or to the floor in the event of a shut down).

2. A separator may not be located between the timing pump and the FDD.

3. A separator may be located on the pasteurized side of the FDD if:

a. A properly installed atmospheric break is located between the FDD and the inlet of the separator.

b. All product rises to at least one foot higher than the highest raw milk in the system and is open to the atmosphere at some point between the outlet of the separator and the inlet of any pasteurized side regenerator.

c. All product rises to at least one foot higher than the highest raw milk in the system and is open to the atmosphere at some point between the outlet of any pasteurized side regenerator and the inlet of a separator.

d. The separator is automatically valved out of the system, and the separator stuffing pump is de-energized:

- when a dual stem FDD is in the first ten minutes of a required ten minute delay in CIP mode.

- when the FDD is diverted in product or inspect mode.

- when the timing pump is not in operation.

- when the temperature is below the required pasteurization temperature and the FDD is not in the fully diverted position.

4. The following criteria applies to installations where a separator must be valved out:

a. A valve must be located to isolate the product supply line from the separator.

b. A valve must be located to prevent all flow exiting the separator from being returned to the pasteurization system down stream of the separator.

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

MAGNETIC FLOW METER BASED TIMING SYSTEMS FOR HTST PASTEURIZERS

Recent developments in the design of HTST pasteurizing systems have introduced the use of magnetic flow meter based timing systems to be used as replacements for positive displacement timing pumps with a fixed or sealed speed below the required holding time.

These systems are of two basic types:

1. Those employing a constant speed centrifugal pump and a control valve, or
2. Those employing an A-C variable frequency motor speed control for the centrifugal pump. In this case the timing pump may be centrifugal or positive displacement type.

Item 16p(B)2(f) of Section 7 provides for their use provided, they meet the following specifications for design, installation and use.

COMPONENTS--Magnetic flow meter based timing systems shall consist of the following components:

1. A sanitary magnetic flow meter which has been reviewed by USPHS/FDA or one which is equally accurate, reliable and will produce six (6) consecutive measurements of holding time within one-half (0.5) second of each other.

2. Suitable converters for conversion of electric and/or air signals to the proper mode for the operation of the system.

3. A suitable flow recorder capable of recording flow at the flow alarm set point and also at least 19 liters (5 gallons) per minute higher than the flow alarm setting. The flow recorder shall have an event pen which shall indicate the position of the flow alarm with respect to flow rate.

4. A flow alarm, with an adjustable set point, shall be installed within the system which will automatically cause the flow-diversion device to be moved to the divert position whenever excessive flow rate causes the product holding time to be less than the legal holding time for the pasteurization process being used. The flow alarm shall be tested by the regulatory agency in accordance with the procedures of Appendix I, Test 11, 2. A and B at the frequency specified. The flow alarm adjustment shall be sealed.

5. A loss of signal alarm shall be installed with the system which will automatically cause the flow-diversion device to be moved to the divert position whenever there is a loss of signal from the meter. The loss of signal provision shall be tested by the regulatory agency in accordance with Appendix I, Test 11.2.C at the frequency specified. The loss of signal provision shall be sealed.

6. When the legal flow rate has been re-established, following an excessive flow rate, a time delay must be instituted which will prevent the flow-diversion device from assuming the forward flow position until at least a 15 seconds (milk) or 25 seconds (frozen dessert mix) continuous legal flow has been re-established. The time delay must be tested by the regulatory agency and if it is of the adjustable type shall be sealed.

7. When a constant speed centrifugal pump is used, a sanitary, spring-loaded-to- close; air-to-open, control valve shall be used to control the rate of flow of product through the HTST system.

8. When an A-C variable frequency motor speed control is used on the timing pump, the control valve is not needed as the flow rate of product through the system is controlled by feeding the signal from the magnetic flow meter to a controller which in turn varies the A-C frequency to the pump motor, thus controlling the flow rate of product through the system. With these A-C variable frequency systems, a sanitary product check valve is needed, in the sanitary milk pipe line to prevent a positive pressure in the raw milk side of the regenerator whenever a power failure, shutdown or flow-diversion occurs.

9. When a regenerator is used with large systems, it will be necessary to bypass the regenerator during start-up and when the flow-diversion device is in the diverted flow position. Care should be taken in the design of such bypass systems to assure that a dead-end does not exist. A dead-end could allow product to remain at ambient temperature for long periods of time and allow bacterial growth in the product. Caution should also be observed with such bypass systems and any valves used in them so that raw milk product will not be trapped, under pressure in the raw regenerator plates, and not have free drainage back to the constant level tank when shutdown occurs.

10. Most systems will utilize a dual stem flow-diversion device and will be using the timing pump during the mechanical cleaning cycle. All public health controls, required of such systems, must be applicable. When switching to the CIP position, the flow-diversion device must move to the divert position and must remain in the diverted flow position for at least 10 minutes, regardless of temperature, and the booster pump cannot run during this 10 minute time delay.

11. All systems shall be designed, installed and operated so that all applicable tests required by Section 7, Item 16p(E) (See Appendix I) can be performed by the regulatory agency, at the frequency specified. Where adjustment or changes can be made to these devices or controls, appropriate seals shall be applied after testing so that changes cannot be made without detection.

12. Except for those requirements directly related to the physical presence of the metering pump, all other requirements of the most recent edition of the *Grade "A" Pasteurized Milk Ordinance* are applicable.

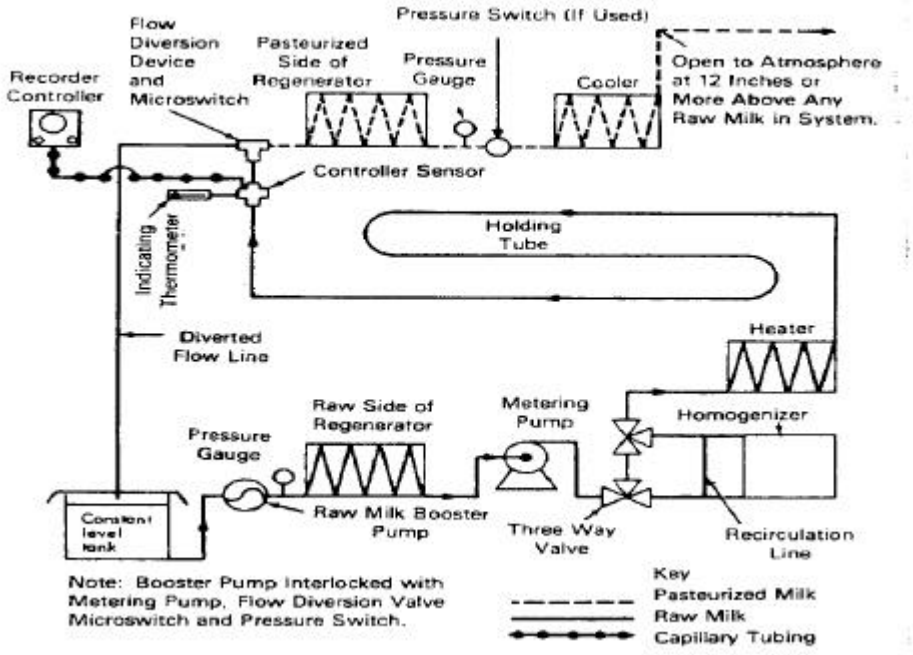

Figure 28. Milk-to-Milk Regeneration--Booster Pump

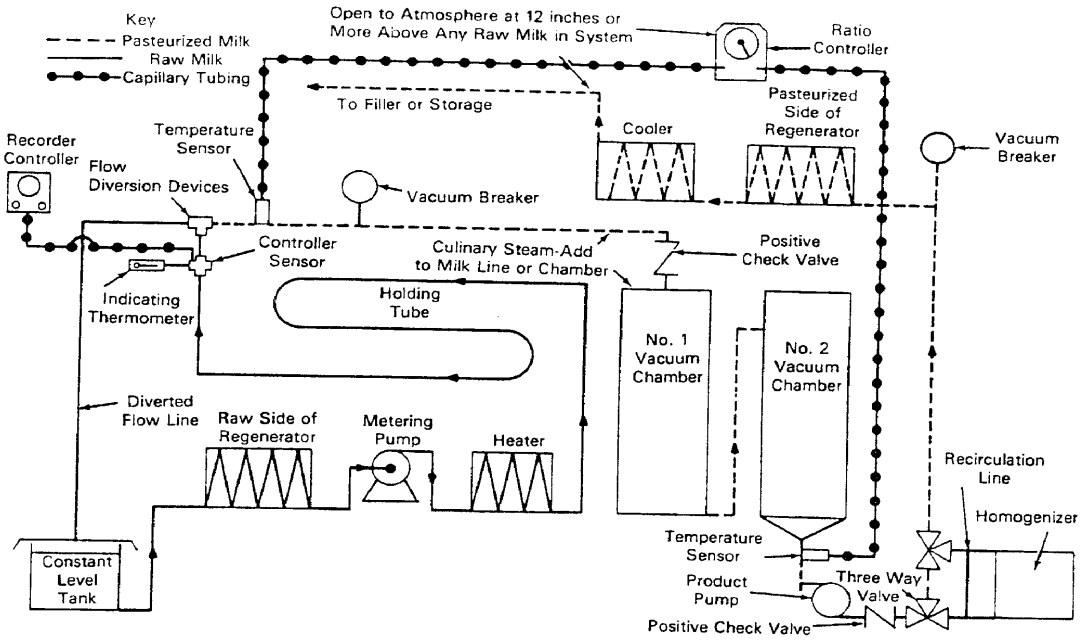

Figure 29. Milk-to-Milk Regeneration--Homogenizer and Vacuum Chambers Downstream from Flow-Diversion Device

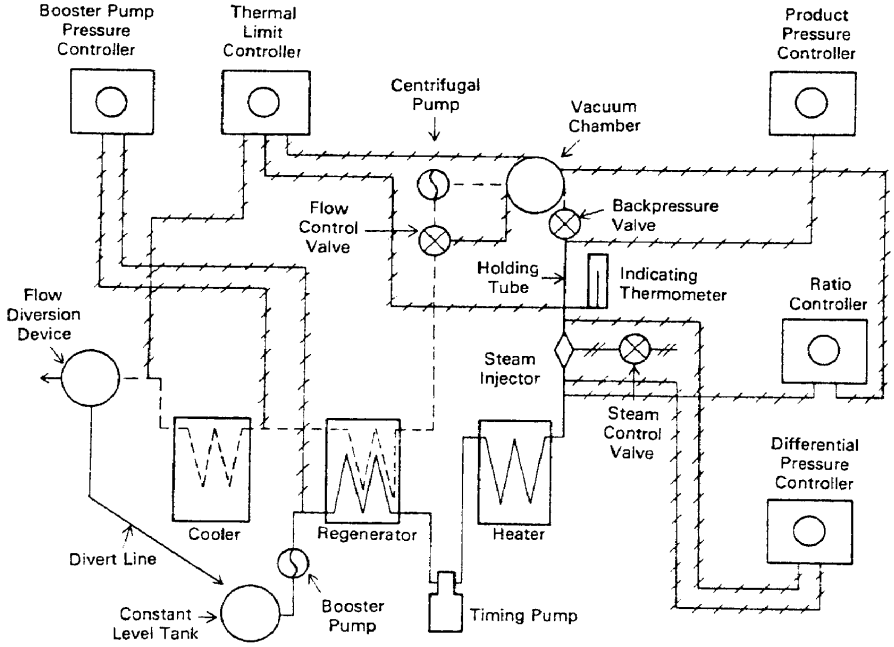

Figure 30. Controls for Steam Injection Pasteurizer

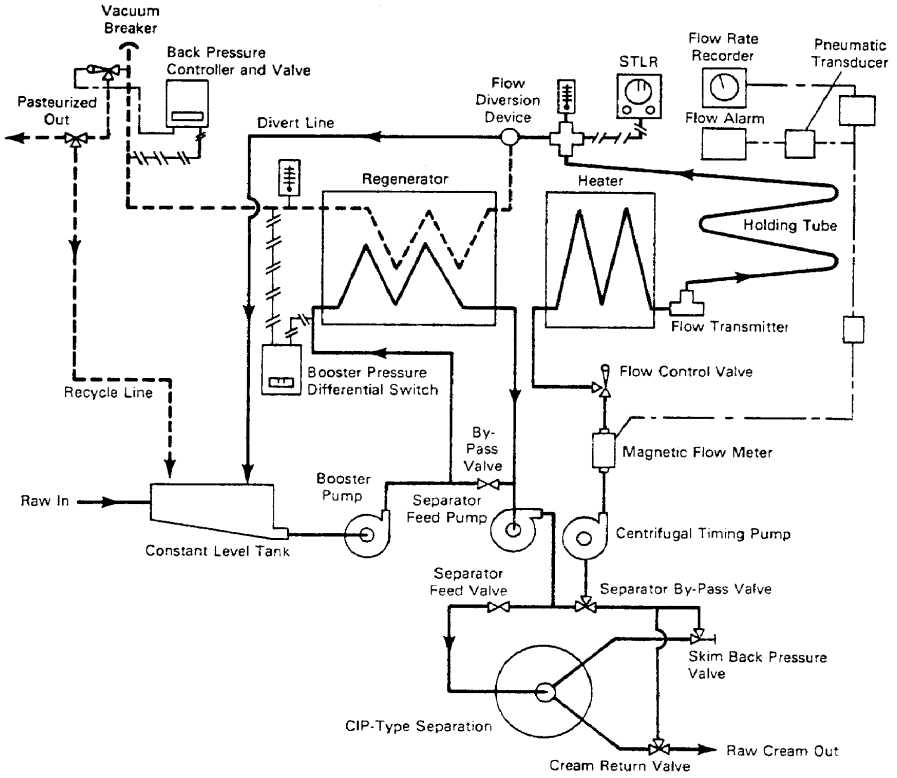

Figure 31. HTST System with a Magnetic Flow Meter Using a Constant Speed Centrifugal Pump and a Control Valve

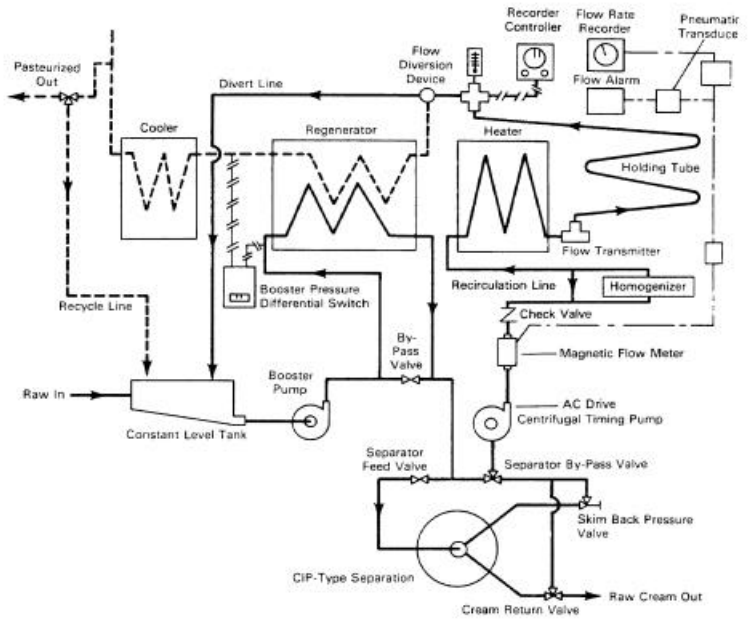

Figure 32. HTST System with a Magnetic Flow Meter Using an A-C Variable Speed Centrifugal Pump

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

1. The timing pump shall be located downstream from the raw milk regenerator section, if a regenerator is used.

2. The magnetic flow meter shall be placed downstream from the timing pump. There shall be no intervening flow promoting components between the timing pump and the meter.

3. The control valve, used with the constant speed timing pump, shall be located downstream of the magnetic flow meter.

4. The timing pump, the magnetic flow meter, the control valve, when used with the constant speed timing pump system, and the sanitary product check valve, when used with the A-C variable frequency motor speed control system, shall all be located upstream from the start of the holding tube.

5. All flow promoting devices, which are upstream of the flow-diversion device, such as timing pumps (constant speed or A-C variable frequency motor control types), booster pumps, stuffer pumps, separators and clarifiers shall be properly interwired with the flow-diversion device so that they may run and produce flow through the system at sublegal temperatures, only when the flow-diversion device is in the fully diverted position, when in product run mode. Separators or clarifiers which continue to run, after power is shut off to them, must be automatically valved out of the system, with fail-safe valves, so that they are incapable of producing flow.

6. There shall be no product entering or leaving the system (i.e., cream or skim from a separator or other product components) between the timing pump and the flow-diversion device.

7. The magnetic flow meter shall be so installed that the product has contact with both electrodes at all times when there is flow through the system. This is most easily accomplished by mounting the flow tube of the magnetic flow meter in a vertical position with the direction of flow from the bottom to the top. However, horizontal mounting is acceptable when other precautions are taken to assure that both electrodes are in contact with product. They should not be mounted on a high horizontal line which may be only partially full and thereby trap air.

8. The magnetic flow meter shall be piped in such a manner that at least 10 pipe diameters of straight pipe exists, upstream and downstream from the center of the meter, before any elbow or change of direction takes place. Figure 31 and 32 are schematic drawings of two typical magnetic flow meter based timing systems which illustrate proper placement of components.

II. AIR UNDER PRESSURE; MILK AND MILK PRODUCT-CONTACT SURFACES

MATERIAL

Filter Media: Air intake and pipeline filters shall consist of fiberglass, cotton flannel, wool flannel, spun metal, electrostatic material or other equally acceptable filtering media, which are non-shedding and which do not release to the air, toxic volatiles, or volatiles which may impart any flavor or odor to the product.

Disposable media filters shall consist of cotton flannel, wool flannel, spun metal, non-woven fabric, U.S.P. absorbent cotton fiber or suitable inorganic materials which, under conditions of use, are non-toxic and non-shedding. Chemical bonding material,

contained in the media, shall be nontoxic, nonvolatile and insoluble under all conditions of use. Disposable media shall not be cleaned and reused.

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

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

Piping: Air distribution piping, fittings and gaskets between the terminal filter and any product-contact surface, shall be sanitary milk piping, except, where the compressing equipment is of the fan or blower type. When the air is used for such operations, as removing containers from mandrels, other non-toxic materials may be used.

FABRICATION AND INSTALLATION

Air Supply Equipment: The compressing equipment shall be designed to preclude contamination of the air with lubricant vapors and fumes. Oil-free air may be produced by one of the following methods or their equivalent:

1. Use of a carbon ring piston compressor.
2. Use of oil-lubricated compressor with effective provision for removal of any oil vapor by cooling the compressed air.
3. Water-lubricated or nonlubricated blowers.

The air supply shall be taken from a clean space or from relatively clean outer air and shall pass through a filter upstream from the compressing equipment. This filter shall be located and constructed so that it is easily accessible for examination, and the filter media are easily removable for cleaning or replacing. The filter shall be protected from weather, drainage, water, product spillage and physical damage.

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

Filters and Moisture Traps: Filters shall be constructed so as to assure effective passage of air through the filter media only.

The air under pressure shall pass through an oil-free filter and moisture trap for removal of solids and liquids. The filter and trap shall be located in the air pipeline, downstream from the compressing equipment, and from the air tank, if one is used. Air pipeline filters and moisture traps, downstream from compressing equipment, shall not be required where the compressing equipment is of the fan or blower type.

A disposable media filter shall be located in the sanitary air pipelines upstream from and as close as possible to each point of application or ultimate use of the air.

Air Piping: The air piping from the compressing equipment to the filter and moisture trap shall be readily drainable.

A product-check valve of sanitary design shall be installed in the air piping, downstream from the disposable media filter, to prevent backflow of product into the air pipeline, except that a check valve shall not be required if the air piping enters the product zone from a point higher than the product overflow level which is open to the atmosphere.

The requirements of this section do not apply when the compressing equipment

is of the fan or blower type. See illustrations depicting various air supply systems.

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

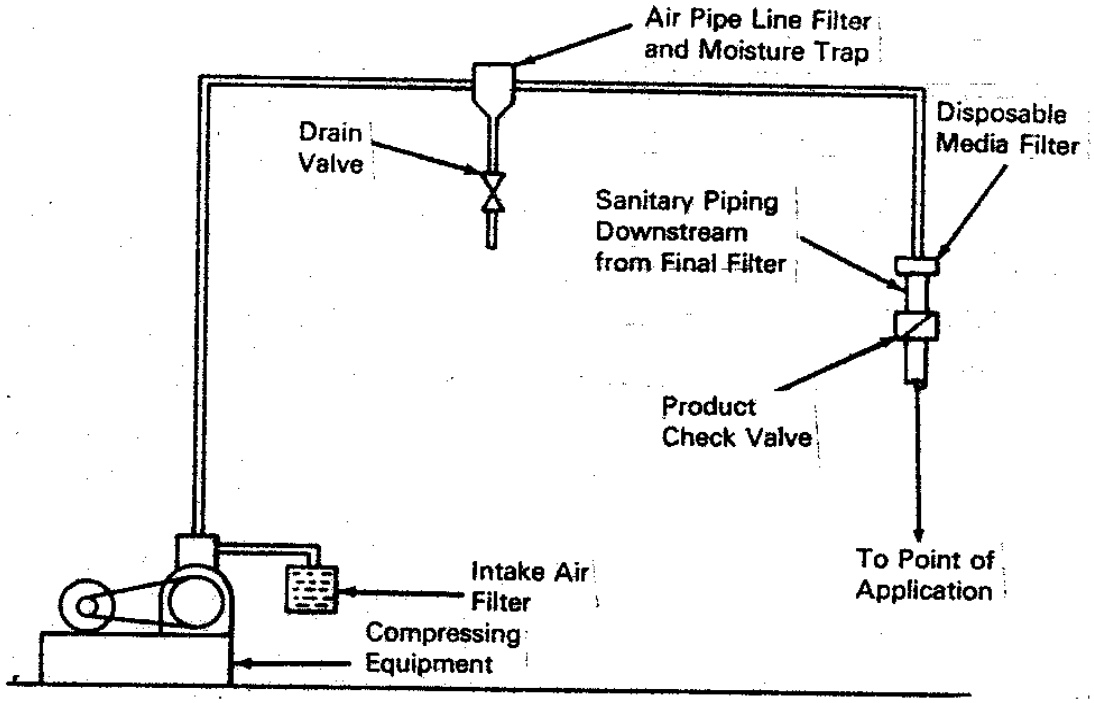

Figure 33. Individual Compression-Type Air Supply

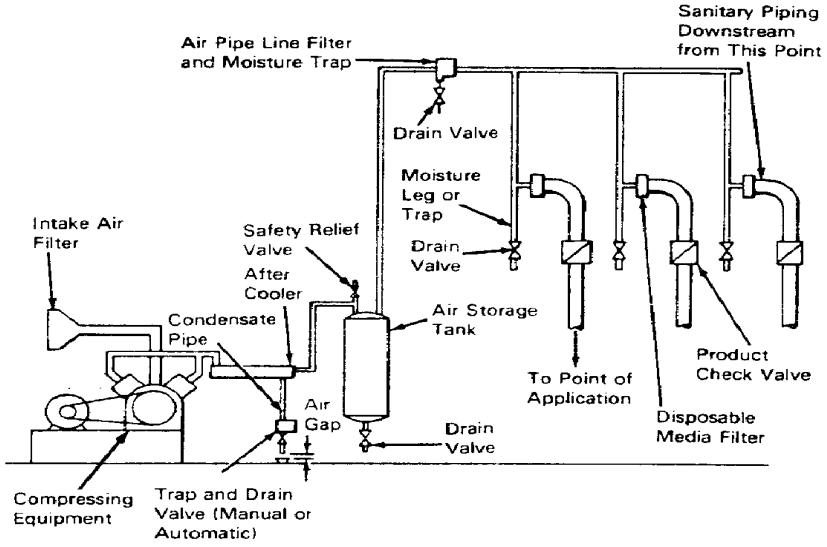

Figure 34. Central Compression-Type Air Supply

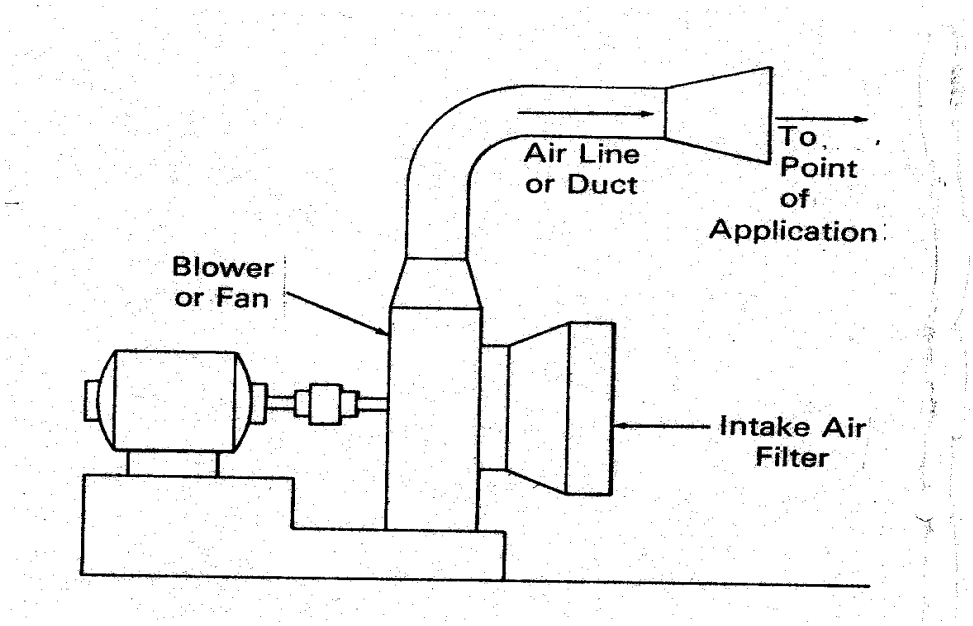

Figure 35. Individual Blower Type Air Supply

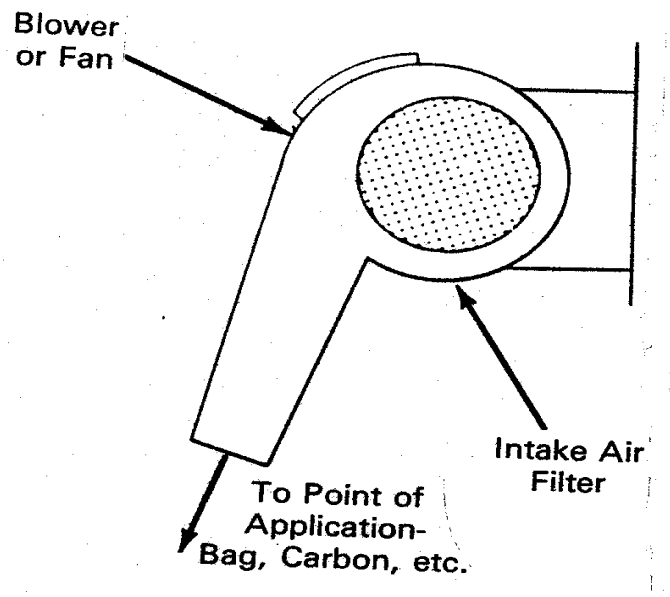

Figure 36. Individual Fan Type Air Supply

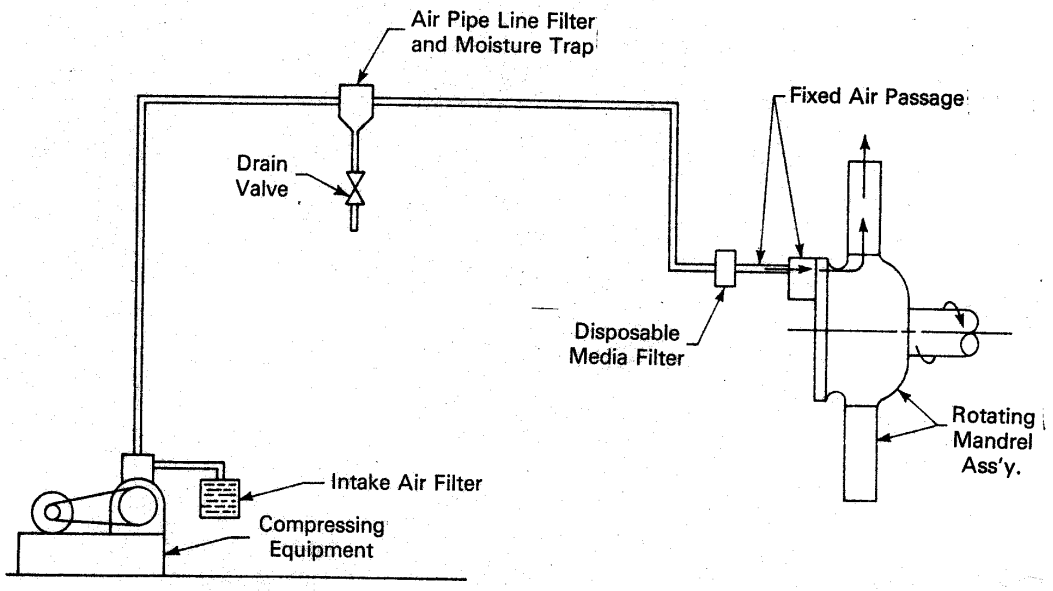

Figure 37. Rotating Mandrel Assembly

III. CULINARY STEAM; MILK AND MILK PRODUCTS

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

SOURCE OF BOILER FEED WATER

Potable water or water supplies, acceptable to the regulatory agency, will be used.

FEED WATER TREATMENT

Feed waters may be treated, if necessary, for proper boiler care and operation. Boiler feed water treatment and control shall be under the supervision of trained personnel or a firm specializing in industrial water conditioning. Such personnel shall be informed that the steam is to be used for culinary purposes. Pretreatment of feed waters for boilers or steam generating systems to reduce water hardness, before entering the boiler or steam generator by ion exchange or other acceptable procedures, is preferable to the addition of conditioning compounds to boiler waters. Only compounds complying with Section 173.310 of Title 21 of the *Code of Federal Regulations* may be used to prevent corrosion and scale in boilers, or to facilitate sludge removal.

Greater amounts shall not be used of the boiler water treatment compounds than the minimum necessary for controlling boiler scale or other boiler water treatment purposes. No greater amount of steam shall be used for the treatment and/or pasteurization of milk and milk products than necessary.

It should be noted that tannin, which is also frequently added to boiler water to facilitate sludge removal during boiler blow-down, has been reported to give rise to odor problems, and should be used with caution.

Boiler compounds containing cyclohexylmine, morpholine, octadecylamine, diethylaminoethanol, trisodium nitrilotriacetae, and hydrazine shall not be permitted for use in steam in contact with milk and milk products.

BOILER OPERATION

A supply of clean, dry saturated steam is necessary for proper equipment operation. Boilers and steam generation equipment shall be operated in such a manner as to prevent foaming, priming, carryover and excessive entrainment of boiler water into the steam. Carryover of boiler water additives can result in the production of milk off-flavors. Manufacturers' instructions regarding recommended water level and blow-down should be consulted and rigorously followed. The blow-down of the boiler should be carefully watched, so that an over-concentration of the boiler water solids and foaming is avoided. It is recommended that periodic analyses be made of condensate samples. Such samples should be taken from the line between the final steam separating equipment and the point of the introduction of steam into the product.

PIPING ASSEMBLIES

Suggested piping assemblies for steam infusion or injection were shown previously.

Other assemblies which will assure a clean, dry saturated steam are acceptable.

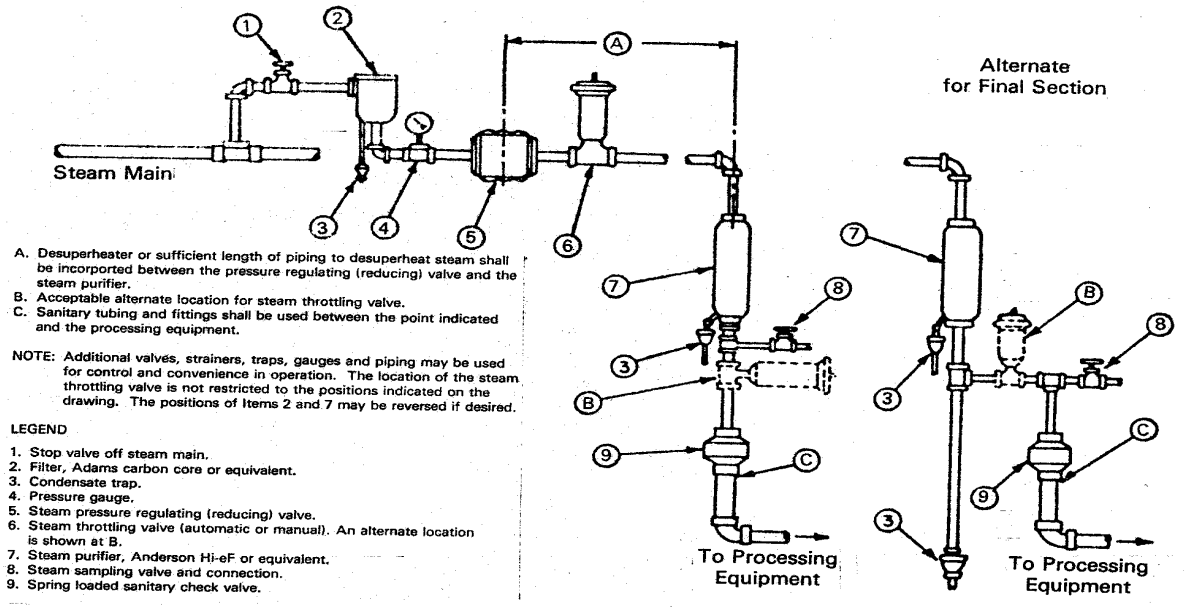

Figure 38. Culinary Steam Piping Assembly for Steam Infusion or Injection

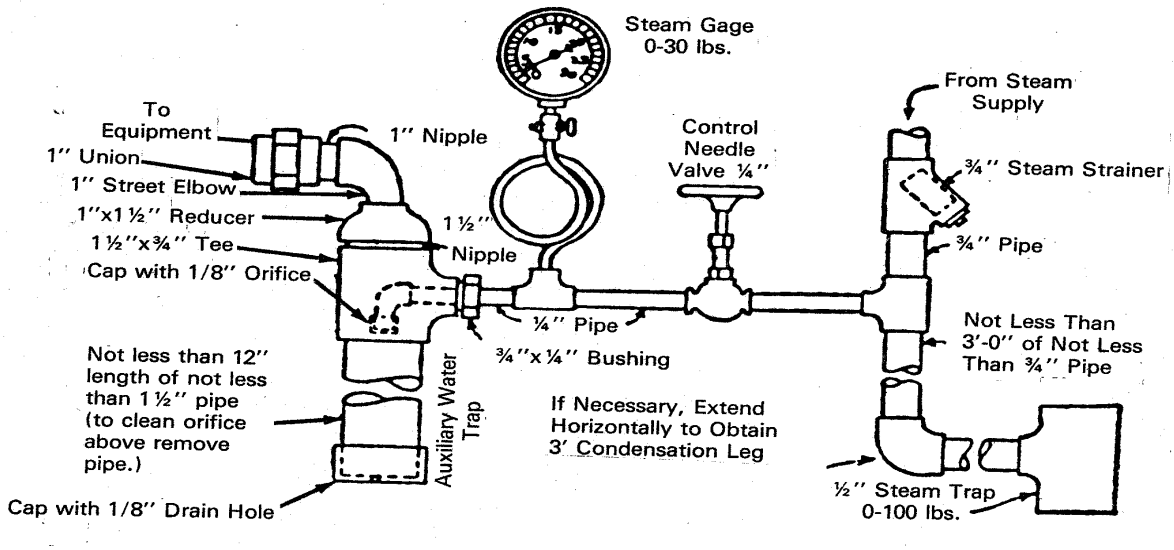

Figure 39. Culinary Steam Piping Assembly for Airspace Heating or Defoaming

IV. THERMOMETER SPECIFICATIONS

INDICATING THERMOMETERS FOR BATCH PASTEURIZERS

Mercury-actuated, direct-reading; contained in a corrosion-resistant case, which protects against breakage and permits easy observation of column and scale; filling above mercury, nitrogen or other suitable gas.

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

Scale: Shall have a span of not less than 14 Celsius degrees (25 Fahrenheit degrees), including the pasteurization temperature, plus and minus 3°C (5 F); graduated in 0.5° C (1 F) divisions, with not more than 9 Celsius degrees (16 Fahrenheit degrees) per inch of span; protected against damage at 105° C (220° F). *Provided*, that on batch pasteurizers used solely for 30-minute pasteurization of milk products at temperatures above 71° C (160° F), indicating thermometers with 1° C (2° F) scale graduations, with not more than 6° C per centimeters (28 Fahrenheit degrees per inch) of span, may be used.

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

Submerged Stem Fitting: Pressure-tight seat against inside wall of holder; no threads exposed to milk; location of seat to conform to that of the 3A Sanitary Standard for a wall-type fitting or other equivalent sanitary fitting.

Bulb: Corning normal or equally suitable thermometric glass.

INDICATING THERMOMETERS LOCATED ON PASTEURIZATION PIPELINES

Type:

1. Mercury-actuated; direct-reading; contained in corrosion-resistant case, which protects against breakage and permits easy observation of column and scale; filling above mercury, nitrogen or equally suitable gas.
2. Digital;

a. No more than 0.2° C (0.5° F) drift over 3 months use on an HTST system compared to a certified temperature source.

b. Self-diagnostic circuitry which provides constant monitoring of all sensing, input and conditioning circuits. The diagnostic circuitry should be capable of detecting "open" circuits, "short" circuits, poor connections and faulty components. Upon detection of failure of any component the device shall blank or become unreadable.

c. The electromagnetic compatibility of this device for this use shall be documented and available to public health authorities. The device must be tested to determine the effects of electrostatic discharge, power fluctuation, conductive emission and susceptibility, and radiative emission and susceptibility. The device must comply to the requirements for performance level characteristics of industrial devices. Protocols for these tests shall be developed by vendors with FDA concurrence.

d. The effect of exposure to specific environmental conditions sahll be

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

e. Both probe and display case shall be constructed so that they may be sealed by a regulatory agency.

f. Calibration of the device shall be protected against unauthorized changes.

g. The device shall be protected against unauthorized component or sensing element replacement. Replacement of any component or sensing element shall be regarded as a replacement of the indicating thermometer and subject to regulatory agency inspection and all applicable tests under Appendix I, Grade "A" PMO.

h. The sensing element shall be encased in appropriate material constructed in such way that the final assembly meets the conditions of PMO item 11p.

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

Scale: Shall have a span of not less than 14 Celsius degrees (25 Fahrenheit degrees), including the pasteurization temperature, plus and minus 02.5° C (5° F) division, protected against damage at 105° C (220° F). Mercury actuated thermometers shall be graduated in 0.2° C (0.5° F) divisions with not more than 4 Celsius degrees (8 Fahrenheit degrees) per 25 millimeters (inch) of scale. Digital thermometer readout shall be display in units with a least count of 0.05° C (0.1°F).

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

Stem Fittings: Pressure-tight seat against inside wall of fittings; no threads exposed to milk. Probe to be designed such that sensitive area is discernible from the remainder of the stem. Overall probe length to be such that the sensitive area is positioned in the product flow path when properly installed.

Thermometric Response: When the thermometer is at room temperature and then is immersed in a well-stirred water bath 11° C (19° F) or less above the pasteurization temperature; the time required for the reading to increase from water bath temperature, minus 11° C (19° F), to water bath temperature, minus 4° C (7° F), shall not exceed 4 seconds. (Appendix I, Test 7). Digital thermometer displays shall change at a rate that can be noted by the operator or regulatory agency during the thermometric lag test (Appendix I, Test 7).

Bulb: Corning normal, or equally suitable thermometric glass.

AIRSPACE INDICATING THERMOMETER FOR BATCH PASTEURIZERS

Type: Mercury-actuated, direct-reading; contained in corrosion-resistant case, which protects against breakage and permits easy observation of column and scale; bottom of bulb chamber, not less than 51 millimeters (2 inches) and not more than 89 millimeters (3.5 inches), below underside of cover; filling above mercury, nitrogen or equally suitable gas.

Magnification of Mercury Column: To apparent width of not less than 159 millimeters (0.0625 of an inch).

Scale: Shall have a span of not less than 14 Celsius degrees (25 Fahrenheit degrees), including the 66° C (150° F), plus and minus 3° C (5° F); graduated in not more than 1° C (2° F) divisions, with not

more than 9 Celsius degrees (16 Fahrenheit degrees) per 25 millimeters (inch) of scale; protected against damage at (105° C) 220° F.

Accuracy: Within 0.5°C (1°F), plus or minus, throughout the specified scale span. (Appendix I, Test 1).

Stem Fittings: Pressure-tight seat or other suitable sanitary fittings. No threads exposed.

RECORDING THERMOMETERS FOR BATCH PASTEURIZERS UTILIZING TEMPERATURES LESS THAN 71°C (160°F)

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

Scale: Shall have a span of not less than 11 Celsius degrees (20 Fahrenheit degrees), including pasteurization temperature, plus and minus 3° C (5.0° F), graduated in temperature-scale divisions of 0.5° C (1° F), spaced not less than 1.6 millimeter (0.0625 of an inch) apart between 60° C and 69° C (140 F° and 155° F). *Provided*, that temperature-scale divisions of 0.5° C (1° F), spaced not less than 1 millimeter (0.040 of an inch) apart, are permitted when the ink line is thin enough to be easily distinguished from the printed line; graduated in time-scale divisions of not more than 10 minutes; and having a chord of straight-line length of not less than 6.3 millimeters (0.25 inch), between 63° C and 66° C (145° F and 150° F).

Temperature Accuracy: Within 0.5° C (1° F), plus or minus, between 60° C and 69° C (140° F and 155° F) (Appendix I, Test 2).

Time Accuracy: The recorded elapsed time, as indicated by the chart rotation, shall not exceed the true elapsed time, as compared to an accurate watch, over a period of at least 30 minutes at pasteurization temperature. Recorders for batch pasteurizers may be equipped with spring operated or electrically operated clocks (Appendix I, Test 3).

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

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

Submerged Stem Fitting: Pressure-tight seat against inside wall of holder, no threads exposed to milk or milk products. Distance from underside of ferrule to the sensitive portion of the bulb to be not less than 76 millimeters (3 inches).

Chart Speed: A circular chart shall make one revolution in not more than 12 hours. Two charts shall be used if operations extend beyond 12 hours in 1 day. Circular charts shall be graduated for a maximum record of 12 hours. Strip-charts may show a continuous recording over a 24-hour period.

Chart Support Drive: The rotating chart support drive shall be provided with a pin to puncture the chart in a manner to prevent its fraudulent rotation.

UTILIZING TEMPERATURES GREATER THAN 71 C (160 F)

Batch pasteurizers used solely for 30-minute pasteurization of milk products at temperature above 71° C (160° F) may use recording thermometers with the following options:

Scale: Graduated in temperature scale divisions of 1° C (2° F), spaced not less than 1 millimeter (.040 of an inch) apart between 65° C and 77° C (150° F and 170° F), graduated in time-scale divisions of not more than 15 minutes and having a chord of straight-line length of not less than 6.3 millimeters (0.25 inch) between 71° C and 77° C (160° F and 170° F).

Temperature Accuracy: Within 1° C (2° F), plus or minus, between 71° C and 77° C (160° F and 170° F).

Chart Speed: A circular chart shall make one revolution in not more than 24 hours and shall be graduated for a maximum record of 24 hours.

RECORDER/CONTROLLERS FOR CONTINUOUS PASTEURIZERS

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

Chart Scale: Shall have a span of not less than 17 Celsius degrees (30 Fahrenheit degrees), including the temperature at which diversion is set, plus and minus, 7° C (12° F), graduated in temperature scale divisions of 0.5° C (1° F), spaced not less than 1.6 millimeter (0.0625 of an inch) apart at the diversion temperature, plus or minus, 0.5° C (1° F). *Provided*, that temperature-scale divisions of 0.5° C (1° F), spaced not less than 1 millimeter (0.040 of an inch) apart, are permitted when the ink line is thin enough to be easily distinguished from the printed line, graduated in time-scale divisions of not more than 15 minutes, and having an equivalent 15 minute chord or straight-line length of not less than 6.3 millimeters (0.25 of an inch) at the diversion temperature, plus or minus 0.5° C (1° F).

Temperature Accuracy: Within 0.5° C (1° F), plus or minus, at the temperature at which the controller is set to divert, plus and minus 3° C (5° F) (Appendix I, Test 2).

Power Operated: All recorder/controllers for continuous pasteurization shall be electrically operated.

Pen-Arm Device: Easily accessible; simple to adjust.

Pen and Chart Paper: Pen designed to give line not over .07 millimeter (0.025 of an inch) wide; easy to maintain.

Temperature Sensing Device: Bulb, tube, spring or thermistor, protected against damage at a temperature of 105° C (220° F). *Provided*, that recorder controller temperature sensing devices, used on HHST systems, shall be protected against damage at temperatures of 149° C (300° F).

Submerge Stem Fitting: Pressure-tight seat against inside wall of pipe; no threads exposed to milk or milk products; and location from underside of ferrule to the sensitive portion of the bulb not less than 76 millimeters (3 inches).

Chart Speed: A circular chart shall make one revolution in not more than 12 hours. Two charts shall be used if operations extend beyond 12 hours in 1 day. Circular charts shall be graduated for a maximum record of 12 hours. Strip-charts may show a continuous recording over a 24-hour period.

Frequency Pen: The recorder/controller shall be provided with an additional pen-arm for recording, on the outer edge of the chart, the record of the time at which the flow-control device is in

the forward-flow, diverted-flow or stopped position. The chart time line shall correspond with the reference arc, and the recording pen shall rest upon the time line matching the reference arc.

Controller: Actuated by same sensor as recorder pen, but cut-in and cut-out response independent of pen-arm movement.

Controller Adjustment: Mechanism for adjustment of response temperature simple, and so designed that the temperature setting cannot be changed or the controller manipulated without detection.

Thermometric Response: With the recorder/controller bulb at room temperature and then immersed in a well stirred water or oil bath at 4oC (7oF) above the cut-in point, the interval between the moment when the recording thermometer reads 7oC (12oF) below the cut-in temperature and the moment of power cut-in shall be not more than 5 seconds (Appendix I, Test 8).

Chart Support Drive: The rotating chart support drive shall be provided with a pin to puncture the chart in a manner to prevent its fraudulent rotation.

INDICATING THERMOMETERS USED IN STORAGE TANKS

Scale Range: Shall have a span not less than 28 Celsius degrees (50 Fahrenheit degrees), including normal storage temperatures, plus and minus 3° C (5° F), with extension of scale on either side permitted and graduated in not more than 1° C (2° F) divisions.

Temperature Scale Division: Spaced not less than 1.6 millimeters (0.0625 of an inch) apart between 2° C and 13° C (35° F and 55° F).

Accuracy: Within 1° C (2° F), plus or minus, throughout the specified scale range.

Stem Fitting: Pressure-tight seat or other suitable sanitary fittings. No threads exposed.

RECORDING THERMOMETERS USED IN STORAGE TANKS

Case: Moistureproof under operating conditions in processing plants.

Scale: Shall have a scale span of not less than 28 Celsius degrees (50 Fahrenheit degrees) including normal storage temperature, plus and minus 3° C (5° F), graduated in not more than 1° C (2° F) divisions, spaced not less than 1 millimeter (0.040 of an inch) apart, are permitted when the ink line is thin enough to be easily distinguished from the printed line and graduated in time scale divisions of not more than 1 hour, having a chord of straight-line length of not less than 3.2 millimeter (0.125 of an inch) at 5° C (40° F). Chart must be capable of recording temperatures up to 83° C (180° F). (Span specifications do not apply to extensions beyond 38° C (100° F).

Temperature Accuracy: Within 1° C (2° F), plus or minus, between specified range limits.

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

Pen and Chart Paper: Designed to give line not over .635 millimeter (0.025 of an inch) thick when in proper adjustment; easy to maintain.

Temperature Sensor: Protected against damage at 100° C. (212° F).

Stem Fittings: Pressure-tight seat or other suitable sanitary fitting. No threads exposed.

Chart Speed: The circular chart shall make one revolution in not more than 7 days and shall be graduated for a maximum record of 7 days. Strip chart shall move not less than 25 millimeter (1 inch) per hour and may be used continuously for 1 calendar month.

RECORDING THERMOMETERS ON MECHANICAL CLEANING SYSTEMS

Location: Temperature sensor in the return solution line downstream from process.

Case: Moistureproof under operation conditions.

Scale: Shall have a range from 16° C to 83° C (60° F to 180° F), with extensions of scale on either side permissible and graduated in time-scale divisions of not more than 15 minutes. Above 44° C (110° F), the chart is to be graduated in temperature divisions of not more than 1° C (2° F), spaced not less than 1.6 millimeters (0.0625 of an inch) apart. Provided, that temperature-scale divisions of 1° C (2° F), spaced not less than 1 millimeter (0.040 of an inch) apart, are permitted when the ink line is thin enough to be easily distinguished from the printed line.

Temperature Accuracy: Within 1° C (2° F), plus or minus, above 44° C (110° F).

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

Pen and Chart Paper: Designed to make a line not over .635 millimeter (0.025 of an inch) wide; easy to maintain.

Temperature Sensor: Protected against damage at 100° C (212° F).

Stem Fitting: Pressure-tight seat against inside wall of pipe; no threads exposed to solution.

Chart Speed: Circular charts shall make one revolution in not more than 24 hours. Strip charts shall not move less than 25 millimeters (1 inch per hour). More than one record of the cleaning operation shall not overlap on the same section of the chart for either circular- or strip-type charts.

INDICATING THERMOMETERS USED IN REFRIGERATED ROOMS.

Indicating thermometers used in refrigerated rooms, where milk and milk products are stored, shall meet the following specifications:

Scale Range: Shall have a span not less than 28 Celsius degrees (50 Fahrenheit degrees), including normal storage temperatures, plus and minus 3° C (5° F), with extensions of scale on either side permitted if graduated in not more than 1° C (2° F) divisions.

Temperature Scale Divisions: Spaced not less than 1.6 millimeter (0.0625 of an inch) apart between 0° C and 13° C (32° F and 55° F).

Accuracy: Within 1° C (2° F), plus or minus, throughout the specified scale ranges.

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

BACKGROUND

Computers are different from hard-wired controls in three major categories. To provide adequate public health protection, the design of computerized public health controls must address these three major differences.

First, unlike conventional hard-wired systems, which provide full-time monitoring of the public health controls, the computer performs its tasks sequentially, and the computer may be in real time contact with the flow-diversion device for only one millisecond. During the next 100 milliseconds (or however long it takes the computer to cycle one time through its tasks), the flow-diversion device remains in forward flow, independent of temperature in the holding tube. Normally, this is not a problem, because most computers can cycle through 100 steps in their program, many times during one second. The problem occurs when the public health computer is directed away from its tasks by another computer, or the computer program is changed, or a seldom used JUMP, BRANCH, or GOTO Instruction diverts the computer away from its public health control tasks.

Second, in a computerized system, the control logic is easily changed because the computer program is easily changed. A few keystrokes at the keyboard will completely change the control logic of the computer program. Conversely, hard-wired systems required tools and a technician to make wiring changes. Once the hard-wired system was properly installed and working, it was never changed. This problem can be solved by sealing the access to the computer, but some procedure is needed to ensure that the computer has the correct program when the computer is resealed by the public health authority.

Finally, some computer experts have stated categorically that no computer program can be written error-free. They were referring primarily to very large programs, with many conditional jumps and branches, with thousands of lines of program code. For these large systems, the programs actually improve with age (the errors are found and corrected under actual conditions of use). For public health controls, the computer program must and can be made error-free, since the programs required for public health control are relatively brief.

GLOSSARY

Address: A numerical label on each memory location of the computer. The computer uses this address when communicating with the input or output.

Computer: A very large number of on-off switches arranged in a manner to sequentially perform logical and numerical functions.

Default mode: The pre-described position of some memory locations during start-up and standby operations.

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

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

EPROM: An **E**rasable, **P**rogrammable, **R**ead-**O**nly **M**emory. The entire memory is erased by exposure to ultra-violet light.

Fail safe: Design considerations that cause the instrument or system to move to the safe position upon failure of electricity, air, or other support systems.

Field alterable: A devise having a specific design or function that is readily changed by user and/or maintenance personnel.

Force off: A programmable computer instruction that places any input or output in the "off" state, independently of any other program instructions.

Force on: A programmable computer instruction that places any input or output in the "on" state, independently of any other program instructions.

Input: Electrical signals applied to the computer that are used by the computer to make logical decisions on whether or not to activate one or more outputs. Input consists of data from temperature and pressure instruments, liquid level controls, microswitches, and operator-controlled panel switches.

Input/Output Terminals: An electrical panel that provides for the connection of all inputs and outputs to the computer. The input/output address labels are found on this panel. Indicator lights showing the status (on/off) of all inputs and outputs may be available on this panel.

Last state switch: A manually operated switch or software setting that instructs the computer to place all outputs in the "on", "off", or "last state" condition during a start-up. The "last state" position instructs the computer to place the outputs in whatever state (on or off) occurred during the last loss of power.

Operator override switch: A manually operated switch that permits the operator to place any input or output in the on or off position, independently or any program instructions.

Output: Electrical signals from the computer that turn on or off: valves, motors, lights, horns, and other devises being controlled by the computer. Outputs may also consist of messages and data to the operator.

Programmable controller: A computer, with only limited mathematical ability, that is used to control industrial machines, instruments and processes. Most computers used on HTST pasteurizers will be programmable controllers.

RAM: **R**andom **A**ccess **M**emory. Memory used by the computer to run programs, store data, read input and control outputs. The computer may either read data from the memory or write data into the memory.

ROM: **R**ead-**O**nly **M**emory. A memory used by the computer to run its own internal unchangeable programs. The computer may only read from the memory; it cannot write into the memory or alter the memory in any way.

Standby status: The computer is turned on, running, and waiting for instructions to start processing input data. This instruction is usually accomplished by a manually-operated switch.

Status printing: Some computers are programmed to interrupt printing of the chart record and print the status of key set points and conditions such as: cold milk

temperature, holding tube temperature, diversion temperature setting and chart speed.

CRITERIA:

The following listed criteria shall be complied with for all computers or programmable controllers when applied to HTST, HHST and UHT pasteurization systems used for Grade 'A' milk and milk products. In addition, all systems shall conform to all other existing requirements of the Grade 'A' Pasteurized Milk ordinance.

1. A computer or programmable controller used for public health control of Grade 'A' pasteurizers must be a system dedicated only to the public health control of the pasteurizer. The public health computer shall have no other assignments involving the routine operation of the plant.

2. The public health computer and its outputs shall not be under the command or control of any other computer system. It shall not have an address to be addressable by any other computer system. A host computer cannot override its commands or place it on standby status. All addresses of the public health computer must be ready to process data at any time.

3. A separate public health computer must be used on each pasteurizing system.

4. The status of the inputs and outputs of the public health computer may be provided as inputs-only, to other computer systems. The wiring connections must be provided with isolation protection such as relays, diodes, or optical-coupling devises to prevent the public health outputs from being driven by the other computer system. Digital outputs from an other computer may be connected to an input of the public health computer in order to request operation of a device controlled by the public health computer.

5. On loss of power to the computer, all public health controls must assume the fail-safe position. Most computers can be placed in standby status by either a program instruction or manual switches. When the computer is in standby status, all public health controls must assume the fail-safe position. Some computers have internal diagnostic checks that are performed automatically during start-up. During this time, the computer places all outputs in default mode. In this default mode, all public health controls must be in the fail-safe position.

6. Some computers or programmable controllers have Input/Output buses with "last state switches" that permit the operator to decide what state the output bus will take on power-up after a shutdown or loss of power. The choices are on, off, or "last state" occurring when the computer lost power. These "last state switches" must be placed in the fail-safe position.

7. The computer performs its tasks sequentially, and for most of real time, the computer outputs are locked in the ON or OFF position, while waiting for the computer to

come back through the cycle. Consequently, the computer program must be written so that the computer monitors all inputs, and updates all outputs on a precise schedule - at least once every second. Most computers will be capable of performing this function many times in one second.

8. Programs must be stored in some form of read-only memory, and be available when the computer is turned on. Tapes or disks are not acceptable.

9. The computer program access must be sealed. Any telephone modem accesses must also be sealed. If the Input/Output Terminals contain "last state switches", the Input/Output Terminals must be sealed. The vendor must supply the Regulatory Official with procedures and instructions to confirm that the program currently in use by the computer is the correct program. The Regulatory Official will use this test procedure to confirm that the correct program is in use, during a start-up, and whenever the seal is broken.

10. If the computer contains FORCE-ON, FORCE-OFF functions, the computer must provide indicator lights showing the status of the FORCE-ON, FORCE-OFF function. The Vendor instructions must remind the Regulatory Official that all FORCE-ON, FORCE-OFF functions must be cleared before the computer is sealed.

11. The Input/Output Terminals of the public health computer shall contain no operator override switches.

12. Computerized systems which provide for printing the recording chart by the computer must ensure that proper calibration is maintained. During chart printing, the computer must not be diverted from its public health tasks for more than one second. Upon returning to public health control, the computer shall complete at least one full cycle of its public health tasks before returning to chart printing.

13. When printing a chart, some systems provide status reports on the chart paper of selected Input/Output conditions. This is usually done by interrupting the printing of the chart and printing the Input/Output conditions. Such interrupts, for status printing, are permitted only when a continuous record is recorded on the chart. When an interrupt is started, the time of the start of the interrupt will be printed on the chart at the beginning of the interrupt and at the end of the interrupt. The time interval during which the computer is diverted from its public health control tasks for status printing shall not exceed one second. Upon returning to public health control, the computer shall complete at least one full cycle of its public health tasks before returning to status printing.

14. When the computer prints the temperature trace of temperature in the holding tube, at specific intervals, rather than a continuously changing line, temperature readings shall be printed not less than once every five seconds, except that

during the thermometric lag test, the temperature shall be printed or indicated fast enough that the Regulatory Official can place the temperature sensor in a bath at a temperature 7EF above the diversion setting and accurately determine the point in time when the temperature rises to a point 12EF below the diversion point setting so that the Regulatory Official can start the timing of the thermometric lag test.

15. When the computer prints the frequency pen position (the position of the flow-diversion device, forward or divert) at specific intervals, rather than continuously, all changes of position shall be recognized by the computer and printed on the chart. In addition, the frequency pen position and temperature in the holding tube must be printed on the chart in a manner that the temperature in the holding tube can be determined at the moment of a change of position of the flow-diversion device.

16. The vendor shall provide a built-in program for test procedures, or a protocol shall be provided so that all applicable public health tests of Appendix I for each instrument can be performed by the Regulatory Official; i.e.
Recording thermometers: temperature accuracy, time accuracy, check against indicating thermometer, thermometric response; Flow-diversion Devices: valve seat leakage, operation of valve stem(s), device assembly, manual diversion, response time, time delay intervals if used;
Booster Pumps: proper wiring, proper pressure control settings; Flow Promoting Devises of Public Health Significance Capable of Generating Flow Through the Holding Tube: holding time in holder, proper wiring interlocks.

17. Computers require high quality (clean) well regulated power supplies to operate reliably and safely. Spurious voltage spikes can cause unwanted changes in computer random access memory (RAM). Some mechanical and electrical components also deteriorate with age. One solution is to have two permanent programs in the computer; one in RAM and one in read-only memory (ROM). Through a self-diagnostic test, these two programs could be compared routinely. If there were differences in the programs, the computer would go into default mode. Another solution would be to down-load the program from ROM to RAM at every start-up. A third solution would be to have the computer read program directly from ROM, that is unchangeable. However, this approach is practical only in large volume applications such as microwave ovens. For most small volume applications, the read-only memories are field alterable, such as erasable, programmable read-only memories (EPROMS), electrically erasable, programmable, read-only memories (EEPROMS) and electrically alterable, programmable read-only memories (EAPROMS). EPROMS, EEPROMS, and EAPROMS cannot be relied upon to maintain a permanent record. Something is needed to ensure that

the proper program is in computer memory when the Regulatory Official seals the computer.

18. Computer programs used for Public Health Controls on Grade 'A' Pasteurizers must conform to the attached logic diagrams. Minor modifications to these diagrams are permissible to accommodate or delete items that are unique to a specific HTST Pasteurizer system such as; magnetic flow meters used as replacement for timing pump, the flush cycle on the detect stem of the flow-diversion device, and the ten minute delay of booster pump and flow-diversion device that permits the timing pump to run during cleaning operations. The vendor must provide a protocol in the user's manual so that the installer, user, and/or Regulatory Official can demonstrate that the program performs as designed under actual production conditions. *Similar appropriate logic flow should be followed for HHST and aseptic processing systems based on modifying these diagrams as needed.*

19. The logic diagrams for the flow-diversion device and booster pump show a programmed mechanical cleaning cycle operation as part of the computerized system. Some plant operators may wish to use another computer for mechanical cleaning operations, so that mechanical cleaning programs may be changed by plant personnel, as needed to achieve good plant sanitation. When this is done, the connections between the flow-diversion device, booster pump, and plant computer, must be provided with solenoid relays or similar devices on the outputs to the flow-diversion device and booster pump to prevent them from being operated by the plant computer, except when the mode switch of the flow-diversion device is in the "CIP" position.

DIAGRAM LEGEND

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

References

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

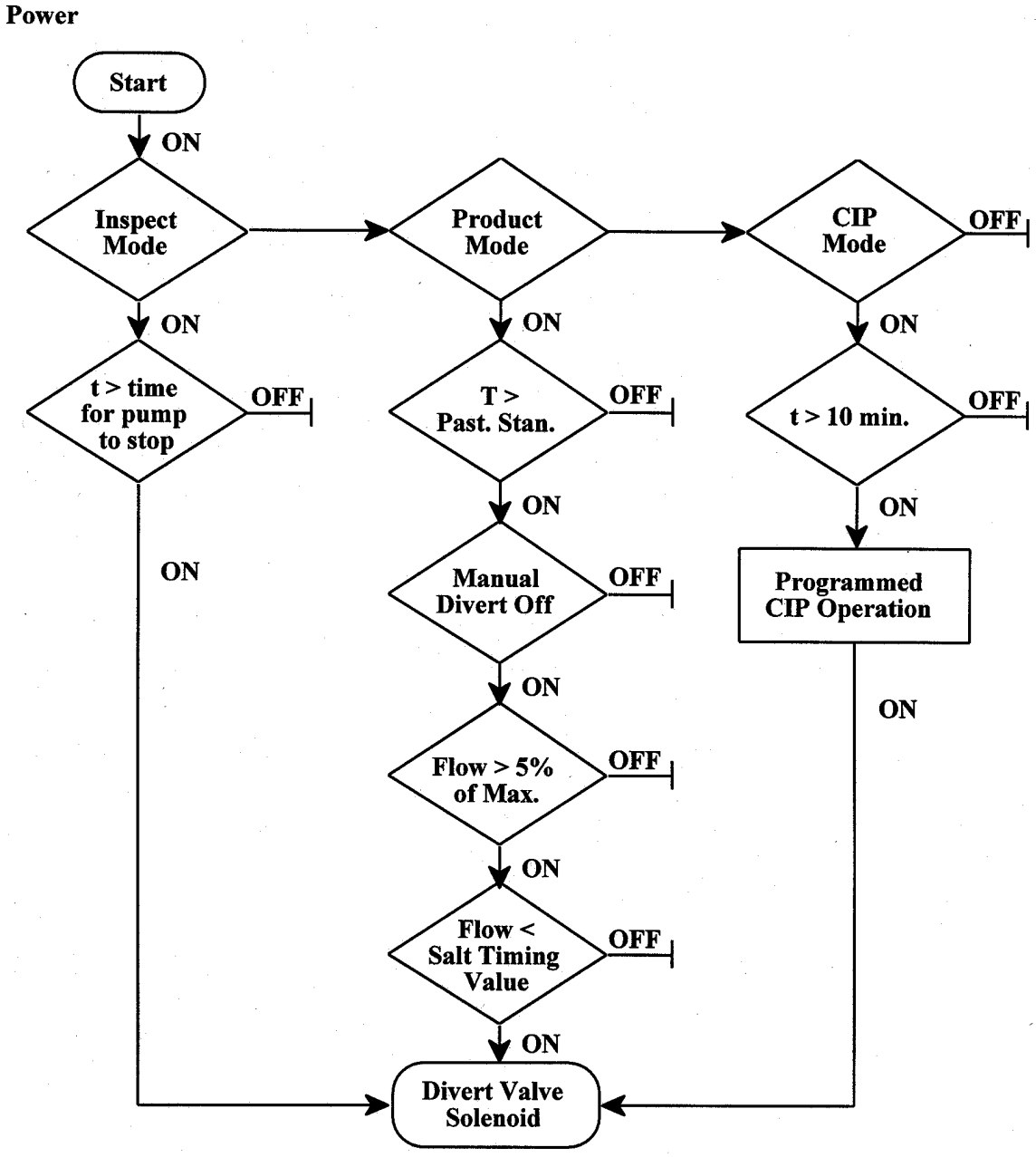


Figure 40. Logic Diagram, Flow-diversion Device, Divert Valve Stem

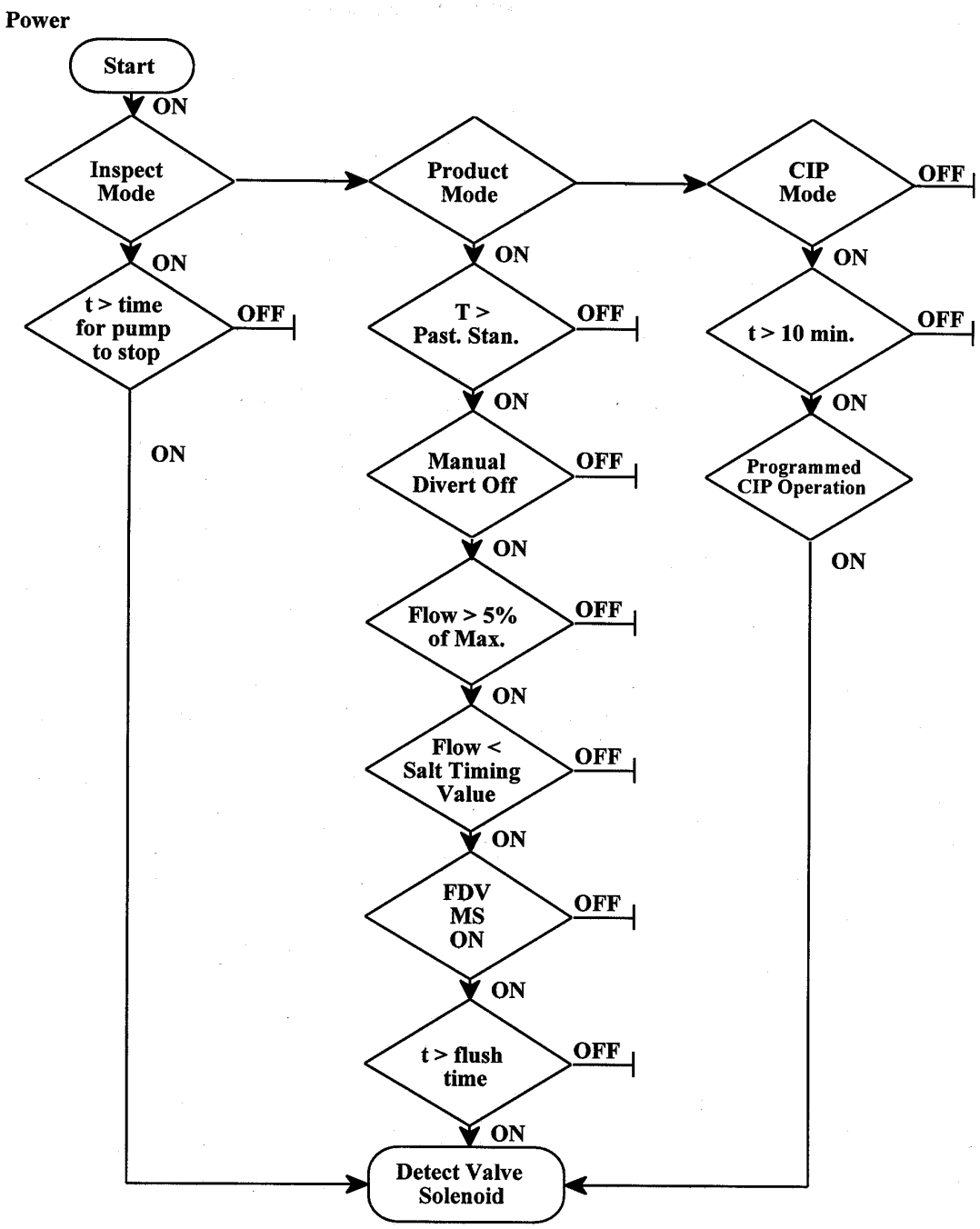


Figure 41. Logic Diagram, Flow-diversion Device, Leak Detect Valve Stem

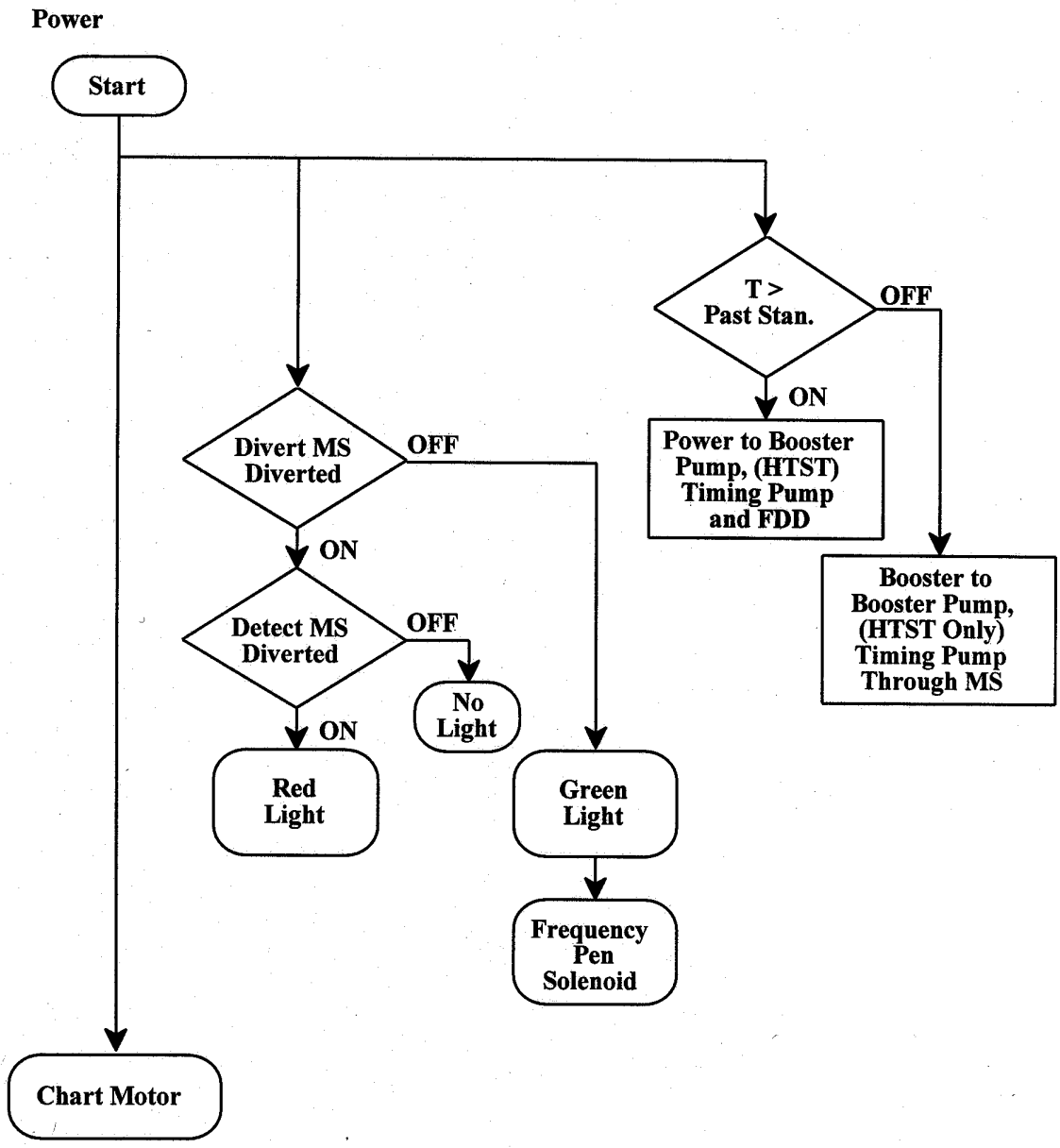


Figure 42. Logic Diagram, Safety Thermal Limit Recorder-Controller

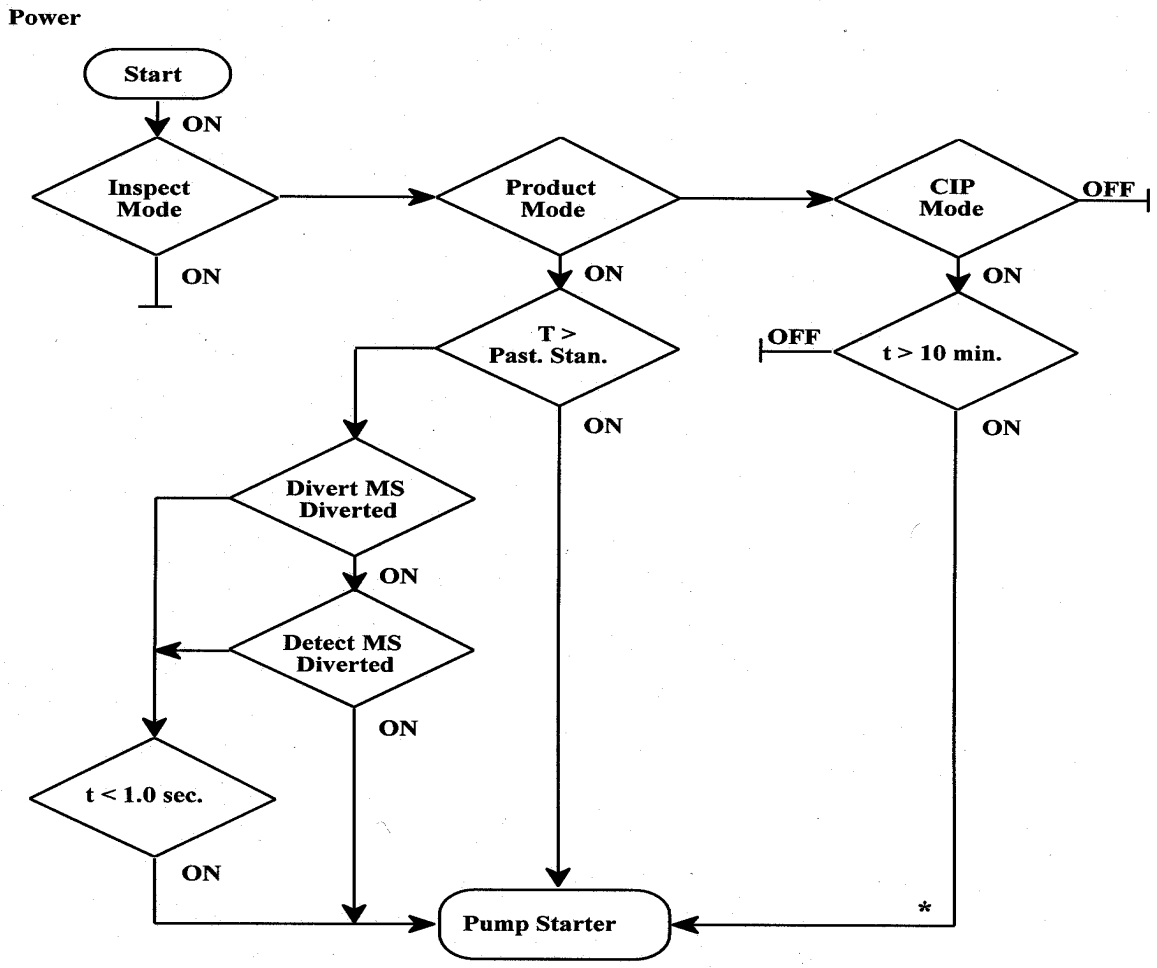
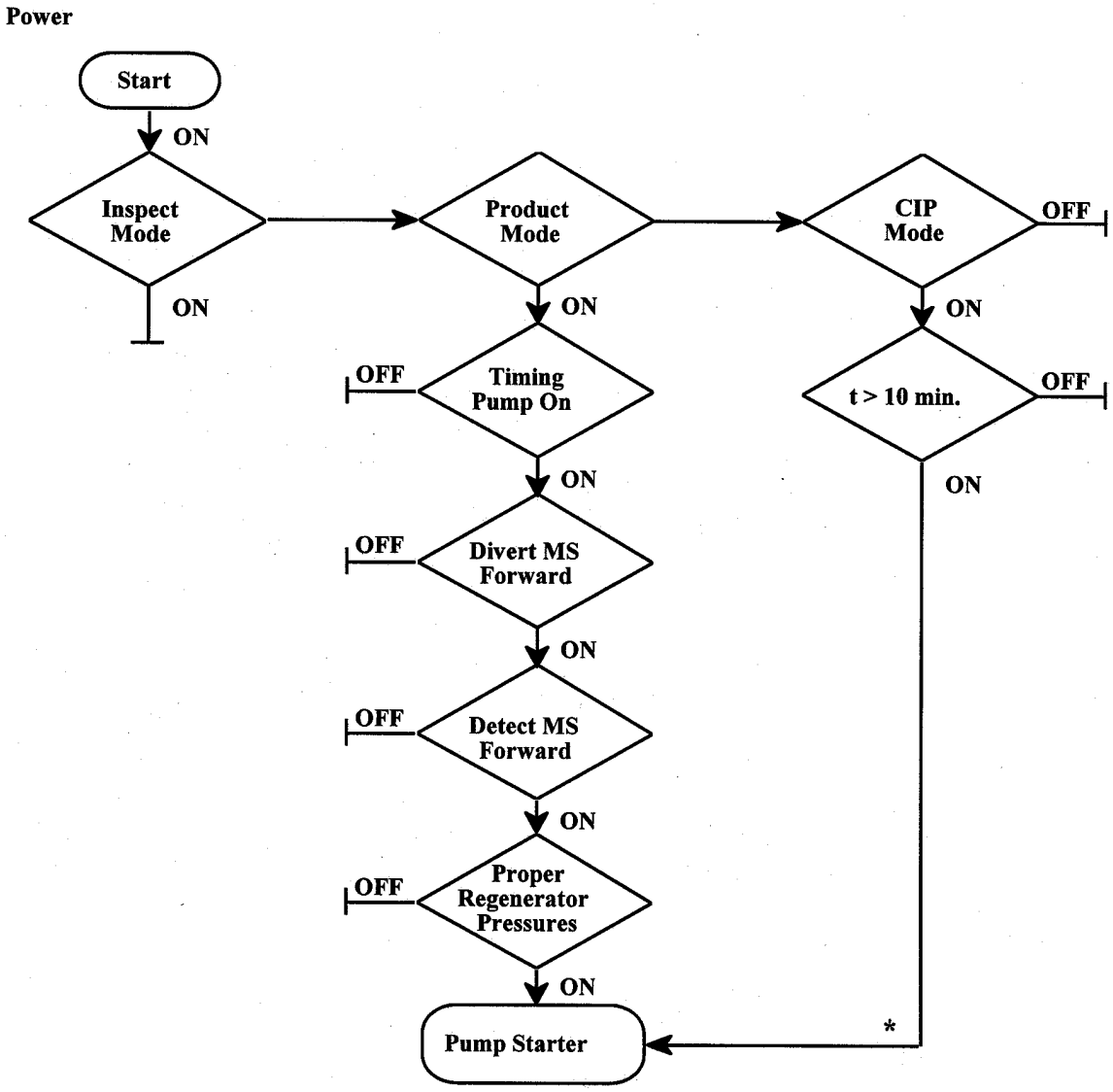


Figure 43. Logic Diagram, Timing Pump



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

Figure 44. Logic Diagram, Booster Pump