	H.H.S.T. and ESL-Flow Schematic
Task	**Inspection Criteria**
1.17.01.01 Flow Schematic (HS=3)	**(A) Flow schematic** • Available; easily accessible • Complete - shows all components of the H.H.S.T. processing system, associated piping/components • Accurate; up-to-date
1.17.01.02 No Cross-Connections (HS=1)	**(A) H.H.S.T. system free of cross-connections between:** • For acceptable segregation between raw and pasteurized products - refer to the specific requirements in Chapter 17. • For other applications (i.e. washes or "mini-washes" while connected to product lines) - refer to Appendix 19 - 10 **(B) H.H.S.T. system verified with schematic and on-site**

	SCHEDULED PROCESS
Task	**Inspection Criteria**
1.17.02.01 Scheduled Process (HS=2)	**(A) Scheduled Process** • Complete and up-to-date • Available; accurate - documentation matches current equipment, controls and process **(B) Documentation of the scheduled process by a process authority that has scientific knowledge and experience in this field** • Scientific basis and theoretical calculations, regulatory requirements, equipment function and location, instrumentation and controls testing procedures, standard operating instructions manual etc. • Variations encountered in commercial production are accounted for in the process • Results of appropriate testing and shelf life studies after commissioning and significant alterations have been made to the system or scheduled process, evaluated to validate scheduled process • Critical factor specifications - Lists all the critical factors that may affect the achievement of pasteurization on the ESL product - Specifies minimum or maximum limits for each factor
1.17.02.02 Operating Instructions (HS=2)	**(A) Written operating instructions available and include:** • Procedures for monitoring critical factors - pasteurization or sterilization procedures at start up (prior to production) - operational procedures during production • Procedures for process deviations - includes product quarantine and release, investigation of occurrence
1.17.02.03 Critical Factor Adherence (HS=1)	**(A) Operation** • Observe the process in operation and evaluate adherence to the critical factor specifications listed in the scheduled process, e.g.: - Pre-process sterilization cycle - Temperature verification and recording at holding tube outlet - Flow rate as established by metering pump or magnetic flow meter system - Differential pressure verification and recording - Other critical factors verified and recorded - Process deviation procedures followed - Entries in plant's process control records and/or a separate file to indicate process deviations

	SCHEDULED PROCESS
Task	**Inspection Criteria**
1.17.02.04 Critical Factor Records (HS=2)	**(A) Records** • A representative sampling of the plant=s historical records must be assessed. • Records must be: - Available; easily accessible - Complete • Information must indicate: - All critical factors are monitored - Critical factor specifications are met - Satisfactory frequency of monitoring and verification • Documentation of process deviations in the plant's process control records and/or a separate file • Satisfactory follow-up on process deviations and documentation of actions taken. **(B) Process Control Records** • Must include the following information in permanent ink on every chart (12 hour charts for processing): - Plant name and address or registration number - Date, shift and batch number where applicable - Recorder unit identification where more than one is used - Product type and amount processed (may be recorded in production records) - Identification of sterilization/pasteurization cycles (e.g. indicate when water or product being run) - Identification of C.I.P., Amini-wash@ (if used) - Unusual occurrences and operator comments - Signature or initials of the operator - No overlapping of chart pen markings • For the S.T.L.R.: - Reading of the official indicating thermometer during processing. This reading must never be lower than the recording thermometer reading - Record of time the FDD is in the forward flow position, as indicated by the event pen - Recording thermometer tracing - Set point tracing when multiple set points used - And all sub-points under (1) above • For Meter Based Timing Systems: - Synchronized time with S.T.L.R. chart - Record of time the flow alarm is activated, as indicated by the event pen - Flow rate tracing - And all sub-points under (1) above • For Pressure Differential Controller-Recorder (Electronic Data can be acceptable) - Synchronized time with S.T.L.R. chart - Pressure tracing for raw product or media side and pasteurized product side OR pressure differential - And all sub-points under (1) above • For Pressure Limit Recorder (Electronic Data can be acceptable) - Synchronized time with S.T.L.R. chart

	SCHEDULED PROCESS
Task	**Inspection Criteria**
	- Holding tube operation pressure - And all sub-points under (1) above • For optional Temperature Recorder Controllers: - Synchronized time with S.T.L.R. chart - Recording thermometer tracing - And all the sub-points under (1) above **(C) Records to be retained at the plant for at least 1 year or the shelf life of the product**

	CONSTANT LEVEL TANK
Task	**Inspection Criteria**
1.17.03.01 General Conditions (HS=3)	**(A) General Inspection Criteria for Dairy Plant Equipment** **(B) Specific Areas of Interest** • Stainless steel construction • Clean and in good condition
1.17.03.02 Design (HS=2)	**(A) Requirements** • Air shall not be drawn in pasteurizer when operating at maximum capacity of F.C.D. - Raw product to drain to the outlet before the outlet becomes uncovered. Could be accomplished by: - bottom of the tank sloped by at least 2% to the outlet - top of the outlet pipe is lower than the lowest point in the tank
1.17.03.03 Cover (HS=3)	**(A) Requirements** • Removable - independent cover; or - inspection port • All openings flanged upwards and covered • Sanitary umbrella deflector on pipelines entering through the cover that are not clamped directly to the cover • Used during processing
1.17.03.04 Airspace and Overflow (HS=2)	**(A) Overflow point** • Tank rim or outlet (twice diameter of largest inlet piping to C.L.T.) **(B) Airspace** • Divert, recycle, C.I.P. line, and potable water lines - terminate and break to atmosphere above overflow point - atmospheric break between overflow point and lines must be at least two pipe diameters of the largest inlet piping to C.L.T.
1.17.03.05 Level Control Device (HS=3)	**(A) Requirements** • Automatic device • Sanitary design and construction

	FEED PUMP
Task	**Inspection Criteria**
1.17.04.01 General Conditions (HS=3)	**(A) Requirements** • Clean and in good condition • Centrifugal type • Entrapment of product in the by-pass line (if used) is precluded by: - close coupled by-pass connections, or - design of the valve permitting slight movement of the product through the by-pass line - other equally effective system
1.17.04.02 Location (HS=3)	**(A) Requirements** • Located between the C.L.T. and inlet to the raw product side of raw regenerator
1.17.04.03 Interwiring (HS=2)	**(A) Requirements** • Pressure differential controller is required when feed pump is used • Stops when F.C.D. is not Aallowed to run@ • Tested upon installation and at least every 6 months thereafter, and when changes occur • Appropriate records of testing on file

	REGENERATION
Task	**Inspection Criteria**
1.17.05.01 General Conditions (HS=2)	**(A) Heat Transfer Equipment** • Stainless steel or other corrosion resistant material • Sanitary design • Clean and good condition • No leakage during operation • Program in place to verify condition of heat transfer plates and tubes, gaskets, clamps, etc. - adequate frequency to ensure integrity - records to be kept that indicate annual pinhole testing or more often if required
1.17.05.02 Pressure Differentials (HS=2)	**(A) Operation** • Pressure on the raw side / media side of the regenerator must always be lower by at least 14 kPa (2 p.s.i.) than the pasteurized side as confirmed by a P.D.C. B recorder

	FLOW CONTROL DEVICE (F.C.D.)
Task	**Inspection Criteria**
1.17.06.01 **General Conditions** **(HS=3)**	**(A) Design** • Approved type of system - positive pump or - homogenizer or - meter based timing system (see Appendix 19 - 4) **(B) Condition** • Stainless steel or corrosion resistant material • Clean and in good condition **(C) Location** • Upstream from holding tube, normally between the outlet of the raw regeneration section and the inlet of the heating section **(D) Operation** • Cannot be excluded from the system during operation
1.17.06.02 **Set and Sealed** **(HS=1)**	**(A) Procedure** • Set at a flow rate to achieve the holding time specified in scheduled process • Means of preventing unauthorized speed changes for variable speed devices and single speed devices capable of being altered (belts, pulleys) - seal on the device to prevent unauthorized adjustments - access to alarm settings sealed on MBTS • Checked upon installation and annually thereafter appropriate records of testing on file • Re-evaluated and sealed (if necessary) after any alterations or repairs **(B) Records** • Holding time calculations and flow rate measurements are available • Testing reflects scheduled process specifications • Records are accurate, complete and available
1.17.06.03 **Fail Safe Capability** **(HS=2)**	**(A) General Conditions** • No by-pass line during processing **(B) Meter Based Timing System Used as F.C.D.** • Must have appropriate controls and recorder etc. (see Appendix 4) • High flow alarm: divert flow occurs when flow rate is higher than the value specified in the scheduled process • Low flow/Signal loss alarm: divert flow occurs upon low flow or signal loss • Alarm pen tracks flow recorder pen

	HEATING SECTION
Task	**Inspection Criteria**
1.17.07.01 General Conditions (HS=2)	**(A) Heat Transfer Equipment** • Stainless steel or other corrosion resistant material • Sanitary design • Clean and good condition • No leakage during operation **(B) Indirect Heating** • Program in place to check condition of heat transfer plates, gaskets, tube, clamps, etc. - appropriate records kept to show testing has occurred **(C) Direct Heating** • Proper design to ensure complete condensing of the steam inside the injector • See Appendix 19 - 15
1.17.07.02 Heating Medium (HS=3)	**(A) Direct addition or exposure to steam** • Only culinary steam (see Appendix 19 - 1) shall be used • Steam shall be as free as possible of non-condensable gases • Boiler chemicals/additives must be dairy safe and approved
1.17.07.03 Pressure Limit Recorder Controllers (HS=2)	**(A) Pressure Limit Recorder Controller** • Required in H.H.S.T. systems capable of operating with less than 518 kPa (75 psi) pressure in the holding tube • Monitors and controls the product pressure in the holding tube to ensure product remains in liquid phase • Pressure switch settings correspond to operating temperature in Appendix 19 - 16 • Product divert valve assumes divert position when product pressure in holding tube drops below a prescribed value, depending on operating temperature **(B) Differential Pressure Limit Indicator** • Required for direct heating systems with steam injectors only, to ensure isolation of the injection chamber so product is uniformly heated in the chamber • Product divert valve assumes divert position when the differential pressure across injector drops below 69 kPa (10 psi) **(C) Records** • Available; easily accessible • Tests completed according to required methods and standards • Satisfactory follow up on out of specification findings and documentation of actions taken
1.17.07.04 Controllers/ Settings Sealed (HS=2)	**(A) Requirements** • Access to controller and switch settings must be sealed to prevent unauthorized adjustments

	HEATING SECTION
Task	**Inspection Criteria**
1.17.07.05 Ratio Controller (Direct Heating Systems) (HS=3)	**(A) Requirements** • A ratio controller shall be used on direct heating systems to prevent water adulteration of the product • Sensors shall be located just prior to the steam injection point, and immediately after the product exits the vacuum chamber • The ratio controller shall automatically control the pre-heat steam supply or the flash chamber vacuum to prevent adulteration of the product with water - interlocked with the vacuum pump and/or steam controller and automatically monitors and controls the amount of vacuum applied and/or the amount of steam injected • Means to be provided to prevent the back up and overflow of water from the vacuum condenser into the vacuum chamber

	HOLDING
Task	**Inspection Criteria**
1.17.08.01 **General Conditions** **(HS=3)**	**(A) Holding Section** • Sanitary design and construction • Clean and in good mechanical condition • Installed in correct location - after F.C.D. with no intervening flow promoters, and - after final heating section and - prior to FDD or any cooling section • No portion of tube can be left out • Free of external heat source
1.17.08.02 **Slope and Support** **(HS=2)**	**(A) Holding Section** • Continuous upwards slope (including elbows) of at least 2% • Permanent support
1.17.08.03 **Holding Verification and Records** **(HS=2)**	**(A) Records** • Evidence of holding time determination by calculation method and is specified in the scheduled process • For Direct Injection Systems: - extra condensate volume from steam added is to be included in the holding tube calculation **(B) Frequency** • Holding tube length calculated at installation and after any change is made to system that could affect the holding time • Corresponding flow rate checked annually, whenever the seal is broken on the F.C.D., and after any change is made to the system that could affect the holding time

	FLOW DIVERSION DEVICE (FDD)
Task	**Inspection Criteria**
1.17.09.01 General Conditions (HS=2)	**(A) Flow Diversion Device** • Accepted design that prevents potentially unpasteurized product from contaminating the fillers or surge tank • Dual-stem or steam-block types: • For dual-stem types: - Incorporate two three-way valves in series - Leak detect line is separate from the divert line and is free draining from the lower port of the leak detect valve back to the CLT or other acceptable receptacles • For steam-block types: - Incorporates a divert valve and one or more steam block valves - Divert valve is fail-safe, position detectable and equipped with means to provide an alarm and protection when required - Steam block valve shall have continuous supply of steam and a continuous visible bleed of steam or condensate to the drain - Steam block valve equipped with an interlocked RTD located at the lowest level of the barrier to detect any fluid leakage into the barrier and a means to alert the operator of a steam barrier failure, with appropriate action taken as indicated by the scheduled process deviation procedure • Designed such that the valve seat which separates the diverted product from forward flow is pasteurized on all sides • Clean and in good condition - valves, seals and "O" rings - valve stem moves with ease • Clean and unrestricted air supply • Proper control panel - free of any device or switches that may jeopardize the safety of the pasteurized product - micro-processor control permitted for valves without 1.17.11.07 conformance, but valve operation must meet test standards • Non-adjustable valve stem length • No quick disconnect couplings on air lines if external solenoids
1.17.09.02 Return Line (HS=2)	**(A) Requirements** • Free flow of product from product divert valve without obstructions • Flash cooler permitted
1.17.09.03 Location (HS=2)	**(A) Requirements** • Installed downstream from the regenerator , prior to surge tanks or fillers

	FLOW DIVERSION DEVICE (FDD)
Task	**Inspection Criteria**
1.17.09.04 Fail Safe Divert Capability (HS=1)	**(A) Divert Conditions (indirect heating systems)** ● FDD will automatically divert product from fillers or surge tanks when: - the product temperature in the sensing chamber drops below the specification in the scheduled process - the differential pressure between pasteurized product and unpasteurized product or heat transfer media is less than 14 kPa (2 psi) in the regenerator - adequate product pressure is not maintained in the holding tube to prevent boiling (less than 69kPa (10 psi) above the boiling pressure of the product in the holding tube) - there is loss of electrical power or compressed air to the FDD solenoids - an excessive flow rate is detected for systems utilizing a magnetic flow meter as a flow control device **(B) Divert Conditions (direct heating systems)** ● FDD will automatically divert product from fillers or surge tanks when: - the product temperature in the holding tube drops below the specification in the scheduled process - the differential pressure between pasteurized product and unpasteurized product or heat transfer media is less than 14 kPa (2 psi) in the regenerator - adequate product pressure is not maintained in the holding tube to prevent boiling (less than 69kPa (10 psi) above the boiling pressure of the product in the holding tube) - there is loss of electrical power or compressed air to the product divert device solenoids - for steam infusion systems, there is loss of predetermined parameters at steam infusion chamber exits - for steam injector systems, improper differential pressures across the steam injectors at the holding tube (a 69kPa (10 psi) drop across the injector is required) - an excessive flow rate is detected for systems utilizing a magnetic flow meter as a flow control device **(C) Inter-wiring** ● **FDD installed with position detection capabilities to provide an electrical signal to the S.T.L.R. or legal panel.** **(D) Equipment pasteurization capability** ● After divert flow events: - all product contact surfaces between the holding tube and the FDD shall be held at or above the required pasteurization temperature continuously and simultaneously for at least the required pasteurization time - during CIP and pasteurization cycles, a properly designed valve system is used in accordance with Appendix 19 - 10 **(E) Records** ● Available; easily accessible ● Tests completed according to required methods and frequency ● Satisfactory follow up on out of specification findings and documentation of actions taken

	FLOW DIVERSION DEVICE (FDD)
Task	**Inspection Criteria**
1.17.09.05 **Leak Detect** **(HS=1)**	**(A) Requirements** • Systems where the filler continues to operate from a surge tank while the FDD is in the divert position, and FDD is a steam-block type, shall use a properly designed aseptic barrier system to separate pasteurized product and potentially under processed product (see Appendix 19 - 10). Aseptic barrier system is not mandatory for systems that use a dual-stem type FDD valve assemble • Barrier may include one or more steam blocks but must include a RTD or other acceptable temperature sensor at the lowest point of the barrier to detect barrier failure due to steam loss or fluid leakage • Barrier failure by temperature sensing device triggers an alarm system to alert operator to the alarm condition, immediately initiating a "shut down sequence" as specified in the scheduled process • Process deviation procedure followed after barrier failure and deviation log book entry completed - deviation procedure includes the date and time of the process deviation, investigation into the cause of the process deviation, action taken on Aheld product@ and other corrective measures **(B) Location** • The segregating valve system is located between the FDD and the surge tank
1.17.09.06 **Device Sealed** **(HS=2)**	**(A) Requirements** • FDD legal panel and valve position detector cover(s) must be sealed appropriately • Valve position detectors, solenoids, relays, and if a PLC or micro-processor is used, access to programming functions, I/O ports must be sealed

	INDICATING THERMOMETER
Task	**Inspection Criteria**
1.17.10.01 General Conditions (HS=2)	**(A) Requirements** • Clean and in good condition • Uniquely identified (e.g. serial #) • Mercury Type - direct reading - no column splitting - easy to read - contained in corrosion resistant case • Resistance Thermal Devices (RTD=s) - approved unit - utilizing two separate RTD sensors verifying each other - meets the design requirements in Appendix 19 - 13
1.17.10.02 Location/ Accessibility (HS=2)	**(A) Requirements** • Sensor located at the end of the holding tube after the S.T.L.R. sensor. The distance between the 2 probes is not more than 30 cm (12 inches) • Easily and safely accessible for reading by the operator
1.17.10.03 Specifications (HS=2)	**(A) Requirements** • Graduated in 0.5ºC (1ºF) divisions with not more than 9.4ºC (17ºF) per 25 mm (1 inch) of graduated scale • No stem fitting threads exposed to product
1.17.10.04 Calibration/ Records (HS=1)	**(A) Calibration** • Temperature accuracy • Thermometric response • Frequency of calibration (upon installation and at least once every 6 months) **(B) Records** • Available; easily accessible • Tests completed according to required methods and standards • Satisfactory follow up on out of specification findings and documentation of actions taken - product safety assessment required
1.17.10.05 Sealed (HS=2)	**(A) Requirements** • Access to thermometer adjustment sealed to prevent tampering

	SAFETY THERMAL LIMIT RECORDER (S.T.L.R.)
Task	**Inspection Criteria**
1.17.11.01 General Conditions (HS=3)	**(A) Requirements** ● Good mechanical and sanitary condition ● Proper design - meets the criteria established by manufacturer - unit manufactured for S.T.L.R. usage - modifications performed by or authorized by manufacturer - moisture proof case ● Operated as specified by the manufacturer ● Covers in place to prevent access to public health adjustments ● Temperature sensing probe for the recording pen installed with a pressure-tight seal against the inside wall of the pipe with no threads exposed to milk or milk products ● Air operated type should have a supply of clean, dry air ● Records and frequency of servicing (at least once a year) ● Absence of unidentified/unauthorized switches or devices that may jeopardize the safety of product
1.17.11.02 Location (HS=2)	**(A) S.T.L.R. Sensing Probe** ● single probe which senses the temperature for both the temperature recording pen and the cut-out control is installed in the sensing chamber before the indicating thermometer probe, with a distance of not more than 30 cm (12 inches) between the probes

	SAFETY THERMAL LIMIT RECORDER (S.T.L.R.)
Task	**Inspection Criteria**
1.17.11.03 Specifications (HS=3)	**(A) Design** • Positive drive mechanism equipped with a system to prevent slippage • Proper charts - correspond with chart # displayed on identification plate of S.T.L.R. • Appropriate chart scale span, graduations and time scale divisions - Graduations not to exceed 1ºC (2ºF) within a range of 5.5ºC (10ºF) of the processing temperature - Chart scale not more than 30ºC (55ºF) per 25 mm (1 inch) within a range of 11ºC (20ºF) of the processing temperature • Pen functional, tracking proper time line • Pen easily calibrated / adjusted
1.17.11.04 Thermal Limit Controller Sequence Logic (HS=1)	**(A) Requirements** • During processing mode, forward flow shall not occur until the temperature of all product contact surfaces from the holding tube to the FDD is at or above the required system pasteurization temperature as specified in the scheduled process • For indirect heating systems, forward flow shall not occur until all conditions identified in the scheduled process have been met which includes requirements that the sensors at the FDD and at the holding tube have reached the required temperature for the necessary length of time specified for system pasteurization/sterilization as per the scheduled process. • For direct heating systems, forward flow shall not occur until the sensors located at the holding tube, the coolest part of the vacuum chamber or other coldest points determined by the process authority, and at the FDD have reached the required temperature for the necessary time period specified for system pasteurization or sterilization as per the scheduled process. • Failure of any safe forward flow condition shall cause the FDD to immediately assume the divert flow position unimpeded by the thermal limit controller unit • The settings and adjustments for the thermal controller unit are enclosed and sealed to prevent unauthorized tampering

	SAFETY THERMAL LIMIT RECORDER (S.T.L.R.)
Task	**Inspection Criteria**
1.17.11.05 Calibration / Records (HS=2)	**(A) Calibration** • Temperature accuracy • Time accuracy • Cut in / Cut out • Thermal limit controller sequence logic • Frequency of calibration (at least once every 6 months) • Recording thermometer check against indicating thermometer (daily) - Recording thermometer not higher than indicating thermometer **(B) Records** • Available; easily accessible • Tests completed according to required methods and standards • Satisfactory follow up on out of specification findings and documentation of actions taken
1.17.11.06 Sealed (HS=2)	**(A) Requirements** • S.T.L.R. cut in / cut out adjustments must be sealed • Enclosure for the settings and adjustments for the thermal limit controller sequence logic must be sealed
1.17.11.07 Program Logic Controllers and Computers (HS=1)	**(A) Non-Public Health Computers** • Computer may not control any public health safeguards when in production cycle • Computer may control public health safeguards during C.I.P. cycle • Computer may control non-public health components during production and C.I.P. cycles **(B) Public Health Computers** See Appendix 19 - 5, Criteria for the Evaluation of Computerized Public *Health Controls.* Logic diagrams in App.5 do not apply to HHST systems • A Computer used for control of the public health functions of a HHST must be a dedicated unit with no other assignments • The computer shall not be controlled or addressable by any other computer: - read-only status of inputs and outputs may be acceptable if suitably isolated - ready to process data at all times • A separate computer must be used for each sterilization / pasteurization system • All public health controls must assume the fail-safe position - upon loss of power to the computer - when the computer is placed on standby - during power-up when outputs are in the default mode • Input/output terminals with last-state switches must have the switches placed in the fail-safe position • Input/output terminals must not have any operator override switches • The computer program must be stored in Read- Only-Memory (ROM) • If the computer also prints the recording charts: - recorder calibrations for temperature and time must be maintained as in Task 1.17.11.05 - recording chart specifications must meet the requirements

	SAFETY THERMAL LIMIT RECORDER (S.T.L.R.)
Task	**Inspection Criteria**
	of Task 1.17.11.03 - recording charts must be printed concurrently with sterilizer operation - computer must not be diverted from its public health tasks for more than 1 second during printing, and must complete one full cycle of its public health tasks before returning to printing - the frequency pen position shall be printed such that the temperature can easily be determined where the product divert valve changes position **(C) Documentation (All)** • Complete and accurate documentation of interwiring, pneumatic controls, programming logic and ladder logic diagrams must be available • Programming logic maybe defined by program listings and descriptive narrative text • Vendor is responsible for ensuring PLC /computer installations comply with requirements of Appendix 19 - 5 **(D) Testing** • Testing procedures must be provided by the vendor • For **Non-Public Health Computers:** - Test procedures to verify that public health safeguards are not under the control of the computer through force-on or other actions during the production cycle • For Public Health Computers: - Test procedures to verify that the correct computer program is installed in ROM - Methods for testing proper operation of all applicable public health controls as required in the testing procedures manual **(E) Access sealed (All)** • Microprocessor access ports, modem ports, and input/output terminals must be sealed to prevent unauthorized changes or tampering • The control panel holding the solenoids for the divert valves must be sealed A reliable third party may connect remotely to the PLC to repair something in the system providing it is not a permanent connection and there is documentation showing date of entry, purpose of re-programming, who did it, who verified repair, seal breakage, re-sealing and new seal number

	PRESSURE DIFFERENTIAL RECORDER CONTROLLERS (P.D.C. - recorder)
Task	**Inspection Criteria**
1.17.12.01 General Conditions (HS=2)	**(A) Pressure Differential Recorder Controllers** • Required to monitor and record pressures • Sensors clean and in good mechanical condition • Easy dismantling of sensors for inspection • Moisture proof enclosure for indicating / recording unit • Interwired with FDD - divert occurs when the pasteurized product pressure in the regenerator does not exceed the pressure on the raw side of the regenerator by at least 14 kPa (2 psi) - in milk-to-heat transfer medium-to-milk regenerators, divert occurs when the pasteurized product pressure in the pasteurized milk section does not exceed the pressure on the heat transfer medium side by at least 14 kPa (2 psi) **(B) Gauges (if used)** • Clean and in good condition
1.17.12.02 Location (HS=2)	**(A) Raw Product-to-Pasteurized Product Regeneration** • Raw product sensor between the feed pump and the raw product inlet to the regenerator • Pasteurized product sensor at, or downstream from, pasteruized product outlet of regenerator **(B) Product to-Heat Transfer Medium-to Product Regeneration** • Raw side pressure sensor in water loop after the water pump (location of highest media pressure) • Pasteurized side pressure sensor in product outlet line from the pasteurized side of the regenerator (location of lowest pasteurized product pressure)

	PRESSURE DIFFERENTIAL RECORDER CONTROLLERS (P.D.C. - recorder)
Task	**Inspection Criteria**
1.17.12.03 Specifications (HS=3)	**(A) Requirements** • Proper Charts - correspond with chart # displayed on identification plate of pressure differential recorder controller - circular charts graduated for 12 hours maximum • Scale divisions not to exceed 14 kPa (2 psi) on scale of not more than 140 kPa (20 psi) • Pens to record raw side pressure and pasteurized side pressure or pressure differential
1.17.12.04 Calibration / Records (HS=2)	**(A) Pressure Differential Recorder Controller Calibration** • Product diversion with improper regenerator pressure differential • Probe calibration • Frequency of calibration (at least once every 6 months) **(B) Gauges** • Checked for accuracy upon installation and at least once every 6 months **(C) Records** • Available; easily accessible • Tests completed according to required methods and standards • Satisfactory follow up on out of specification findings and documentation of actions taken
1.17.12.05 Sealed (HS=2)	**(A) Pressure Differential Controller / Recorder** • Access to calibration adjustments must be sealed to prevent tampering

	AUXILIARY TEMPERATURE RECORDERS / CONTROLLERS
Task	**Inspection Criteria**
1.17.13.01 Temperature Recorders / Controllers (HS=3)	**(A) Requirements** • Clean and in good condition • Moisture proof • Positive drive mechanism equipped with a system to prevent slippage of chart • Proper charts, corresponding to chart part number • Pens operational, easily calibrated, tracking proper time line • Records and frequency of servicing (at least once a year)

	COOLING SECTION
Task	**Inspection Criteria**
1.17.14.01 General Conditions (HS=2)	**(A) Requirements** • Clean and in good condition • Stainless steel or other corrosion resistant material • Sanitary design • No leakage during operation • Program in place to check condition of heat transfer plates and tubes, gaskets, tube, clamps, etc. - adequate frequency to ensure integrity - records to be kept
1.17.14.02 Pressure Differentials (HS=2)	**(A) Monitored or Controlled** • Pressure of the cooling media shall be 14 kPa (2psi) less than the product pressure during forward flow. During diverted flow and shutdown conditions pressure on the cooling media side is less than the pasteurized product side • If there is no automated mechanism, establishment has a written program which includes: - person responsible, what is done, how it is done, how often it is done (frequency), records to be kept, and results of monitoring, verification procedures (both on-site and record review) and actions taken for deviant situations. - records of pressures recorded a minimum of twice a day during production, at beginning and end of run - microbiological cooling media checks at least once per week - pH testing of cooling media at least once per week - visual cooling media checks at least once per week - pinhole testing and plate teardowns at least once every six months - plate replacement program **(B) Gauges** • Clean and in good condition • Calibrated • Located at cooling media inlet and pasteruized product outlet

	COOLING SECTION
Task	**Inspection Criteria**
1.17.14.03 **Cooling Medium** **(HS=2)**	**(A) Requirements** • Checked at least monthly for microorganisms (e.g. psychrotrophs, coliforms) • Any additives used must be dairy safe and approved

	HOMOGENIZER
Task	**Inspection Criteria**
1.17.15.01 **General Conditions** **(HS=3)**	**(A) General Inspection Criteria for Dairy Plant Equipment** **(B) Specific Areas of Interest** • Stainless steel product contact surfaces • Clean and in good condition - filters - homogenizer valves - pistons - seat valves - pressure gauges • Appropriate gauges
1.17.15.02 **Homogenizer Larger Than F.C.D.** **(HS=2)**	**(A) Homogenizer Larger Than F.C.D., Downstream From F.C.D.** • Must not reduce pressure in the holding tube • Must not reduce holding time • Manufacturer to demonstrate that flow rate not affected

	SURGE TANK
Task	**Inspection Criteria**
1.17.16.01 **General Conditions** **(HS=2)**	**(A) General Inspection Criteria for Dairy Plant Equipment** **(B) Specific Areas of Interest** • Clean and in good condition - tank, valves, thermometers, sensors • Installed downstream from FDD • After a divert event, the fillers and surge tanks must be emptied and re-sanitized unless the surge tank is protected by one or more steam barriers at the FDD (See Appendix 19 - 10)

	STUFFING PUMP
Task	**Inspection Criteria**
1.17.17.01 General Conditions (HS=2)	**(A) General Inspection Criteria for Dairy Plant Equipment** **(B) Specific Areas of Interest** • Clean and in good condition - impellers - back plates • Painted exterior - clean - free of flaking paint and rust
1.17.17.02 Proper Installation/ Operation (HS=2)	**(A) Requirements** • Interwired so that the pump shuts off when F.C.D. is not allowed to run - Test performed upon installation, at least once every 6 months and when micro-switch is re-set or replaced and records kept • Must not influence the proper pressure relationship within the regeneration section • Must not reduce the holding time

	PACKAGING
Task	**Inspection Criteria**
1.17.18.01 Packaging Conditions (HS=2)	**(A) Requirements** • Packaging materials are received and stored in a sanitary manner • Handling and loading of packaging materials from the time they are received into the processing area and when they are in use does not pose a contamination risk • ESL pasteurized products stored at 4ºCor less

	RECORD KEEPING
Task	**Inspection Criteria**
1.17.19.01 Packaging Records (HS = 3)	**(A) Requirements** • All critical factors specified in the scheduled process must be measured and recorded at intervals of sufficient frequency to ensure that the factors are within limits specified in the scheduled process • Records available, easily accessible • Satisfactory follow up on out of specification findings and documentation of actions taken