



Task	Inspection Criteria
<b>1.14.01.01 Flow Schematic (HS=3)</b>	<b>(A) Flow schematic</b> <ul style="list-style-type: none"><li>• Available; easily accessible</li><li>• Complete<ul style="list-style-type: none"><li>○ shows all components of the aseptic processing, aseptic storage (if applicable), associated piping/components and aseptic packaging</li></ul></li><li>• Accurate; up-to-date</li></ul>
<b>1.14.01.02 No Cross-Connections (HS=1)</b>	<b>(A) System free of cross-connections:</b> <ul style="list-style-type: none"><li>• Proper segregation of incompatible products<ul style="list-style-type: none"><li>○ separate vessels and pipelines for incompatible products</li><li>○ physical breaks at connections between incompatible products</li></ul></li><li>• If part of the APPS is cleaned/sterilized while product is processed:<ul style="list-style-type: none"><li>○ properly designed valve arrangement for segregation of cleaning solutions from raw milk (see Appendix 19 - 10), properly designed aseptic barrier for segregation of cleaning solutions from sterilized milk products, and</li><li>○ process deviation procedure in place to handle aseptic barrier alarms</li></ul></li></ul> <b>(B) Verified on schematic and on-site</b>

	SCHEDULED PROCESS
Task	Inspection Criteria
<b>1.14.02.01</b> <b>Scheduled Process</b> <b>(HS=2)</b>	<p><b>(A) Scheduled Process</b></p> <ul style="list-style-type: none"> <li>• Complete and up-to-date</li> <li>• Available; accurate             <ul style="list-style-type: none"> <li>◦ documentation matches current equipment, controls and process</li> </ul> </li> </ul> <p><b>(B) Documentation of the scheduled process by the qualified Process Authority (equipment supplier, academia etc)</b></p> <ul style="list-style-type: none"> <li>• Scientific basis and theoretical calculations, regulatory requirements, equipment function and location, instrumentation and controls testing procedures, standard operating instructions manual etc.</li> <li>• Identifies aseptic zones and methods of maintaining commercial sterility</li> <li>• Results of incubation trials after commissioning and significant alterations, evaluated to validate scheduled process</li> <li>• Critical factor specifications             <ul style="list-style-type: none"> <li>◦ Lists all the critical factors necessary to reach and maintain commercial sterility for the product contact surfaces, the product, and the container</li> <li>◦ Specifies minimum or maximum limits for each factor</li> </ul> </li> </ul>
<b>1.14.02.02</b> <b>Operating Instructions</b> <b>(HS=2)</b>	<p><b>(A) Written operating instructions available and include:</b></p> <ul style="list-style-type: none"> <li>• Procedures for monitoring critical factors             <ul style="list-style-type: none"> <li>◦ pre-sterilization procedures to bring the system to commercial sterility prior to production</li> <li>◦ operational procedures to ensure commercial sterility is maintained during production</li> </ul> </li> <li>• Procedures for process deviations             <ul style="list-style-type: none"> <li>◦ includes product quarantine and release, investigation of occurrence</li> </ul> </li> </ul>
<b>1.14.02.03</b> <b>Critical Factor Adherence</b> <b>(HS=1)</b>	<p><b>(A) Operation</b></p> <ul style="list-style-type: none"> <li>• Observe the process in operation and evaluate adherence to the critical factor specifications listed in the scheduled process, e.g.:             <ul style="list-style-type: none"> <li>◦ Pre-process sterilization cycle</li> <li>◦ Temperature verification and recording at holding tube outlet</li> <li>◦ Flow rate as established by metering pump or magnetic flow meter system</li> <li>◦ Differential pressure verification and recording</li> <li>◦ Sterile air pressure in surge tank</li> <li>◦ Aseptic valve performance</li> <li>◦ Other critical factors verified and recorded</li> <li>◦ Process deviation procedures followed</li> <li>◦ Entries in log book to indicate process deviations</li> </ul> </li> </ul>

	SCHEDULED PROCESS
Task	Inspection Criteria
<b>1.14.02.04</b> <b>Critical Factor</b> <b>Records</b> <b>(HS=2)</b>	<p><b>(A) Records</b></p> <ul style="list-style-type: none"> <li>• A representative sampling of the plant=s historical records must be assessed.</li> <li>• Records must be: <ul style="list-style-type: none"> <li>○ Available; easily accessible</li> <li>○ Complete</li> </ul> </li> <li>• Information must indicate: <ul style="list-style-type: none"> <li>○ All critical factors are monitored</li> <li>○ Critical factor specifications are met</li> <li>○ Satisfactory frequency of monitoring and verification</li> </ul> </li> <li>• Documentation of process deviations in deviation log book</li> <li>• Satisfactory follow-up on process deviations and documentation of actions taken.</li> </ul> <p><b>(B) Recording Charts</b></p> <ul style="list-style-type: none"> <li>• Must include the following information in permanent ink on every chart (12 hour charts for processing). (If operations extend beyond 12 hours, a 24-hour chart can be used if it can provide an equivalent level of accuracy and clarity to a 12-hour chart): <ul style="list-style-type: none"> <li>○ Plant name and address or registration number</li> <li>○ Date, shift and batch number where applicable</li> <li>○ Recorder unit identification where more than one is used</li> <li>○ Product type and amount processed</li> <li>○ Identification of sterilization cycles</li> <li>○ Identification of C.I.P., Amini-wash® (if used)</li> <li>○ Unusual occurrences</li> <li>○ Signature or initials of the operator</li> <li>○ No overlapping of chart pen markings</li> </ul> </li> <li>• For the S.T.L.R.: <ul style="list-style-type: none"> <li>○ Reading of the official indicating thermometer during processing. This reading must never be lower than the recording thermometer reading</li> <li>○ Record of time the product divert valve is in the forward flow position as indicated by the event pen</li> <li>○ Recording thermometer tracing</li> <li>○ Set point tracing when multiple set points used</li> <li>○ And all sub-points under (1) above</li> </ul> </li> <li>• For Meter Based Timing Systems: <ul style="list-style-type: none"> <li>○ Synchronized time with S.T.L.R. chart</li> <li>○ Record of time the flow alarm is activated, as indicated by the event pen</li> <li>○ Flow rate tracing</li> <li>○ And all sub-points under (1) above</li> </ul> </li> </ul>

	SCHEDULED PROCESS
Task	Inspection Criteria
<b>1.14.02.04</b> <b>Critical Factor</b> <b>Records</b> <b>(HS=2)</b> <b>(continued)</b>	<ul style="list-style-type: none"> <li>• For Pressure Differential Controller-Recorder               <ul style="list-style-type: none"> <li>○ Synchronized time with S.T.L.R. chart</li> <li>○ Pressure tracing for raw product or media side and sterilized product side OR pressure differential</li> <li>○ And all sub-points under (1) above</li> </ul> </li> <li>• For Pressure Limit Recorder               <ul style="list-style-type: none"> <li>○ Synchronized time with S.T.L.R. chart</li> <li>○ Holding tube operation pressure</li> <li>○ And all sub-points under (1) above</li> </ul> </li> <li>• For the aseptic surge tank(s):               <ul style="list-style-type: none"> <li>○ Record of tank sterilization</li> <li>○ Record of pressure</li> <li>○ And all sub-points under (1) above</li> </ul> </li> <li>• For Temperature Recorder Controllers:               <ul style="list-style-type: none"> <li>○ Synchronized time with S.T.L.R. chart</li> <li>○ Recording thermometer tracing</li> <li>○ And all the sub-points under (1) above</li> </ul> </li> </ul> <p><b>(C) Records to be retained at the plant for at least 3 years or the shelf life of the product (if more than 3 years)</b></p>

	CONSTANT LEVEL TANK
Task	Inspection Criteria
1.14.03.01 General Conditions (HS=3)	<p>(A) General Inspection Criteria for Dairy Plant Equipment</p> <p>(B) Specific Areas of Interest</p> <ul style="list-style-type: none"> <li>Stainless steel construction</li> <li>Clean and in good condition</li> </ul>
1.14.03.02 Design (HS=2)	<p>(A) Requirements</p> <ul style="list-style-type: none"> <li>Air shall not be drawn in the system when operating at maximum capacity of F.C.D. <ul style="list-style-type: none"> <li>Raw product to drain to the outlet before the outlet becomes uncovered. Could be accomplished by: <ul style="list-style-type: none"> <li>bottom of the tank sloped by at least 2% to the outlet</li> <li>top of the outlet pipe is lower than the lowest point in the tank</li> </ul> </li> </ul> </li> </ul>
1.14.03.03 Cover (HS=3)	<p>(A) Requirements</p> <ul style="list-style-type: none"> <li>Removable <ul style="list-style-type: none"> <li>independent cover; or</li> <li>inspection port</li> </ul> </li> <li>All openings flanged upwards and covered</li> <li>Sanitary umbrella deflector on pipelines entering through the cover that are not clamped directly to the cover</li> <li>Used during processing</li> </ul>
1.14.03.04 Airspace and Overflow (HS=2)	<p>(A) Overflow point</p> <ul style="list-style-type: none"> <li>Tank rim or outlet (twice diameter of largest inlet piping to C.L.T.)</li> </ul> <p>(B) Airspace</p> <ul style="list-style-type: none"> <li>Divert, recycle, C.I.P. line/spray ball, and potable water lines <ul style="list-style-type: none"> <li>terminate and break to atmosphere above overflow point</li> <li>atmospheric break between overflow point and lines must be at least two pipe diameters of the largest inlet piping to C.L.T.</li> </ul> </li> </ul>
1.14.03.05 Level Control Device (HS=3)	<p>(A) Requirements</p> <ul style="list-style-type: none"> <li>Automatic device</li> <li>Sanitary design and construction</li> </ul>

	FEED PUMP
Task	Inspection Criteria
<b>1.14.04.01</b> <b>General Conditions</b> <b>(HS=3)</b>	<b>(A) Requirements</b> <ul style="list-style-type: none"> <li>• Clean and in good condition</li> <li>• Centrifugal type</li> <li>• Entrapment of product in the by-pass line (if used) is precluded by: <ul style="list-style-type: none"> <li>○ close coupled by-pass connections, or</li> <li>○ design of the valve permitting slight movement of the product through the by-pass line</li> <li>○ other equally effective system</li> </ul> </li> </ul>
<b>1.14.04.02</b> <b>Location</b> <b>(HS=3)</b>	<b>(A) Requirements</b> <ul style="list-style-type: none"> <li>• Located between the C.L.T. and inlet of raw regenerator</li> </ul>
<b>1.14.04.03</b> <b>Interwiring</b> <b>(HS=2)</b>	<b>(A) Requirements</b> <ul style="list-style-type: none"> <li>• Pressure differential controller is required when feed pump is used</li> <li>• Stops when F.C.D. is not allowed to run</li> <li>• Tested upon installation and at least every 6 months thereafter, and when changes occur</li> <li>• Appropriate records of testing on file</li> </ul>

	REGENERATION
Task	Inspection Criteria
<b>1.14.05.01</b> <b>General Conditions</b> <b>(HS=2)</b>	<b>(A) Heat Transfer Equipment</b> <ul style="list-style-type: none"> <li>• Stainless steel or other corrosion resistant material</li> <li>• Sanitary design</li> <li>• Clean and good condition</li> <li>• No leakage during operation</li> <li>• Program in place to verify condition of heat transfer plates, gaskets, tubes, clamps, etc. <ul style="list-style-type: none"> <li>○ adequate frequency to ensure integrity</li> <li>○ records to be kept that indicate annual pinhole testing or more often if required</li> <li>○ document the cause of failure (e.g. age, compression, metal fatigue), action taken to correct failure, plate replacement</li> </ul> </li> </ul>
<b>1.14.05.02</b> <b>Pressure</b> <b>Differentials</b> <b>(HS=2)</b>	<b>(A) Operation</b> <ul style="list-style-type: none"> <li>• Pressure on the raw side / media side of the regenerator must always be lower by 14 kPa (2 p.s.i.) than the sterilized side as confirmed by a P.D.C. B recorder</li> </ul>

	FLOW CONTROL DEVICE (F.C.D.)
Task	Inspection Criteria
<b>1.14.06.01</b> <b>General Conditions</b> <b>(HS=3)</b>	<p>(A) <b>Design</b></p> <ul style="list-style-type: none"> <li>Approved type of system <ul style="list-style-type: none"> <li>positive pump or</li> <li>homogenizer or</li> <li>meter based timing system (see Appendix 19 - 4)</li> </ul> </li> </ul> <p>(B) <b>Condition</b></p> <ul style="list-style-type: none"> <li>Stainless steel or corrosion resistant material</li> <li>Clean and in good condition</li> </ul> <p>(C) <b>Location</b></p> <ul style="list-style-type: none"> <li>Upstream from holding tube</li> </ul> <p>(D) <b>Operation</b></p> <ul style="list-style-type: none"> <li>Cannot be excluded from the system during operation</li> </ul>
<b>1.14.06.02</b> <b>Set and Sealed</b> <b>(HS=1)</b>	<p>(A) <b>Procedure</b></p> <ul style="list-style-type: none"> <li>Set at a flow rate to achieve the holding time specified in scheduled process</li> <li>Means of preventing unauthorized speed changes for variable speed devices and single speed devices capable of being altered (belts, pulleys) <ul style="list-style-type: none"> <li>seal on the device to prevent unauthorized adjustments</li> <li>access to alarm settings sealed on MBTS</li> </ul> </li> <li>Checked upon installation and annually thereafter <ul style="list-style-type: none"> <li>appropriate records of testing on file</li> </ul> </li> <li>Re-evaluated and re-sealed (if necessary) after any alterations or repairs</li> </ul> <p>(B) <b>Records</b></p> <ul style="list-style-type: none"> <li>Holding time calculations and flow rate measurements are available</li> <li>Testing reflects scheduled process specifications</li> <li>Records are accurate, complete and available</li> </ul>
<b>1.14.06.03</b> <b>Fail Safe Capability</b> <b>(HS=2)</b>	<p>(A) <b>General Conditions</b></p> <ul style="list-style-type: none"> <li>No by-pass line during processing</li> </ul> <p>(B) <b>Meter Based Timing System Used as F.C.D.</b></p> <ul style="list-style-type: none"> <li>Must have appropriate controls and recorder etc. (see Appendix 19 - 4)</li> <li>High flow alarm: divert flow occurs when flow rate is higher than the value specified in the scheduled process</li> <li>Low flow/Signal loss alarm: divert flow occurs upon low flow or signal loss</li> <li>Alarm pen tracks flow recorder pen</li> </ul>



	HEATING SECTION
Task	Inspection Criteria
<b>1.14.07.01</b> <b>General Conditions</b> <b>(HS=2)</b>	<p>(A) <b>Heat Transfer Equipment</b></p> <ul style="list-style-type: none"> <li>Stainless steel or other corrosion resistant material</li> <li>Sanitary design</li> <li>Clean and good condition</li> <li>No leakage during operation</li> </ul> <p>(B) <b>Indirect Heating</b></p> <ul style="list-style-type: none"> <li>Program in place to check condition of heat transfer plates, gaskets, tube clamps, etc. <ul style="list-style-type: none"> <li>appropriate records kept to show testing has occurred</li> </ul> </li> </ul> <p>(C) <b>Direct Heating</b></p> <ul style="list-style-type: none"> <li>Proper design to ensure complete condensing of the steam inside the injector</li> <li>See Appendix 19 - 15</li> </ul>
<b>1.14.07.02</b> <b>Heating Medium</b> <b>(HS=3)</b>	<p>(A) <b>Direct addition or exposure to steam</b></p> <ul style="list-style-type: none"> <li>Only culinary steam (see Appendix 19 - 1) shall be used</li> <li>Steam shall be as free as possible of non-condensable gases</li> <li>Boiler chemicals/additives must be dairy safe and approved</li> </ul>
<b>1.14.07.03</b> <b>Pressure Limit Recorder Controllers</b> <b>(HS=2)</b>	<p>(A) <b>Pressure Limit Controller</b></p> <ul style="list-style-type: none"> <li>Required for direct and indirect heating systems</li> <li>Monitors and controls the product pressure in the holding tube to ensure product remains in liquid phase</li> <li>Must be in systems that are capable of operating with less than 518 kPa (75 psi) pressure in the holding tube</li> <li>Pressure switch settings correspond to operating temperature in Appendix 19 - 16</li> <li>Product divert valve assumes divert position when product pressure in holding tube drops below a prescribed value, depending on operating temperature</li> </ul> <p>(B) <b>Differential Pressure Limit Indicator</b></p> <ul style="list-style-type: none"> <li>Required for direct heating systems with steam injectors only, to ensure isolation of the injection chamber so product is uniformly heated in the chamber</li> <li>Product divert valve assumes divert position when the differential pressure across injector drops below 69 kPa (10 psi)</li> </ul> <p>(C) <b>Records</b></p> <ul style="list-style-type: none"> <li>Available; easily accessible</li> <li>Tests completed according to required methods and standards</li> <li>Satisfactory follow up on out of specification findings and documentation of actions taken</li> </ul>
<b>1.14.07.04</b> <b>Controllers/ Settings Sealed (HS=2)</b>	<p>(A) <b>Requirements</b></p> <ul style="list-style-type: none"> <li>Access to controller and switch settings must be sealed to prevent unauthorized adjustments</li> </ul>

	HEATING SECTION
Task	Inspection Criteria
<b>1.14.07.05 Ratio Controller (Direct Heating Systems) (HS=3)</b>	<b>(A) Requirements</b> <ul style="list-style-type: none"><li>• A ratio controller shall be used on direct heating systems to prevent water adulteration of the product</li><li>• Sensors shall be located just prior to the steam injection point, and immediately after the product exits the vacuum chamber</li><li>• The controller shall automatically control the pre-heat steam supply or the flash chamber vacuum to prevent adulteration of the product with water<ul style="list-style-type: none"><li>○ interlocked with the vacuum pump and/or steam controller</li></ul></li><li>• Means to be provided to prevent the back up and overflow of water from the vacuum condenser into the vacuum chamber</li></ul>

	HOLDING
Task	Inspection Criteria
<b>1.14.08.01</b> <b>General Conditions</b> <b>(HS=3)</b>	<b>(A) Holding Section</b> <ul style="list-style-type: none"> <li>• Clean and in good condition</li> <li>• Installed in correct location               <ul style="list-style-type: none"> <li>◦ after F.C.D. with no intervening flow promoters</li> <li>◦ after heating section</li> <li>◦ prior to product divert device</li> </ul> </li> <li>• No portion of tube can be left out</li> <li>• Free of external heat source</li> </ul>
<b>1.14.08.02</b> <b>Slope and Support</b> <b>(HS=2)</b>	<b>(A) Holding Section (required for holding tube only)</b> <ul style="list-style-type: none"> <li>• Continuous 2% upwards slope (including elbows)</li> <li>• Permanent support</li> </ul>
<b>1.14.08.03</b> <b>Holding Verification</b> <b>and Records</b> <b>(HS=2)</b>	<b>(A) Records</b> <ul style="list-style-type: none"> <li>• Evidence of holding time determination by calculation method</li> <li>• For Direct Injection Systems:               <ul style="list-style-type: none"> <li>◦ extra volume from steam to be considered in the holding tube calculation</li> </ul> </li> </ul> <b>(B) Frequency</b> <ul style="list-style-type: none"> <li>• Holding tube length calculated at installation and after any change is made to system that could affect the holding time</li> <li>• 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</li> </ul>

	FLOW DIVERSION DEVICE
Task	Inspection Criteria
<b>1.14.09.01</b> <b>General Conditions</b> <b>(HS=2)</b>	<b>(A) Product Divert Device</b> <ul style="list-style-type: none"> <li>Accepted aseptic design</li> <li>Single, dual or multiple stem systems</li> <li>Designed such that the valve seat which separates the diverted product from forward flow is sterilized on all sides</li> <li>Clean and in good condition <ul style="list-style-type: none"> <li>valves, seals and "O" rings</li> <li>valve stem moves with ease</li> </ul> </li> <li>Clean and unrestricted air supply</li> <li>Proper control panel <ul style="list-style-type: none"> <li>free of any device or switches that may jeopardize the safety of the sterilized product</li> <li>micro-processor control permitted for valves without 1.14.11.07 conformance, but valve operation must meet test standards</li> </ul> </li> <li>Non-adjustable valve stem length</li> <li>No quick disconnect couplings on air lines if external solenoids</li> </ul>
<b>1.14.09.02</b> <b>Return Line</b> <b>(HS=2)</b>	<b>(A) Requirements</b> <ul style="list-style-type: none"> <li>Free flow of product from product divert valve without obstructions</li> <li>Flash cooler permitted</li> </ul>
<b>1.14.09.03</b> <b>Location</b> <b>(HS=2)</b>	<b>(A) Requirements</b> <ul style="list-style-type: none"> <li>Installed downstream from the regenerator and cooling sections, prior to fillers or aseptic surge tanks</li> </ul>

	FLOW DIVERSION DEVICE
Task	Inspection Criteria
1.14.09.04 Fail Safe Divert Capability (HS=1)	<p>(A) <b>Divert Conditions (indirect heating systems)</b></p> <ul style="list-style-type: none"> <li>Device will automatically divert product from fillers or aseptic surge tanks when: <ul style="list-style-type: none"> <li>the product temperature in the sensing chamber drops below the specification in the scheduled process</li> <li>the differential pressure between sterilized product and unsterilized product /media is less than 14 kPa (2 psi) in the regenerator</li> <li>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)</li> <li>there is loss of electrical power or compressed air to the product divert device solenoids</li> <li>an excessive flow rate is detected for systems utilizing a magnetic flow meter as a flow control device</li> <li>pressure in the surge tank drops below the value specified in the scheduled process</li> </ul> </li> </ul> <p>(B) <b>Divert Conditions (direct heating systems)</b></p> <ul style="list-style-type: none"> <li>Device will automatically divert product from fillers or aseptic surge tanks when: <ul style="list-style-type: none"> <li>the product temperature in the holding tube drops below the specification in the scheduled process</li> <li>the differential pressure between sterilized product and unsterilized product /media is less than 14 kPa (2 psi) in the regenerator</li> <li>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)</li> <li>there is loss of electrical power or compressed air to the product divert device solenoids</li> <li>for steam infusion systems, there is loss of predetermined parameters at steam infusion chamber exits</li> <li>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)</li> <li>an excessive flow rate is detected for systems utilizing a magnetic flow meter as a flow control device</li> <li>pressure in the surge tank drops below the value specified in the scheduled process</li> </ul> </li> </ul> <p>(C) <b>Inter-wiring</b></p> <ul style="list-style-type: none"> <li>Valve position signal to the S.T.L.R. flow indicating lights and event pen</li> </ul> <p>(D) <b>Equipment sterilization capability</b></p> <ul style="list-style-type: none"> <li>After divert flow events: <ul style="list-style-type: none"> <li>product holding tube and entire aseptic zone shall be re-sterilized before product flow is resumed to the filler or aseptic surge tank</li> </ul> </li> </ul> <p>(E) <b>Records</b></p> <ul style="list-style-type: none"> <li>Available; easily accessible</li> <li>Tests completed according to required methods and frequency</li> <li>Satisfactory follow up on out of specification findings and documentation of actions taken</li> </ul>

	FLOW DIVERSION DEVICE
Task	Inspection Criteria
<b>1.14.09.05</b> <b>Leak Detect</b> <b>(HS=1)</b>	<p><b>(A) Requirements</b></p> <ul style="list-style-type: none"> <li>• Systems where the filler continues to operate from an aseptic surge tank while in divert mode shall use a properly designed aseptic barrier between sterile product and potentially non-sterile product (see Appendix 19 - 10)</li> <li>• Barrier failure initiates system shutdown, as specified in the scheduled process</li> <li>• RTD or other acceptable system used to monitor barriers for leakage</li> <li>• Process deviation procedure followed after barrier failure and deviation log book entry completed             <ul style="list-style-type: none"> <li>○ deviation procedure includes the date and time of the process deviation, investigation into the cause of the process deviation and action taken on Aheld product@.</li> </ul> </li> </ul> <p><b>(B) Location</b></p> <ul style="list-style-type: none"> <li>• Aseptic barriers located on forward flow side of the product divert device and upstream from aseptic surge tank /filler blocking valve</li> </ul>
<b>1.14.09.06</b> <b>Device/Panel Sealed</b> <b>(HS=2)</b>	<p><b>(A) Requirements</b></p> <ul style="list-style-type: none"> <li>• Device must be sealed appropriately</li> <li>• Valve position detectors, solenoids, relays access to programming functions, I/O ports</li> </ul>

	INDICATING THERMOMETER
Task	Inspection Criteria
<b>1.14.10.01</b> <b>General Conditions</b> <b>(HS=2)</b>	<b>(A) Requirements</b> <ul style="list-style-type: none"> <li>• Clean and in good condition</li> <li>• Uniquely identified (e.g. serial #)</li> <li>• Mercury Type <ul style="list-style-type: none"> <li>○ direct reading</li> <li>○ no column splitting</li> <li>○ easy to read</li> <li>○ contained in corrosion resistant case</li> </ul> </li> <li>• Resistance Thermal Devices (RTD=s) <ul style="list-style-type: none"> <li>○ approved unit</li> <li>○ utilizing two separate RTD sensors verifying each other</li> <li>○ meets the design requirements in Appendix 19 - 13</li> </ul> </li> </ul>
<b>1.14.10.02</b> <b>Location/</b> <b>Accessibility</b> <b>(HS=2)</b>	<b>(A) Requirements</b> <ul style="list-style-type: none"> <li>• Sensor located at the end of the holding tube after the S.T.L.R. sensor; distance between the two should not be more that 30 cm (12 inches)</li> <li>• Easily and safely accessible for reading by the operator</li> </ul>
<b>1.14.10.03</b> <b>Specifications</b> <b>(HS=2)</b>	<b>(A) Requirements</b> <ul style="list-style-type: none"> <li>• Graduated in 0.5EC (1EF) divisions with not more than 9.4EC (17EF) per 25 mm (1 inch) of graduated scale</li> <li>• No stem fitting threads exposed to product</li> </ul>
<b>1.14.10.04</b> <b>Calibration/ Records</b> <b>(HS=1)</b>	<b>(A) Calibration</b> <ul style="list-style-type: none"> <li>• Temperature accuracy</li> <li>• Thermometric response</li> <li>• Frequency of calibration (upon installation and at least once every 6 months)</li> </ul> <b>(B) Records</b> <ul style="list-style-type: none"> <li>• Available; easily accessible</li> <li>• Tests completed according to required methods and standards</li> <li>• Satisfactory follow up on out of specification findings and documentation of actions taken <ul style="list-style-type: none"> <li>○ product safety assessment required</li> </ul> </li> </ul>
<b>1.14.10.05</b> <b>Sealed</b> <b>(HS=2)</b>	<b>(A) Requirements</b> <ul style="list-style-type: none"> <li>• Access to thermometer adjustment sealed to prevent tampering</li> </ul>

	<b>SAFETY THERMAL LIMIT RECORDER (S.T.L.R.)</b>
<b>Task</b>	<b>Inspection Criteria</b>
<b>1.14.11.01</b> <b>General Conditions</b> <b>(HS=3)</b>	<b>(A) Requirements</b> <ul style="list-style-type: none"> <li>• Good mechanical and sanitary condition</li> <li>• Proper design <ul style="list-style-type: none"> <li>- meets the criteria established by manufacturer</li> <li>- unit manufactured for S.T.L.R. usage</li> <li>- modifications performed by or authorized by manufacturer</li> <li>- moisture proof case</li> </ul> </li> <li>• Operated as specified by the manufacturer</li> <li>• Covers in place to prevent access to public health adjustments</li> <li>• Cut in/cut out independent of temperature recording arm movement</li> <li>• Temperature sensing probe for the recording pen and the cut in/cut/out control installed with a pressure-tight seal</li> <li>• Flow indicating lights (green for forward and red for divert) operating</li> <li>• Air operated type should have a supply of clean, dry air</li> <li>• Records and frequency of servicing (at least once a year)</li> <li>• Absence of unidentified/unauthorized switches or devices that may jeopardize the safety of product</li> </ul>
<b>1.14.11.02</b> <b>Location</b> <b>(HS=2)</b>	<b>(A) S.T.L.R. Sensing Probe</b> <ul style="list-style-type: none"> <li>• located at the end of the holding tube outlet after the indicating thermometer; distance between the two should not be more than 30 cm (12 inches)</li> </ul>



	<b>SAFETY THERMAL LIMIT RECORDER (S.T.L.R.)</b>
<b>Task</b>	<b>Inspection Criteria</b>
<b>1.14.11.03</b> <b>Specifications</b> <b>(HS=3)</b>	<p><b>(A) Design</b></p> <ul style="list-style-type: none"> <li>• Positive drive mechanism equipped with a system to prevent slippage</li> <li>• Proper charts <ul style="list-style-type: none"> <li>◦ correspond with chart # displayed on identification plate of S.T.L.R.</li> </ul> </li> <li>• Appropriate chart scale span, graduations and time scale divisions; If operations extend beyond 12 hours, a 24-hour chart can be used if it can provide an equivalent level of accuracy and clarity <ul style="list-style-type: none"> <li>◦ Graduations not to exceed 1EC (2EF) within a range of 5.5EC (10EF) of the processing temperature</li> <li>◦ Chart scale not more than 30EC (55EF) per 25 mm (1 inch) within a range of 11EC (20EF) of the processing temperature</li> </ul> </li> <li>• Pens (recording and frequency) functional, tracking proper time line</li> <li>• Recording temperature not greater than indicating temperature, but if it is, necessary measures must be taken and documented to correct the situation</li> <li>• Frequency pen is energized by a position detector in the FDD as the FDD moves into forward position and de-energized during diverted flow and it moves down to indicate a divert. In cases where the event pen indicates the critical factors required to enable forward or diverted flow, the event pen will be de-energized when at least one of those pre-determined critical factors is not met.</li> <li>• Pen easily calibrated / adjusted</li> </ul>
<b>1.14.11.04</b> <b>Thermal Limit</b> <b>Controller Sequence</b> <b>Logic</b> <b>(HS=1)</b>	<p><b>(A) Requirements</b></p> <ul style="list-style-type: none"> <li>• During processing mode, forward flow shall not occur unless the temperature is at or above the sterilizing temperature as outlined in the scheduled process</li> <li>• At start-up or after a divert event, forward flow shall not occur until all product contact surfaces from the holding tube to the product divert device have been sterilized</li> <li>• Failure of any safe forward flow condition shall cause the product divert device to immediately assume the divert flow position</li> <li>• Inaccessible mechanism for altering the temperature settings</li> </ul>

	SAFETY THERMAL LIMIT RECORDER (S.T.L.R.)
Task	Inspection Criteria
<b>1.14.11.05 Calibration / Records (HS=2)</b>	<p><b>(A) Calibration</b></p> <ul style="list-style-type: none"> <li>• Temperature accuracy</li> <li>• Time accuracy</li> <li>• Cut in / Cut out</li> <li>• Thermal limit controller sequence logic</li> <li>• Frequency of calibration (at least once every 6 months)</li> <li>• Recording thermometer check against indicating thermometer (daily) <ul style="list-style-type: none"> <li>○ Recording thermometer not higher than indicating thermometer</li> </ul> </li> </ul> <p><b>(B) Records</b></p> <ul style="list-style-type: none"> <li>• Available; easily accessible</li> <li>• Tests completed according to required methods and standards</li> <li>• Satisfactory follow up on out of specification findings and documentation of actions taken</li> </ul>
<b>1.14.11.06 Sealed (HS=2)</b>	<p><b>(A) Requirements</b></p> <ul style="list-style-type: none"> <li>• S.T.L.R. cut in / cut out adjustments must be sealed</li> <li>• Access to thermal limit controller sequence logic settings for public health controls must be sealed</li> </ul>
<b>1.14.11.07 Programmable Logic Controllers and Computers (HS=1)</b>	<p><b>(A) Non-Public Health Computers</b></p> <ul style="list-style-type: none"> <li>• Computer may not control any public health safeguards when in production cycle</li> <li>• Computer may control public health safeguards during C.I.P. cycle</li> <li>• Computer may control non-public health components during production and C.I.P. cycles</li> </ul> <p><b>(B) Public Health Computers</b></p> <ul style="list-style-type: none"> <li>• See Appendix 19 - 5, Criteria for the Evaluation of Computerized Public Health Controls. Logic diagrams in App.5 do not apply to APPS systems</li> <li>• A Computer used for control of the public health functions of a APPS must be a dedicated unit with no other assignments</li> <li>• The computer shall not be controlled or addressable by any other computer: <ul style="list-style-type: none"> <li>○ read-only status of inputs and outputs may be acceptable if suitably isolated</li> <li>○ ready to process data at all times</li> </ul> </li> <li>• A separate computer must be used for each sterilization / pasteurization system</li> <li>• All public health controls must assume the fail-safe position <ul style="list-style-type: none"> <li>○ upon loss of power to the computer</li> <li>○ when the computer is placed on standby</li> <li>○ during power-up when outputs are in the default mode</li> </ul> </li> <li>• Input/output terminals with last-state switches must have the switches placed in the fail-safe position</li> <li>• Input/output terminals must not have any operator override switches</li> <li>• The computer program must be stored in Read- Only-Memory (ROM)</li> <li>• If the computer also prints the recording charts: <ul style="list-style-type: none"> <li>○ recorder calibrations for temperature and time must be maintained as in Task 1.14.11.05</li> </ul> </li> </ul>

	SAFETY THERMAL LIMIT RECORDER (S.T.L.R.)
Task	Inspection Criteria
	<ul style="list-style-type: none"> <li>○ recording chart specifications must meet the requirements of Task 1.14.11.03</li> <li>○ recording charts must be printed concurrently with sterilizer operation</li> <li>○ 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</li> <li>○ the frequency pen position shall be printed such that the temperature can easily be determined where the product divert valve changes position</li> </ul> <p><b>(C) Documentation (All)</b></p> <ul style="list-style-type: none"> <li>• Complete and accurate documentation of interwiring, pneumatic controls, programming logic and ladder logic diagrams must be available</li> <li>• Programming logic maybe defined by program listings and descriptive narrative text</li> <li>• Vendor is responsible for ensuring PLC /computer installations comply with requirements of Appendix 19 - 5</li> </ul> <p><b>(D) Testing</b></p> <ul style="list-style-type: none"> <li>• Testing procedures must be provided by the vendor</li> <li>• For <b>Non-Public Health Computers:</b> <ul style="list-style-type: none"> <li>○ 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</li> </ul> </li> <li>• For Public Health Computers:           <ul style="list-style-type: none"> <li>○ Test procedures to verify that the correct computer program is installed in ROM</li> <li>○ Methods for testing proper operation of all applicable public health controls as required in the testing procedures manual</li> </ul> </li> </ul> <p><b>(E) Access sealed (All)</b></p> <ul style="list-style-type: none"> <li>○ Microprocessor access ports, modem ports, and input/output terminals must be sealed to prevent unauthorized changes or tampering</li> </ul>

	<b>PRESSURE DIFFERENTIAL RECORDER CONTROLLERS (P.D.C. - recorder)</b>
<b>Task</b>	<b>Inspection Criteria</b>
<b>1.14.12.01 General Conditions (HS=2)</b>	<p><b>(A) Pressure Differential Recorder Controllers</b></p> <ul style="list-style-type: none"> <li>• Required to monitor and record pressures</li> <li>• Sensors clean and in good mechanical condition</li> <li>• Easy dismantling of sensors for inspection</li> <li>• Moisture proof enclosure for indicating / recording unit</li> <li>• Interwired with product divert valve <ul style="list-style-type: none"> <li>○ divert occurs when the sterilized product pressure in the regenerator does not exceed the raw side pressure by 14 kPa (2 psi) or more</li> <li>○ it is considered acceptable to use a legal PLC to control the pressure differential.</li> </ul> </li> </ul> <p><b>(B) Gauges (if used)</b></p> <ul style="list-style-type: none"> <li>• Clean and in good condition</li> </ul>
<b>1.14.12.02 Location (HS=2)</b>	<p><b>(A) Raw Product-to-Sterilized Product Regeneration</b></p> <ul style="list-style-type: none"> <li>• Raw product sensor between the booster pump and the raw product inlet to the regenerator</li> <li>• Sterilized product sensor at, or downstream from, sterilized product outlet of regenerator</li> </ul> <p><b>(B) Product-to-Heat Transfer Medium-to-Product Regeneration</b></p> <ul style="list-style-type: none"> <li>• Raw side pressure sensor in water loop after the water pump (highest pressure)</li> <li>• Sterilized side pressure sensor in product outlet line from the sterilized side of the regenerator (lowest pressure)</li> </ul>

	<b>PRESSURE DIFFERENTIAL RECORDER CONTROLLERS (P.D.C. - recorder)</b>
<b>Task</b>	<b>Inspection Criteria</b>
<b>1.14.12.03 Specifications (HS=3)</b>	<p><b>(A) Requirements</b></p> <ul style="list-style-type: none"> <li>• Proper Charts             <ul style="list-style-type: none"> <li>○ correspond with chart # displayed on identification plate of pressure differential recorder controller</li> <li>○ circular charts graduated for 12 hours maximum; If operations extend beyond 12 hours, a 24-hour chart can be used if it can provide an equivalent level of accuracy and clarity.</li> </ul> </li> <li>• Scale divisions not to exceed 14 kPa (2 psi) on scale of not more than 140 kPa (20 psi)</li> <li>• Pens to record raw side pressure and sterilized side pressure or pressure differential</li> <li>• Electronic data collection, storage and reporting of pressure differentials, with or without hard copy printouts, may be <i>acceptable</i>.</li> </ul>
<b>1.14.12.04 Calibration / Records (HS=2)</b>	<p><b>(A) Pressure Differential Recorder Controller Calibration</b></p> <ul style="list-style-type: none"> <li>• Product diversion with improper regenerator pressure differential</li> <li>• Probe calibration</li> <li>• Frequency of calibration (at least once every 6 months)</li> </ul> <p><b>(B) Gauges</b></p> <ul style="list-style-type: none"> <li>• Checked for accuracy upon installation and at least once every 6 months</li> </ul> <p><b>(C) Records</b></p> <ul style="list-style-type: none"> <li>• Available; easily accessible</li> <li>• Tests completed according to required methods and standards</li> <li>• Satisfactory follow up on out of specification findings and documentation of actions taken</li> </ul>
<b>1.14.12.05 Sealed (HS=2)</b>	<p><b>(A) Pressure Differential Controller / Recorder</b></p> <ul style="list-style-type: none"> <li>• Access to calibration adjustments/legal panel must be sealed to prevent tampering</li> </ul>

	<b>AUXILIARY TEMPERATURE RECORDERS / CONTROLLERS</b>
<b>Task</b>	<b>Inspection Criteria</b>
<b>1.14.13.01 General Conditions (HS=3)</b>	<p><b>(A) Requirements</b></p> <ul style="list-style-type: none"> <li>• Clean and in good condition</li> <li>• Moisture proof</li> <li>• Positive drive mechanism equipped with a system to prevent slippage of chart</li> <li>• Proper charts, corresponding to chart part number</li> <li>• Pens operational, easily calibrated, tracking proper time line</li> <li>• Records and frequency of servicing (at least once a year)</li> </ul>

	COOLING SECTION
Task	Inspection Criteria
<b>1.14.14.01</b> <b>General Conditions</b> <b>(HS=2)</b>	<b>(A) Requirements</b> <ul style="list-style-type: none"> <li>• Clean and in good condition</li> <li>• Stainless steel or other corrosion resistant material</li> <li>• Sanitary design</li> <li>• No leakage during operation</li> <li>• Program in place to check condition of heat transfer plates, gaskets, tube clamps, etc. <ul style="list-style-type: none"> <li>○ adequate frequency to ensure integrity</li> <li>○ records to be kept</li> </ul> </li> </ul>
<b>1.14.14.02</b> <b>Pressure Differentials</b> <b>(HS=2)</b>	<b>(A) Monitored or Controlled</b> <ul style="list-style-type: none"> <li>• Pressure of the cooling media shall be 14 kPa (2psi) less than the product pressure during forward flow</li> <li>• During diverted flow conditions, higher pressure must be maintained on the sterilized product side of the plates than on the medium side of the plates.</li> <li>• An automated mechanism is the only acceptable means to achieve the correct pressure relationship</li> <li>• Checked daily and recorded</li> </ul> <b>(B) Gauges</b> <ul style="list-style-type: none"> <li>• Clean and in good condition</li> <li>• Calibrated</li> <li>• Located at cooling media inlet and sterilized product outlet</li> </ul>
<b>1.14.14.03</b> <b>Cooling Medium</b> <b>(HS=2)</b>	<b>(A) Quality</b> <ul style="list-style-type: none"> <li>• Cooling media checked at least monthly for microorganisms (psychrotrophs, coliforms)</li> <li>• Cooling medium chemicals/additives must be dairy safe and approved</li> <li>• Records of cooling water additives and cooling media products used and microbial testing results</li> <li>• Appropriate follow-up documented</li> </ul>

	HOMOGENIZER
Task	Inspection Criteria
<b>1.14.15.01</b> <b>General Conditions</b> <b>(HS=3)</b>	<p><b>(A) General Inspection Criteria for Dairy Plant Equipment</b></p> <p><b>(B) Specific Areas of Interest</b></p> <ul style="list-style-type: none"> <li>• Stainless steel product contact surfaces</li> <li>• Clean and in good condition <ul style="list-style-type: none"> <li>○ filters</li> <li>○ homogenizer valves</li> <li>○ pistons</li> <li>○ seat valves</li> <li>○ pressure gauges</li> </ul> </li> <li>• Appropriate gauges</li> <li>• Aseptic design homo if located downstream from the holding tube in sterile zone</li> </ul>
<b>1.14.15.02</b> <b>Homogenizer Larger</b> <b>Than F.C.D.</b> <b>(HS=2)</b>	<p><b>(A) Homogenizer Larger Than F.C.D., Downstream From F.C.D.</b></p> <ul style="list-style-type: none"> <li>• Must not reduce pressure in the holding tube</li> <li>• Must not reduce holding time</li> <li>• Manufacturer to demonstrate that flow rate not affected</li> </ul>

	ASEPTIC SURGE TANK
Task	Inspection Criteria
<b>1.14.16.01</b> <b>General Conditions</b> <b>(HS=2)</b>	<p>(A) <b>General Inspection Criteria for Dairy Plant Equipment</b></p> <p>(B) <b>Specific Areas of Interest</b></p> <ul style="list-style-type: none"> <li>• Clean and in good condition <ul style="list-style-type: none"> <li>○ tank, valves, thermometers, sensors</li> <li>○ Instrumentation and Control</li> </ul> </li> <li>• Instrumentation (temperature recording chart) installed to verify and record sterilization cycle</li> </ul> <p>(C) <b>Sterile air pressure transmitter / controller</b></p> <ul style="list-style-type: none"> <li>○ when the sterile over-pressure or other means of protection drops below the scheduled process value, product flow to and from the aseptic surge tank shall not be resumed until: <ul style="list-style-type: none"> <li>(a) potentially contaminated product in the tank is removed</li> <li>(b) aseptic surge tank, filler, valves and pipelines have been returned to a condition of commercial sterility</li> </ul> </li> </ul>
<b>1.14.16.02</b> <b>Sterile Air</b> <b>(HS=2)</b>	<p>(A) <b>Requirements</b></p> <ul style="list-style-type: none"> <li>• Sterile air must be pressurized to prevent the development of negative pressure inside the aseptic surge tank</li> <li>• Venting or air purge schedule established by process authority</li> <li>• Sterile air over-pressure is maintained on aseptic surge tanks to ensure proper operation</li> <li>• Establishment monitors sterile air over-pressure and method of achieving sterility (either use incineration and/or filtration) <ul style="list-style-type: none"> <li>○ if incineration is used, a temperature sensing device is employed</li> <li>○ if a sterile filter is used, filter specifications, filter location and number of filters must be monitored. Filter must be changed at intervals recommended by the manufacturer or process authority for their method of use and documented in the processing records.</li> </ul> </li> <li>• Sterile air pressure controller or transmitter is used to monitor the sterile air pressure in the tank <ul style="list-style-type: none"> <li>○ records of tests performed to determine the controller's/transmitter's calibrations are maintained in plant files. Tests include accuracy, upon installation and at least every 6 months.</li> </ul> </li> <li>• Testing methods comply with required standards show satisfactory follow-up on out of specification findings.</li> </ul>



	STUFFING PUMP
Task	Inspection Criteria
<b>1.14.17.01</b> <b>General Conditions</b> <b>(HS=2)</b>	<p>(A) <b>General Inspection Criteria for Dairy Plant Equipment</b></p> <ul style="list-style-type: none"> <li>• All pumps installed in a sterile zone must be aseptic type</li> </ul> <p>(B) <b>Specific Areas of Interest</b></p> <ul style="list-style-type: none"> <li>• Clean and in good condition <ul style="list-style-type: none"> <li>○ impellers</li> <li>○ back plates</li> </ul> </li> <li>• Painted exterior <ul style="list-style-type: none"> <li>○ clean</li> <li>○ free of flaking paint and rust</li> </ul> </li> </ul>
<b>1.14.17.02</b> <b>Proper Installation/</b> <b>Operation</b> <b>(HS=2)</b>	<p>(A) <b>Requirements</b></p> <ul style="list-style-type: none"> <li>• Interwired so that the pump shuts off when F.C.D. is not allowed to run <ul style="list-style-type: none"> <li>○ Test performed upon installation, at least once every 6 months and when micro-switch is re-set or replaced and records kept</li> </ul> </li> <li>• Must not influence the proper pressure relationship within the regeneration section</li> <li>• Must not reduce the holding time or holding tube pressure</li> </ul>

	PACKAGING CONDITIONS
Task	Inspection Criteria
<b>1.14.18.01</b> <b>Packaging Material</b> <b>(HS = 2)</b>	<b>(A) Requirements</b> <ul style="list-style-type: none"> <li>• Appropriate program to ensure packaging materials meet the requirements identified in scheduled process</li> <li>• Visually examine packaging material for damage and defects</li> <li>• Store and handle packaging material so as to reduce risks of contaminating or physically damaging the material</li> </ul>
<b>1.14.18.02</b> <b>Sterilant</b> <b>(HS = 2)</b>	<b>(A) Requirements</b> <ul style="list-style-type: none"> <li>• Hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>) or a combination of H<sub>2</sub>O<sub>2</sub> and peracetic acid are most commonly used</li> <li>• Testing of the residue must be performed at an appropriate frequency and must be at or below the level specified by the scheduled process</li> <li>• Sterilants used to sterilize the package are dairy safe and approved for dairy plant purposes. If dilution is required, sterilants must be diluted as per manufacturer's recommendations. See Appendix 19 - 12 B for sterile water requirements</li> <li>• Two important factors to consider when using sterilants: microbiological efficiency of the sterilization process and elimination of chemical residues from the package which can subsequently contaminate the filled product</li> </ul>

	PACKAGING CONDITIONS
Task	Inspection Criteria
<b>1.14.18.03 Head Space Gas (HS = 2)</b>	<b>(A) Requirements</b> <ul style="list-style-type: none"><li>• Nitrogen gas or other media is filtered or treated in other ways to remove or destroy microorganisms</li></ul>
<b>1.14.18.04 Packaging/Filling Room Air Quality (HS = 2)</b>	<b>(A) Requirements</b> <ul style="list-style-type: none"><li>• The packaging/filling room must be under positive pressure, relative to rest of the plant</li><li>• Microbial analysis of air quality conducted and recorded at a specified timeframe</li></ul>

	PACKAGING AND FILLING CONTROLS
Task	Inspection Criteria
<b>1.14.19.01 Calibration of Controls (HS = 2)</b>	<b>(A) Requirements</b> <ul style="list-style-type: none"> <li>• Packaging controls specified in the scheduled process are calibrated to fail-safe on a regular basis</li> </ul>
<b>1.14.19.02 Setting of Controls (HS = 1)</b>	<b>(A) Requirements</b> <ul style="list-style-type: none"> <li>• Critical controls as specified in the scheduled process must be adhered to during the packaging and filling operation</li> <li>• Automatic controls are protected from manual over-ride by unauthorized personnel</li> </ul>
<b>1.14.19.03 Setting Deviation (HS = 2)</b>	<b>(A) Requirements</b> <ul style="list-style-type: none"> <li>• Acceptable variations from specified settings are described in the operator=s log book</li> <li>• In case of critical deviation from the settings: <ul style="list-style-type: none"> <li>○ packaging operations stop</li> <li>○ product segregated</li> <li>○ system returned to commercial sterility before resuming packaging operations</li> </ul> </li> </ul>

	QUALITY CONTROL
Task	Inspection Criteria
<b>1.14.20.01</b> <b>Finished Product</b> <b>Testing</b> <b>(HS = 2)</b>	<p>(A) <b>Sampling Plan</b></p> <ul style="list-style-type: none"> <li>Quantity of containers taken, tests to be performed etc. based on the scheduled process</li> <li>Statistically valid sampling</li> </ul> <p>(B) <b>Inspection of Heat Seals</b></p> <ul style="list-style-type: none"> <li>Done <ul style="list-style-type: none"> <li>before production start, during production</li> <li>after jam-ups</li> <li>as per manufacturer's recommendation</li> </ul> </li> </ul> <p>(C) <b>Incubation</b></p> <ul style="list-style-type: none"> <li>Statistically valid number of containers taken from each filling head for incubation</li> <li>Incubate at a specified temperature for a specified time to demonstrate no spoilage</li> </ul> <p>(D) <b>Microbial Evaluation</b></p> <ul style="list-style-type: none"> <li>Microbial analysis done for commercial sterility</li> <li>Microbial growth further investigated <ul style="list-style-type: none"> <li>lot(s) detained</li> </ul> </li> </ul> <p>(E) <b>Product Release</b></p> <ul style="list-style-type: none"> <li>All package integrity, incubation testing, processing record review and the investigation of any process deviations be satisfactory before product as released</li> </ul> <p>(F) <b>Records</b></p> <ul style="list-style-type: none"> <li>Available, easily accessible, complete</li> <li>Satisfactory follow up on out of specification findings and documentation of actions taken</li> </ul>

	RECORD KEEPING
Task	Inspection Criteria
<b>1.14.21.01 Packaging Records (HS = 3)</b>	<b>(A) Requirements</b> <ul style="list-style-type: none"><li>• 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</li><li>• Records available, easily accessible</li><li>• Satisfactory follow up on out of specification findings and documentation of actions taken</li></ul>