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CASE STUDIES

CASE STUDIES

CASE STUDIES IN THE DESIGN, INSTALLATION AND OPERATION OF HTST PASTEURIZATION SYSTEMS

PURPOSE: The purpose of these case studies are to provide the participant with some guidance and insight into milk flow sequences within a pasteurization system. Also this should to give the participant an opportunity to make determinations for the placement of public health controls in various systems.

METHOD: Using the list of pasteurizer components provided on the following page, and your assigned case study, construct an acceptable flow diagram showing the proper location of each component in the system including the following parameters.

1. The effects that your flow arrangement has on the **TIME-TEMPERATURE-PRESSURE** relationship within the system.

2. The flow promoting equipment operational requirements during **divert, shut-down, inspect, CIP, and improper flow diversion device seating**.

3. The **location of all public health controls and the location of regulatory seals required to safeguard the system**.

The **major** public health consideration in using **auxiliary equipment** is to determine effects on **time-temperature-pressure** relationships within the system. Specifically, this equipment must be installed so that:

1. It will not reduce the **minimum required holding time** below the requirements.

2. It will not interfere with the detection of, or stoppage of forward flow of milk which is **below the minimum pasteurization temperature.**

3. It will not disturb the maintenance of **proper pressure relationships within the regenerator section** of the system.

EQUIPMENT COMPONENT LIST

recorder-controller	booster pump
flow diversion device	cooler section
holding tube	heater section
divert line	homogenizer
regenerator	leak detect line
balance tank	timing pump
recirculation line	by-pass line
recycle line	pressure differential controller
vacuum breaker	indicating thermometer
separator	by-pass valve
stuffing pump	positive shut-off valve
back pressure valve	magnetic flow meter
check valve	pressure sensor
centrifugal pump	flow recorder-controller
regulatory seal	sight glass

CASE STUDIES

CASE #1 a). HTST pasteurizer with a homogenizer of larger capacity than the timing pump and booster pump.

b). Cream pasteurizer with conventional timing pump, without a milk-to-milk regenerator.

CASE STUDIES

CASE #2 HTST pasteurizer with homogenizer as timing pump with a stuffing pump and a booster pump.

CASE #3 HTST pasteurizer with a booster pump, homogenizer as the timing pump, and a raw milk separator with a stuffing pump.

CASE #4 HTST pasteurizer with a booster pump, stuffing pump, and a homogenizer as the timing pump. There is separator on the pasteurized side of the system and an automatic back pressure control valve. One of the milk to milk regenerators is a "vacuum" regenerator.

CASE #5 HTST pasteurizer with a booster pump, homogenizer of equal capacity to the timing pump, a separator on the raw side of the regenerator, and a regenerator back pressure control valve.

CASE #6 HTST pasteurizer with a booster pump, a homogenizer of larger capacity than the timing pump, a separator on raw side, a stuffer pump, a meter based timing system, with AC variable speed drive.

CASE #7 HTST pasteurizer with a booster pump, a meter based timing system, a separator on the pasteurized side, and a flow control valve.

CASE STUDIES

CASE #8 HTST pasteurizer with flavor control equipment and a CIP separator on the raw side, with a homogenizer as timing pump. (centrifugal pumps as needed).

CASE #9 HTST pasteurizer with a CIP separator on the pasteurized side between regenerator #1 and #2, with a homogenizer located on the pasteurized side and a meter based variable frequency AC drive system. In this particular system, the booster pump is located between raw regenerator #1 and raw regenerator #2. Cream is precooled through raw regenerator #1.

CASE #10 HHST pasteurizer with positive displacement timing pump, a vacuum chamber (flash chamber) with direct steam infusion, using milk-water-milk regenerative heating, FDD at the end of the cooler section, and a centrifugal pump between the balance tank and the raw regenerator.

CASE STUDIES

COURSE CRITIQUE

MILK PASTEURIZATION CONTROLS AND TESTS #302

DATE/LOCATION:____
____
_____________.

	Excellent					Poor
1. What is you overall rating of this course?	6	5	4	3	2	1
2. How would you rate the facility?	6	5	4	3	2	1

3.What was the most useful aspect of the program?____
____
____.

4.What suggestions can you offer for improving this course.____
____
____
____.

5. Please give us your comments on course handouts and manuals._______________________________________
____
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____.

6. Would you recommend this course to others working in the milk sanitation field? Y( ) N( ) explain____
____
_.

7. What subject matter or topics would you like to include in future courses?
____
____

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____.

Comments____

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____.

BEST PART OF THE COURSE:

1.

2.

3.

WORST PART OF THE COURSE:

1.

DEFINITIONS

DEFINITIONS

AMPERAGE (AMPS) - The amount of current flow through a conductor.

ATMOSPHERIC PRESSURE- The force exerted on an area by the column of air above that area. Atmospheric pressure at sea level is 14.7 pounds per square inch.

BALANCE TANK - Raw product tank located at the start of a pasteurization system used to maintain a constant supply of product to the pasteurizer.

BOOSTER PUMP - A centrifugal pump placed in a pasteurizing system between the balance tank and the raw regenerator and capable of producing positive pressure in the raw regenerator.

BOURDON COIL (spring) **-** A sealed flat metal tube filled with a gas mixture that has been formed into a coiled spiral, located inside the recorder-controller. This spiral expands or contracts in response to the vapor pressure of the gas mixture. This coil is located on one end of the capillary tube with the recorder-controller temperature sensing bulb at the other.

CMR - A temperature recording device, usually installed at the end of the cooler section on a pasteurizer system providing constant record or milk temperature.

CAPILLARY TUBE - A thin metal tube, containing a mixture of liquids with low vapor pressures, that connects the bourdon tube in the recorder-controller with the temperature sensor bulb located at the flow diversion device. This thin tube is usually protected by a flexible metal cable.

CENTRIFUGAL PUMP - A high speed pump that produces product flow due to the velocity increase of the liquid caused by the rotation of the pump impeller.

CONSTANT LEVEL TANK - See Balance Tank.

COOLING SECTION - The section of a heat exchanger (press) in which one of several non-toxic coolants flows in a counter current direction on the opposite side of a stainless steel plate of the pasteurized product.

DEFLECTOR PLATE - A stainless steel plate in the regenerator section of the press designed to change the direction of flow.

DMO - The latest edition of the Dry Milk Ordinance. This Ordinance covers all Grade A milk drying and condensing plants.

DRT - Digital Reference Thermometer. This is usually referred to the electronic indicating thermometer which provides a readable L.E.D. display provided by a signal from a dual element, 8 wire, resistive (1000 ohm) type sensor element.

FLOW DIVERSION DEVICE - Either a single stem (one three-way valve) or dual stem device (two, three-way valves connected by a common yoke), designed to change the direction of product flow,controlled by the recorder-controller. (FDD).Prevents the forward flow of raw milk.

FLOW CONTROLLER - An instrument used in meter based systems which compares the flow signal from the flow transmitter to a set point and either controls the centrifugal pump speed or regulates a flow control valve downstream of the meter and centrifugal pump. (FC)

FLOW TRANSMITTER - An instrument used in meter based systems which converts signals from the magnetic flow meter to a 4-20ma current. (FT)

FREQUENCY PEN - A solenoid actuated recording pen (located on the outer edge of the recording chart) that records the position of the flow diversion device in a continuous flow pasteurization system. This pen on a meter based system only records the flow diversion device position that has been electronically signaled by the flow recorder/controller.

HEAT EXCHANGER - Equipment designed to effect heat transfer between two or more mediums.(plate type, triple tubes, etc).

HOLDING TUBE - The section of piping in continuous flow pasteurizers of sufficient length to provide the minimum legal residence time for heated milk.

HOT WATER TEMPERATURE CONTROLLER - A system which controls the temperature of the heating medium by regulating a mixture of steam and water that circulates through the heating section of the press.

I/P Transducer - An instrument used in a meter based system that converts a 4-20ma current signal to an air signal (usually 15-30 psi) which drives the flow recorder pen.

kPa - Metric measurement equivalency (kilograms) of pounds per square inch. Conversion factor is 0.1449 divided by psi=kPa, ie, 1 psi=6.9 kPa.

LAMINAR FLOW - The movement of high viscosity products through a pipe in concentric layers where the fastest particle may move at twice the speed of the average particle.

METERING PUMP - See Timing Pump

METER BASED SYSTEM - The term used for those pasteurization systems employing the use of approved components of a magnetic flow control system to replace other conventional timing pumps in a HTST system.

MICROSWITCH - A mechanically activated electric NO (normally open), NC (normally closed) switch. It is a small level actuated switch used in the control circuit and is sometimes referred to as a limit switch. Microswitches may have three terminals, one to supply current, and the two others are marked "no" for normally open and "NC" for normally closed. External pressure on the lever will change the position from "NO" to "NC" or vice versa, depending on the switch wiring. Used to "break" or "make" a control circuit.

PMO - The current edition of the Pasteurized Milk Ordinance.

PNEUMATIC - Operated by compressed air.

PRESSURE RELIEF VALVE - A valve which is designed to automatically open when subjected to the determined pre-set pressure. AKA “pop-off valve”.

REGENERATOR BY-PASS VALVE - A automatic or manually controlled valve used in combination with the booster pump for the purposes of start up of a continuous pasteurizer with a milk to milk regenerator. This valve allows for by-passing the regenerator in order to provide the proper pressure relationships in the regenerator, thus allowing the booster pump to operate.

SANITIZATION - The application of any effective method or substance to a **clean** surface for the destruction of pathogens, and of other organisms as far as is practicable. Such treatment must not adversely affect the equipment , the milk or milk product or the health of consumers. Sanitization may be accomplished by either the application of heat or suitable chemicals used in accordance with good manufacturing practices.

SAFETY THERMAL LIMIT CONTROLLER The term sometimes used interchangeably when referring to the recorder-controller.

SOLENOID - An electronically operated valve used in to open or close a valve or to open or close a magnetic relay switch.
SNAFU - Situation normal, all fouled up.

STUFFING PUMP - Any centrifugal pump used in the system for the purposes of enhancing product flow to a component, other that those located between the balance tank and the raw regenerator.

TIME DELAY RELAY (TDR) - An adjustable timer(either mechanical or electronically controlled) used to maintain a set time period equal to or greater than the required minimum. All required TDR's must be sealed by the regulatory agency.

TIMING PUMP - Sanitary , positive displacement -type (rotary or piston) or in the case of meter based systems a centrifugal product pump, which provides a constant measured rate of flow to the continuous pasteurization system. Homogenizers may be used as timing pumps since they are piston type (always odd numbers of pistons) pumps and positive displacement pumps. All timing pumps are capable of crating suction and do not slow down under discharge pressure.

THROTTLING VALVE - A spring-to-close valve used in conjuction with a magnetic flow meter timing system having a single speed timing pump, to control flow speed of product.

TURBULENT FLOW - Flow where considerable mixing occurs across a pipe cross section and the velocity is nearly the same across this section. Turbulent flow occurs most frequently in less viscous liquids and is often characterized by higher friction losses than would be expected.

VACUUM BREAKER - An air relief valve held in the closed position by product flow pressures and which opens and admits air when the product pressure goes below atmospheric pressure. Uses include maintaining proper pressures in a milk to milk regenerator during system shut-down and preventing suction of product past the flow diversion device during operation. Other uses are to provide protection on pasteurized installed vacuum chambers.

VOLTAGE - The force between the electrical leads or from one lead to ground. It is measured across two unconnected leads (open circuit voltage) and standard voltages are 6, 12, 24, 110, 220, or 440. Neutral or ground is used as the second lead for measurement of the lower voltages (single phase).

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Note: The use of trade names or equipment photographs is for training and educational purposes only and does not constitute endorsement by the U.S. Department of Heath and Human Services, Public Health Service, Food and Drug Administration.
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APPENDIX

HTST PASTEURIZATION EQUIPMENT TESTS

PLANT______________________________ DATE:___________________
Address____________________________ HTST #__________________
____________________________ SANITARIAN_______________

NO	(√)	CRITERIA/METHOD	PROCEDURE	RESULTS
#3		STLR-Time Accuracy	Compare at 30 Min	STLR Time________ Actual_______
#1		IND-TEMP Accuracy(IND=.5^o F;AS=1^o F)	At Past. Temp, using Cert Therm	Ind___________ AS____________
#2		STLR-Temp ±1^o F	5 Min Stabilization @ Past 5 Min @Boil;5 Min @ Stabilization 5 Min in Ice;5 min @ Past(RTD=2 min)	Ind__________ STLR_________
#4		STLR v.s.Ind(Daily) ±1 STLR not higher	Compare at past temp using milk	Ind__________ STLR_________
#10		Cut-In;Cut-Out	Ind Therm reading when valve changes FF,DF; (<1^o F/30 sec)	Cut-In___________ Cut-Out__________
#7		Ind Therm-Response	<4 sec; 12 ^{o} F span, H20 bath,173^o F, Start-154. stop-166	Time____________
#8		STLR Therm-Resp	<5 sec; start 12^o F below cut-in, stop @ system cut-in.(bath 7^o above cut-in)	Time____________

#9		(#4)Regenerator Pressure Controls (#5)Booster pump wiring	(#4) ≥1 psi on Past side (set Taylor DPC @2 psi) (#5) a. interwired w/FDD b. " w/PDC c. " w/timing pump	(#4)Using device: range travel, quick release, and differential pressure: diff pressure=_______psi. (#5) a. FF to DF, BP should stop( ) b. @FF, <2psi stops BP( ) c. TP off = BP off( )
# 11		Holding Time	Salt test 6X w/i .5 sec	DF:1___2___3___4___5 ___6___ FF:1___2___3___4___5 ___6___ Can fill time:FF_____DF_____
#5		Flow Diversion Device(FDD) Proper Assembly	DUAL STEM 1. leakage past seat 2. operation of valve stem 4. device assembly 5. manual diversion 6. response time 7. interlock with flow promoters (INSPECT and CIP time delays) 8. 10 min CIP time delay (if applies) SINGLE STEM 1,2,3 (hex nut <½ turn stops TP),5,6,omit #7&8).	1. no leakage( ) 2. operates freely ( ) 3. metering pump stops when improperly assembled yes( ) no( ) 4. <1 sec ( ) 5. manual divert;a,b,&c parts 6. response time <1 sec 7. Time delays (INS,____sec;CIP,____sec) 8. 10 minute TD in CIP(whenapplies) ___min.

RDE/FDA/STB

WATER TO MILK HOLDING TIME CONVERSION

METHOD: VOLUME (   )   WEIGHT (   )

Time required to fill measured volume of water =____________seconds.

Time required to fill identical measured volume of milk =__________seconds.

Compute adjusted holding time using formula where:

<u>Volume method:</u>

T = salt time test results____________.
Mv = average time required to deliver measured volume of   milk__________.
Wv = average time required to deliver equal volume of water____________.

$$\frac{T(Mv)}{Wv} = \text{calculated holding time for milk}$$

<u>Weight method:</u>

T = salt time testing results___________.
Mw = average time required to deliver measured weight of milk__________.
Wv = average time required to deliver equal weight of water____________.
1.032 = specific gravity of milk.

$$\frac{1.032(TMw)}{Ww} = \text{calculated holding time for milk}$$

Note: This test is not required for meter based systems; nor for those homogenizer based timing systems with a measured holding time of ≥120% of the minimum required holding time. (Example; 15 second = 18 seconds, 25 seconds = 30 seconds)

ALL GEAR DRIVEN TIMING SYSTEMS REQUIRE CALCULATED HOLDING TIMES

Public Health Service MILK PASTEURIZATION CONTROLS TEST REPORT
Food and Drug Administration

TEST NO.	TEST		TEST FREQ.	TESTED (X or NA)	TEST RESULTS
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 Thermometer Checked against Indicating Thermometer		3 months	Daily by operator	
5	FDD Assembly and Function				
	5.1	Leakage past valve seat			
	5.2	Operation of valve stem	3 months		
	5.3	Device assembly (microswotch), single stem	3 months		
	5.4	Device assembly micro-switches) Dual stem	3 months		
	5.5	Manual Diversion, Parts A,B,and C,	3 months	HTST ONLY	
	5.6	Response Time	3 months		
	5.7	Time Delay-Inspect	3 months		
	5.8	Time Delay-CIP			
	5.9	Time Delay-LD Flush			
6	Leak -protector, outlet, valves:leakage(Vats)		3 months		
7	Indicating Thermometers in Pipeline: Thermometric Response		3 months	HTST ONLY	
8	Recorder Controller: Thermometric Response		3 months	HTST ONLY	
9	Setting of controls:Regenerator				
	9.1	Pressure switches	3 months	HTST ONLY	
	9.2	Differential Pressure Controllers	3 months		
	9.2.1	Calibration	3 months		
	9.2.2	Interwiring-Booster Pump	3 months	HTST ONLY	
	9.2.3	Interwiring - FDD (HHST and Aseptic Only)	3 months		
	9.3	Additional interwiring			

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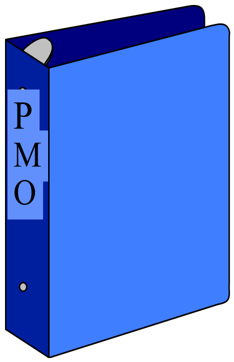
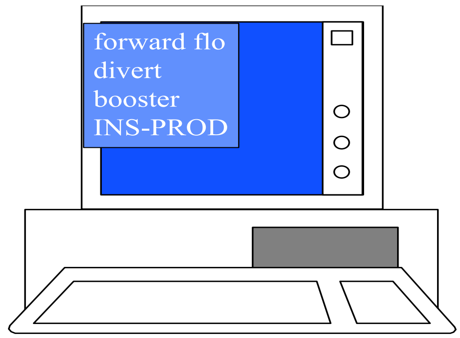
Food and Drug Administration

9 continued	9.3.1	Booster pump interwired with FDD	3 months	HTST ONLY	
	9.3.2	Booster Pumps Interwired with metering pump	3 months		
10	Milk-flow controls: cut-in and cut-out temperatures		3 months		Daily by operator(except HHST)
11	Holding TimeVerification		6 months		
	11.1	HTST except magnetic flow meter systems)	6 months		Adjusted product time if applicable
	11.2 a	Magnetic Flow Meters	6 months	HTST ONLY	
	11.2 b	Flow Alarm(HTST, HHST, and Aseptic	6 months		
	11.2 c	Loss of signal/low flow alarm(HTST,HHST and Aseptic) Flow cut-in/cut-out	6 months		
	11.2 d	Flow cut-in and Cut-out,	6 months	HTST ONLY	
	11.2 e	Time Delay (after divert)	6 months	HTST ONLY	
	11.3	HHST Indirect heating	6 months		
	11.4	HHST Direct Injection Heating	6 months		
	11.5	Direct Infusion Heating	3 months		
12	Controller: Sequence logic (HHST and Aseptic 12.2 or 12.2)		3 months		
13	Product pressure control switch setting (HHST and Aseptic)		3 months		
14	Injector differential pressure				
Remarks					
PLANT	IDENTITY OF PASTEURIZER		LOCATION	DATE	SANITARIAN





The evaluation of Computer Controlled Milk Pasteurization Systems

Reference FDA/MSB MI-88-11

CRITERIA FOR THE EVALUATION
OF
COMPUTERIZED SYSTEMS FOR
GRADE A MILK PASTEURIZATION SYSTEMS

BACKGROUND

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

1. **The computer**, unlike conventional systems which provide full-time monitoring of the public health controls, **performs its tasks sequentially**. 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;

    a) the public health computer is directed away from its tasks by another computer, or

    b) the computer program is changed, or

    c) a seldom used JUMP, BRANCH, OR GO TO INSTRUCTION, diverts the computer away from its public health control tasks.

2. In a computerized system, **the logic is easily changed** because the computer program is easily changed. A few keystrokes at the keyboard will completely change the control logic of the computer program. Conversely, hard wired systems require tools and a technician to make wiring changes. Once the hard-wired systems were properly installed and working, it was never changed. **This problem can be solved by sealing the access to the computer.** Some procedure is needed to ensure that the computer has the correct program when the regulatory seal is applied.

3. Error free computer installations cannot always be assured. For public health controls, the computer program must and can be made error-free. Since the programs required for public

health controls, unlike the very large complex programs, are relatively brief, error-free installations are attainable.

GLOSSARY

Address: The Numerical label on each input or output of the computer. The computer uses this address when communicating with the input or output.

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

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

EAPROM: An electrically alterable programmable, read-only memory. Individual memory locations may be altered without erasing the remaining memory.

EEPROM: An electrically erasable programmable, read-only memory. The entire memory is erased with one electrical signal.

EPROM: An erasable, programmable, read-only memory. The entire memory is erased by exposure to ultra-violet light.

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

Field alterable: A device 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: A data set applied to the input bus of the computer that is 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, tachometers, microswitches, and operator-controlled panel switches.

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

Last state switch: A manually operated switch located on the input/output bus that instructs the computer to place all outputs in the "on" or "off" or "last state" 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 located on the input/output bus that permits the operator to place any input or output in the on or off position, independently of any program instructions.

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

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

RAM: Random access memory. A memory used by the computer to run programs, store data, read input and control outputs. The computer may either read the memory or write data into the memory.

ROM: Read-only memory. A memory used by the computer to run its own internal unchangeable programs. The computer may only read from the memory; it cannot write in to the memory or alter the memory in any way.

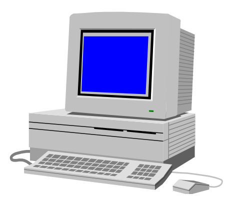
Standby status: the computer is turned on, running, and waiting for instructions to start processing input data. This instruction is usually accomplished by a manually-operated switch.

Status printing: Some computers are programmed to interrupt printing of the chart record and print the status of the 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 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 output addresses of the public health computer must be ready to process date at any time.

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

4. **The status of the Input/Output bus 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 solenoid relays, diodes, or optical-coupling devices to prevent the public health Input/Output bus from being driven by the other computer system.

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 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. **Computer programs must be stored in some form of read-only memory or (ROM),** and be available when the computer is turned on. Tapes or discs which allow access to the public health controls of the pasteurizer are not acceptable.

9. **The computer program access must be sealed.** Any telephone modem accesses must also be sealed. If the Input/Output bus contains "LAST STATE" switches, the Input/Output bus must also 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 or 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 buses 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 RESPONSE test, the temperature shall be printed or indicated fast enough that the Regulatory Official can place the temperature sensor in a water bath at a temperature 7^{o} F above "CUT-IN" and accurately determine the elapsed time when the temperature rises from a point 12^{o} F below CUT-IN to the time of CUT-IN which accurately times the thermometric response for pasteurizer recorder-controllers.

15. When the computer prints the frequency pen position (the position of the flow diversion device, forward or divert) at specific intervals, rather that 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. **<u>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.,</u>**

RECORDING THERMOMETER:

Temperature Accuracy
Time Accuracy
Daily accuracy check against indicating thermometer
Thermometric Response

FLOW DIVERSION DEVICE:

Valve seat leakage
Operation of valve stem(s)
Device assembly
Manual diversion
Response time
time delay intervals, if used

BOOSTER PUMP:

Proper wiring
proper pressure control settings

FLOW PROMOTING DEVICES:

Holding time
Auxiliary (separator, product pumps) 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 ROM (read only memory). 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 larger volume applications such as microwave ovens. For most small volume applications, the ROM 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 system, such as; magnetic flow meter timing systems and flow diversion device time delays. 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.

19. The logic diagrams for the flow diversion device and booster pump show programmed CIP operation as part of the computerized system. Some plant operators may wish to use another computer for CIP operations, so that CIP programs may be changed by plant personnel as needed. 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.

20. The public health computer logic must also **prevent illegal operation of flow promoting devices (timing pump, booster pump, other product pumps) when the mode switch is placed in the INSPECT position**. This will prohibit any forward flow of any sub-legal product when the flow diversion device assumes the forward flow position following (after the required time delay).

CONSIDERATIONS FOR USE OF NON-PUBLIC HEALTH COMPUTERS ON PASTEURIZER CONTROLS

1. BOOSTER PUMP.

The booster pump may be operated by the plant computer ONLY IN THE CIP MODE. Its operation must be interfaced through the flow diversion device control panel. If the booster pump has an address, which it will, in the computer, key it up. If the Output red light is "on" and blinking, then examine whether it is actually operating. It shouldn't in the PRODUCT mode. It may run in the CIP mode.

2. TIMING PUMP.

The timing pump may be operated by the plant computer only if the flow diversion device is properly assembled and only in the PRODUCT OR CIP MODE. NEVER IN THE INSPECT MODE.

3. STUFFING PUMP.

Stuffing pumps may be operated by the plant computer at any time the timing pump may be allowed to operate.

4. SEPARATOR BY-PASS VALVES.

a. Pasteurized separator by-pass valves may not be operated by the plant computer during diverted flow.

b. Raw product separator by-pass valves may not be operated by the plant computer when the timing pump is not running.

5. FLOW DIVERSION VALVE.

Flow diversion valves may be operated by plant computer only in the CIP mode.

Flow diversion device microswitches must not be controlled directly or overridden by the computer. There shall be no output "override" switches on the Output bus.

6. **MANUAL DIVERT.**

There are no direct wiring connections operable by the plant computer to the flow diversion device, i.e., FORCE ON or FORCE OFF capabilities.

7. **COMPUTERIZED PUBLIC HEALTH CONTROLS.**

ROMS and PROMS require verification only one time at the factory. EPROMS. EEPROMS, and EAPROMS require verification each time the unit is sealed.

RAMS, computer disks, and/or tapes are NOT ACCEPTABLE to operate computerized public health controls for pasteurizers.