# An Indian Standard for specification of any equipment is used as an agreement document between manufacturer and purchaser. Though all the Indian Standards are voluntary in nature but can be implemented through respective ministry for mandatory compliance or can be voluntarily used by any purchaser or procuring agency as a document for technical screening of equipment to be procured.

Therefore, each and every written in requirement section of this draft standard, should be in contractual language only, which can be done through following guidelines:

As per IS 12 : 2005 “Guide for Drafting and Presentation of Indian Standards”, each sentence or requirement of standard will have words like either shall, should, can or may or combination thereof.

Where,

1. “Shall” is used for mandatory requirement (must).

e.g. All component of pasteurizer ‘shall’ be made of stainless steel.

2. ‘Can’ is used for giving information.

e.g. This equipment ‘can’ process milk and milk products.

Similarly,

3. “Should’ is used for recommendatory requirement.(suggestion)

4. ‘May’ is used for permission or to allow something. (permission)

Therefore, all the additional information needs to be removed and draft needs to be modified accordingly.

Note – In terminology section, language of definition can be used.

In general, in case of any equipment standard,

Material Requirement, Contractional Requirements, Performance Requirements, Safety Requirements and Test Methods (if required) are given.

# FOREWARD

The principle of thermal sterilization is simple and like that of pasteurization. The product to be sterilized is heated to a specified temperature and maintained at or above that temperature for a fixed time. The main difference between sterilization and pasteurization is that the temperature required for sterilization are significantly higher that pasteurization (120°C plus as compared to 70-90°C).

Pasteurization is primarily intended to destroy vegetative cells of bacteria and most bacterial spores will survive the process. Pasteurization is therefore used for example with high acid products where growth of spore forming bacteria does not occur. Another example is where the product self-life is too short to allow spore germination and growth to reach unacceptable levels.

Sterilization is typically applied to low acid products requiring an extended shelf life at ambient temperature. Continuous flow sterilization plant is therefore operated in conjunction with aseptic filler or further processed under aseptic conditions.

For microbiologically safe sterilization, it is essential that.

1. The correct sterilization condition is maintained during the entire period of operation
2. The re-infection of sterilized product is prevented.

***Indian Standard (Draft)***

STERILIZER — CONTINUOUS FLOW TYPE — SPECIFICATION

1. **SCOPE**

This code of practice is concerned with the aseptic processing and packaging of low-acid foods as defined in this code. It does not apply to those low-acid foods in hermetically sealed containers processed by conventional canning procedures nor to those that require refrigeration for their preservation, nor to acid and acidified low-acid products.

1. **REFERENCES**
* Food Safety and Standards (Food Products Standards and Food Additives) Regulation, 2011
* IS 3382 (1965): Reaffirmed 2000: Specification for stainless steel milk pipes and fittings
* IS 4251 (1967): Quality tolerances for water for processed food industry
* Canadian Food Inspection Agency Dairy Establishment Inspection Manual – Aseptic Processing and Packaging Systems
* ISO 14159 (2002): Safety of Machinery — Hygiene Requirements for the Design of Machinery
* EHEDG Document No.6, The Microbiologically safe continuous flow thermal sterilization of liquid foods.
* CODEX Standards (*CAC/RCP 40-1993*): Code of Hygienic Practice for Aseptically Processed and Packaged Low-Acid Foods
* 3A Sanitary Standards (11/2003). 12-07: 3-A Sanitary Standards for Tubular Heat Exchangers
* USFDA PMO (2017). Grade “A” Pasteurized Milk Ordinance. United State Department of Health and Human Services
1. **TERMINOLOGY**
	1. **Aseptic processing-** Aseptic processing and packaging mean the processing and packaging of a commercially sterile product into sterilized containers followed by hermetic sealing with a sterilized closure in a manner which prevents viable microbiological recontamination of the sterile product.
	2. **Aseptic zone**- The area required to be made and maintained sterile such that sterile product and containers will not be re-contaminated by microorganisms. This zone is bounded by physical barriers such as structural features or sterile air flows.
	3. **Canned food** - Commercially sterile food in hermetically sealed containers.
	4. **Cleaning**- The removal of food residues, dirt, grease or other objectionable material.
	5. **Code Lot** - All products produced during a period identified by a specific container code mark.
	6. **Commercial sterility**- The absence of microorganisms capable of growing in the food at nor**m**al non-refrigerated conditions at which the food is likely to be held during manufacture, distribution and storage.
	7. **Disinfection- T**he reduction, without adversely affecting the food, by means of hygienically satisfactory chemical agents and/or physical methods, of the number of microorganisms to a level that will not lead to harmful contamination of food.
	8. **Equilibrium pH-** the pH of a finished food once all components have attained pH uniformity.
	9. **Flow diversion system**- Product piping and valving designed to divert potentially non-sterile product from the filler or aseptic surge tank.
	10. **Headspace** means the volume in a container not occupied by the food.
	11. **Hermetically sealed containers** mean containers which are designed and intended to protect the contents against the entry of viable microorganisms after closing.
	12. **Flexible container** means that the shape or contours of the filled, sealed container are affected by the enclosed product.
	13. **Semi-rigid container** means that the shape or contours of the filled, sealed container are not affected by the enclosed product under normal atmospheric temperature and pressure but can be deformed by an external mechanical pressure of less than 0.7 kg/cm2 (10 psi), i.e., normal finger pressure.
	14. **Rigid container** means that the shape or contours of the filled and sealed container are neither affected by the enclosed product nor deformed by an external mechanical pressure of up to 0.7 kg /cm2 (10 psi), i.e., normal finger pressure.
	15. **Hold Section** means the section (for example, hold tube) of the food product sterilizing system in which the heated food is maintained for a time and temperature enough to attain commercial sterility of the food.
	16. **Incubation** tests means tests in which the heat processed product is kept at a specific temperature for a specified period in order to determine if outgrowth of microorganisms occurs under these conditions.
	17. **Classification of food** **based on pH-**
* **Low acid food pH > 4.5**
* **Medium acid food pH 3.7-4.5**
* **High Acid food pH < 3.7**
	1. **Potable water** means water fit for human consumption. Standards of potability should be no less strict than those contained in the latest edition of the "Guidelines for Drinking Water Quality - Volume 1", World Health Organization.
	2. **Preproduction sterilization** means the commercial sterilization of all necessary equipment before commencement of production.
	3. **Product-to-product regenerator** means the equipment designed to exchange heat between hot product and cold product aseptically.
	4. **Scheduled process** means all the conditions needed to achieve and maintain commercial sterility of equipment, containers and food.
	5. **Seals** mean those parts of a container which are formed, bonded or fused together in order to close the container.
	6. **Steam** seal means an enclosure that utilizes steam as a barrier to entry of microorganisms.
	7. **Sterilant** means any physical and/or chemical treatment used to achieve commercial sterility.
	8. **Sterility** means commercial sterility.
	9. **Sterilization temperature** means the temperature of the thermal process as specified in the scheduled process.
	10. **Sterilization** time means the time specified in the scheduled process.
1. **MATERIALS**

Equipment and all attachments that are in, or may come into, contact with milk and other liquid dairy product shall be manufactured from stainless steel or materials which are resistant to products being processed, non-toxic, resistant to cleaning agents and disinfection agents in normal conditions of dosage and temperature, and shall not impart a taint to milk and other liquid dairy product.

The grade of stainless steel shall be of a quality at least equivalent to the grade specified in ASTM A480/A480M, especially regarding suitability for welding and resistance to corrosion.

All product contact surfaces shall be smooth and free of crevices.

Stainless steel product contact surfaces should have a surface roughness (Ra) less than or equal to 1.0 μm, where Ra is as defined in ISO 4288. A roughness of greater than 1.0 μm may be acceptable if test results have shown that required cleanability is achievable because of design features.

1. **CONSTRUCTION AND CLEANING AND SANITIZING REQUIREMENTS**
	1. All component shall be designed, constructed and maintained to prevent contamination of the product with extraneous matter.
	2. All components of equipment shall be constructed so that they can be dismantled for inspection, cleaning and sanitizing or shall be designed and constructed for cleaning-in-place (CIP) with suitable provision for inspection.
	3. Pasteurizers shall be sanitized, using heat or chemically, prior to processing product.
2. **GENERAL REQUIREMENTS FOR HEAT EXCHANGER**

The primary function of a heat exchanger in a sterilization plant is to deliver the desired
heat transfer whether heating or cooling, for the range of products being processed. The
heat exchanger should be capable of functioning reproducibly and reliably on a routine
basis. A heat exchanger in a sterilization plant will not necessarily be designed for maximum heat transfer efficiency. This is because other factors such as the fouling of
heat transfer surfaces and the balance between capital and running costs, are also taken
into account. There are a wide variety of heat exchangers used for heating and cooling
duties in both direct and indirect systems and the following requirements are common to
all types:

* + 1. The heat exchangers should be fully cleanable and preferably drainable.
		2. Any CIP fluids used must be compatible with the materials of construction under
		the in-use conditions.
		3. Service fluids in contact with the heat exchanger should not be corrosive.
		4. If the service side of the heat exchanger is to be drained, complete removal of all
		service liquid must be assured.
		5. Pockets (dead legs) should not be present at the product side as they present areas
		where product will reside for a much longer time than the mean residence time.
		Pockets moreover are difficult to clean.
		6. All connections in the sterile area of the plant must be of aseptic design (i.e.
		cleanable, sterilisable and bacteria-tight).
		7. Where gaskets are used to separate the product from heating or cooling medium,
		there must always be two gaskets between the two flows, while it must be
		impossible to build up pressure between these two gaskets. Hence, the space
		between the two gaskets must have vent and drain wooves, large enough to ensure
		that they cannot be blocked by leaking product, heating medium or coolant.
		Replacement gaskets must fulfil the requirements specified by the manufacturer of
		the heat exchanger.
		8. In the case of high fouling products, the flow passage shall not be too narrow
		in order to avoid blockage. For some products however, an increased velocity
		can assist in controlling fouling and this must be considered in conjunction with the likelihood of product blockage.
		9. To prevent stress corrosion, the design should be such that differences in expansion
		and contraction do not lead to unacceptable stress at times of maximum differences
		in temperature, such as start-up, shutdown and cleaning.
		10. The design should be such as to minimize the risk of recontamination in case of a
		material failure. Methods of minimizing risk include the use of an intermediate
		water circuit for cooling and maintenance of a positive pressure difference between
		the sterile and non-sterile product.
	1. **Tubular heat-exchangers (THE's)**

All THE's must satisfy the following important requirements in addition to those already
stated in the general requirements:

* + 1. Crevices must be absent in the product side and preferably on the heating/cooling
		fluid Side also. On both Sides, they present areas where corrosion IS easily initiated;
		on the product side they also adversely affect clean ability.
		2. The manufacturer must ensure that the welds are of enough quality considering process and cleaning conditions.
		3. Spacers, if necessary, to ensure correct positioning of tubes in the product side, must
		be designed such that they are easy to clean.
		4. In the case of highly VISCOUS products, the design should consider the
		prevention of channelling. If required turbulence cannot be achieved, mixing
		elements may be necessary to ensure a homogeneous temperature at the end of the
		heating section. Mixing elements and their mounting should be hygienic.
		5. If the product contains fibres, for example fruit juices, the cross section should
		be large enough everywhere to prevent blockage of the flow of product. Designs
		with spacers are not suitable for products with fibres,
		6. The design should be such that no vibrations are generated, 'due to for example
		resonance or vibration of tubes, as this may lead to loosening of screwed connections
		such as pipe couplings, in case of unavoidable sources of pulsations or vibrations,
		installation of pulsation dampeners is recommended.

In addition to the above requirements, it is desirable to ensure that, as far as possible, the
flow of product is upwards through the entire installation to eliminate the possibility of
air being trapped in the system. An upward flow is particularly necessary in the case of
low product velocities.

The provision of access for inspection of cleanliness and corrosion is desirable. In certain
countries such cleanliness provisions may be legally required.

* 1. **Types of heat exchanger**

There is a wide variety of THE's ranging from the simple jacketed pipe to the more
complex forms such as the concentric multi tube heat exchanger.

**a) Jacketed pipe or mono-tube heat exchangers**

Although the least efficient with respect to heat transfer, jacketed pipes are amongst the
most hygienic heat exchangers, if well designed and constructed.

**b) Concentric multitube heat exchangers with single product channel**

To ensure that the design is hygienic, care should be taken to ensure that the inlets as well
as outlets (including connections between elements) are cleanable and are without dead
areas. Depending on the length of the tubes, pacers may be needed for support.

* 1. **Coiled tube heat exchangers**

Their characteristics are like those of the jacketed pipe heat exchanger and
concentric multitube heat exchangers with one product channel. Coiled heat exchangers,
however, are difficult to inspect for cleanliness or corrosion, other than with radiographic
(Roentgen) methods. Consequently, coiled heat exchangers are not suited for products that
would require regular inspection of the heat transfer surfaces. If concentric tubes with an
annular channel are used, spacers will be needed in the product channel.

* 1. **Concentric multi tube heat exchangers with more than one product channel**

If there is more than one annular product channel, it is extremely difficult to meet
hygienic requirements. It will also be difficult to ensure that pressure build-up between
gaskets is prevented. This type of heat exchanger is not recommended for sterilization
applications where microbiological safety of the product is paramount.

* 1. **Shell-and-tube heat exchangers**

This type of heat exchanger can be of acceptable design, provided that aseptic couplings
are used and welds are of good quality. Product pipes may be connected m series or in
parallel. If connected in series by welds, inspection will be difficult. If used in parallel,
shadow areas are difficult to avoid at the tube plates. Product flow should preferably be
through the tube side only as the shell side will be difficult to clean and inspect.

* 1. **Cleaning in-Place**

In some tubular heat exchangers. a shadow effect is unavoidable. This must be taken into
consideration in devising the cleaning procedure. Often increasing the velocity of the
cleaning fluid will be sufficient. In other cases, reversal of the direction of the flow of
cleaning fluid may improve cleaning although this may not be practical in the majority of
cases. In cases where a detergent concentrate is added in-line. The potential for low
mixing efficiency of THE's must be considered. Also, for in line addition, care
must be taken to ensure that vulnerable components such as gaskets and seals are not
exposed to high concentrations of chemicals at elevated temperatures.

**6.10 Plate Heat Exchangers (PHE's)**

PHE's are widely used for continuous sterilization plant. In addition to the general
requirements stated above. the following points should be considered:

* + 1. It is recommended that heat exchanger plates should have a surface roughness not
		exceeding an average RA value of 1.0~m as determined by International Standards
		Organization (ISO) standard 468. 1982.
	1. **Scraped surface heat exchangers (SSHE's)**

SSHE's are particularly suited to the heat treatment of viscous products. They may be of
horizontal or vertical design and typically 150-200 mm in diameter with a rotating dasher
assembly. holding blades that scrape or sweep product from the surface to maintain
effective heat transfer.

Any cooling medium can be used but direct regenerative heating or cooling with product
is impractical. Steam is the normal heating medium. Since the heat transfer area available
is generally much less than other types of heat exchangers. the temperature differences
required to achieve required heat fluxes are high. In the case of product heating this can
result in increased fouling.

Aseptic seals are available for use in sterilization systems and must be used downstream
of holding to prevent reinfection where, for example aseptic filling follows.

SSHE's should satisfy the following in addition to the general requirements:

* + 1. Any internal bearings must be hygienic in design and cleanable.
		2. Single seals are satisfactory for static applications; dynamic seals should be double
		with continuous steam or other antimicrobial fluid flushing.
		3. There should be clear indication of the correct position and orientation of blades
		and rotational direction.
		4. The design should ensure that air pockets cannot remain trapped in the barre1.
		Hence, the product outlet should be at the highest point.
		5. The inlet should be below the outlet and the barrel should be drainable.
		Consequently, the inlet should be at the lowest point.

Other factors to be taken into account when selecting and using a scraped surface heat
exchanger is:

* + 1. If the product is an immiscible mixture of liquids with different densities. it is
		necessary to consider the relative densities and viscosities of the liquids when
		selecting a horizontal or vertical machine. in order to avoid settling or separation.
		The consequences of blade configuration may be considerable. For example, a fully
		bladed machine may give plug flow/mass rotation which gives consistent residence
		time but may also lead to temperature distribution problems.
		2. During ClP. the velocity through the annular space may well be lower than in
		rest of the line. Design of an adequate ClP process is therefore essential.
1. **Sterilization Processes for liquid products**

There are many types of continuous sterilization system available, but they all come into one of two categories, direct or indirect.

In a direct system the product is heated by condensation of steam brought into direct contact with the product.

An indirect system is one where the heating medium (steam/ hot water) is separated from the product by a physical barrier and heat transferred across the barrier to heat the product.

The choice of system is dependent on many factors related to product quality, product characteristic (viscosity, susceptibility to fouling), production requirements (capacity, run length) and economics (capital, running costs).

* 1. **Direct Heating:**

There are two types of direct heating, steam injection and steam infusion. In a steam injection process, stem is injected into the product whereas in infusion process the product is sprayed into a steam atmosphere.

* 1. **Stem Injection:**

A typical steam injection system, with product preheated in a heat exchanger prior to being heated to sterilizing temperature in the steam injector. The product at sterilising temperature passes into the holding tube, which is maintained under pressure to prevent boiling of the product. After the holding tube the product is passed into a vessel operated under vacuum resulting in boiling of the product. This causes removal of the steam added during injection and evaporative cooling takes place. By controlling the temperature difference between the preheat and vacuum cooling temperature, all the steam condensed can be removed and dilution or concentration of the product avoided. The cooled sterile product can then be extracted from the vessel and further cooled indirectly and aseptically prior to filling, buffer storage or further processing.

A key requirement is that the steam condenses immediately when comes in contact with the product thus giving up its latent heat. Failure to achieve this will result in uncondensed steam entering the holding tube resulting in variable holding times. In addition, the response of the temperature probe may not be able to differentiate between alternate slugs of steam and cold product. Failure to achieve effective condensation in the injector may result in audible noise and vibration in the holding tube.

* 1. **Steam Infusion:**

Steam infusion is a similar process to that of steam injection, the major difference being the replacement of the steam injector by a steam infuser vessel into which the product is sprayed. The product is heated as it falls through the steam atmosphere to the bottom of the vessel, from where it is pumped to a holding tube and subsequent evaporative cooling vessel if required. The infuser vessel is maintained at a controlled pressure to give the desired temperature. This is important for non-deaerated products as otherwise non-condensable can accumulate in the vessel and must be continually removed. Product is extracted from the base of the vessel by a positive displacement pump at a constant rate and fed into the holding section of the plant. While the level in the infuser vessel is controlled by the feed pump. Level control could also be achieved by altering the outlet flow rate from the vessel rather than the inlet flow rate via the feed pump. Both methods are technically feasible, but the following should be noted.

* + 1. The recommended arrangement is for level control via the feed pump and a
		constant extraction rate and, hence holding time. When the feed pump is used for
		level control, the effect of flowrate fluctuations on the performance of the flow
		distributor will need to be considered. If the flowrate falls, the efficiency of the
		distributor may be reduced and hence the performance of the infuser.
		2. If the vessel extraction pump rate is controlled, the flowrate in the holding tube
		and hence the holding time will be variable. It is, therefore, essential that, at the
		maximum flowrate delivered by this pump, the residence time in the holding tube is sufficient.

Control of the liquid level in the infuser is a key requirement for product quality since
even small variations in level will result in substantial changes in holding time at an elevated temperature. An adequate holding time for microbiological safety must be
provided in the holding tube. No allowance should be made for the residence time in the
infuser vessel or its outlet pipework due to the potential for variations in holding time.

* 1. **Indirect heating**

Indirect heating is probably the most widely used technique for the sterilization of liquid
foods and is. m principle simpler than the direct heating techniques. The simplest
sterilizer configuration. It consists of a heating section. a holding
section and a product cooling section. A back-pressure device is also installed to prevent
the product from boiling as the temperatures used are in excess of 100°C. The heating
medium used can be steam or hot water although hot water tends to be favoured as a
means of minimising fouling. The system shown m Figure 3 has no form of heat recovery
and as such would be economically unattractive. After final heating to sterilizing temperature and holding the sterile product is cooled to the filling temperature in two stages via a pre-cooler and final
cooler. The heat recovery system is more complex in terms of plant design but has a much
reduced energy requirement. There are fewer control loops than for direct systems, the
key ones being for flow and temperature control.

* 1. **System components**

Construction materials must be corrosion resistant under normal conditions of use taking
into account the properties of the product at the sterilization temperature and of the
cleaning solution at the cleaning temperature. All materials used should be acceptable for
contact with food and therefore comply with US Food and Drug Administration (FDA) or
German Bundesgesundheitsamt (BGA) guidelines.

* 1. **Steam injector and steam supply**

A key requirement for direct heating is the availability of dry, saturated, food quality
steam, produced by evaporation of potable water. As the steam condenses into the
product. it must be considered a part of the product formulation and care must be taken
over the steam supply and the use of boiler water treatment chemicals. There are
legislative restrictions on the use of such chemicals.

In practice. the design of the injector, the pressure of the steam and hence the amount of
steam, the number of nozzles and the product characteristics such as viscosity, all
influence the way in which the steam condenses and heats the product. The suitability of
a chosen configuration should be checked experimentally with the product to be sterilized.

The steam supply line and injection unit should be of hygienic design. inside and outside.
During shutdown. product may enter the steam supply line through the injection unit.
Consequently. it must be possible to clean both the inside and outside of the nozzle. The
injection unit must be capable of being cleaned and the cleaning process must ensure that
no residues of cleaning chemicals are left in the steam supply line or injection unit.

* 1. **Process vessels for direct heating**

Process vessels specific to direct heating systems are the steam infuser vessel and vacuum
cooling vessels. They should meet the following requirements:

* They should be cleanable and fully drainable.
* All internals and connections should meet the same standards as the vessel itself i.e.
cleanable. sterilizable and bacteria tight for aseptic operation (e.g., vacuum vessel),
hygienic (e.g. infuser vessel).

In the case of the infuser, the product flow distributor may require special attention to
ensure that it can be cleaned. For vacuum vessels all connections are particularly critical
as the vacuum conditions in the vessel provide an increased risk of bacterial ingress.
Consideration may be given to the use of double seals for increased assurance, with the
gap between the seals flushed with steam, antimicrobial fluid or operated under vacuum.

1. **Scheduled Process**
	1. The scheduled process is developed and documented by a qualified Process Authority who has scientific knowledge and experience in this field. The documentation required to validate the process covers the scientific basis for selecting certain specifications and requirements, calculations used to derive numerical values for the specifications, a review of applicable regulations and guidelines, and a descriptive commentary on what equipment and controls are being used and why. The combinations of variations encountered in commercial production are to be accounted for in the process, and critical factors that may affect the achievement of commercial sterility need to be specified. To achieve commercial sterility, Health Canada requires that the process be designed to meet a Fo = 3.0 as a minimum.
	2. If the process is designed to meet commercial sterility as per the Food and Drug Regulations B.27.001 but does not meet a minimum Fo = 3.0, a submission must be made to Health Canada to request an evaluation of the process to determine its acceptability.
		1. Testing procedures and operator instructions are to be included in the process documentation.
		2. Upon initial commissioning of the processing unit or after significant alterations have been made to the system or scheduled process, incubation trials and analysis must be used to confirm that the process is valid. Any changes to an aseptic processing and packaging system must be assessed by the qualified authority as to the potential impact they will have on the system, to maintain the safety of the product.
		3. Operating Instructions- Detailed operating instructions are to be made available to the operator, to ensure that the process is operated according to the design of the scheduled process. These instructions must include procedures for monitoring for critical factors during pre-sterilizing at start-up, and during production, and what to do if the critical factor limits are not met (process deviation procedures). A process deviation occurs whenever any process is less than the scheduled process or when critical factors are outside of specified limits.
		4. Critical Factor Adherence

The critical factors are those factors specified in the **scheduled process** as being necessary for the achievement of commercial sterility in the product. The inspector must review the scheduled process to see what critical factors were established. If during on-site observation, any of these critical factors are not within the limits documented in the schedule process, this is a process deviation and the product cannot be considered commercially sterile. The affected product must be placed under detention pending a thorough and documented investigation. The results of the investigation must be reviewed by a competent process authority. Prior to the release of any affected product, the process authority must authorize in writing that the results of the investigation scientifically demonstrate that the product is commercially sterile.

The process authority must be able to provide the appropriate evidence obtained through documented sterility trials that the product is commercially sterile. If the scientifically derived evidence to support the out-of-limit critical factor does not exist, the process authority cannot authorize the release of the product until such evidence is obtained. The lack of spoilage in incubated samples is not, by itself, indicative of commercially sterility but rather only indicates that other problems do not exist (e.g. low-level container closure failure).

* + 1. Critical Factor Records

The processing records must contain all the required information and indicate if the products were processed within the acceptable limits for the critical factors (no process deviations). Process deviations require detailed documentation in the plant's deviation log book and/or a separate file for follow up by the plant management to determine the cause and corrective action for the deviation and to ensure any compromised product is properly identified and handled to prevent distribution or sale.

Process deviation records must include date and time of the process deviation, amount of product involved, product quarantine and release of affected product, investigation into the cause of the process deviation (e.g. equipment breakdown, power failure, low temperature at outlet of holding tube), the action taken (e.g. line cleared, repairs performed, system re-sterilized) and review by appropriate company personnel.

Recording charts are part of the critical factor records. This information must be recorded in ink to provide a permanent record. Since this information provides a processing record, it will assist the plant in tracking down quality and safety problems and help prevent recall of their products. All production records must be reviewed on a timely basis by a member of plant management. Any operator's notes concerning unusual occurrences must be evaluated by plant management to ensure that a critical process parameter was not violated (i.e. that an unusual occurrence was not in fact a process deviation requiring product quarantine).

1. **CONSTANT LEVEL TANK (CLT)**
	1. **The constant level tank (CLT**) is a reservoir for supply, at atmospheric pressure, of raw product to the sterilizer to permit continuous operation of the aseptic processing and packaging system. The constant level tank is located at the start of the APPS system. The constant level tank controls the milk level and provides a uniform head pressure to the product leaving the tank.
	2. **General Conditions**
		1. The tank shall be constructed of stainless steel and be in good mechanical and sanitary condition. The tank's design features will be assessed under the subsequent tasks.
	3. **Design**
		1. The tank shall be of such design and capacity that air shall not be drawn in the system with the product when operating at the maximum sealed capacity of the flow control device. The constant level tank shall therefore be fabricated so that the raw product will drain to the outlet before the outlet becomes uncovered. One method of complying with this requirement is to have the bottom of the tank pitched to the outlet at a minimum downward slope of at least 2% (0.2 cm per 10 cm) and the top of the outlet pipe lower than the lowest point in the tank.
	4. **Cover**
		1. The tank shall be fitted with a removable cover, or an inspection port with a removable cover, of suitable design to maintain atmospheric pressure and to minimize the risk of contamination. The cover shall be pitched to an outside edge to provide drainage. All openings in the cover shall be flanged upwards and covered. Pipelines entering through the cover (excluding directly clamped lines) shall be fitted with a sanitary umbrella deflector that overlaps the edges of the opening and is located as close to the tank cover as practical. The cover shall be used during processing.
	5. **Airspace and Overflow**
		1. Any product diverts lines, recycle lines and water lines coming into the constant level tank (CLT) must be installed in a way that prevents the siphoning of raw milk or cleaning products into finished product or potable water lines (a cross connection). This is accomplished by having an overflow outlet at least twice the diameter of the largest inlet to the constant level tank, and ensuring that the divert, recycle, water lines terminate and break to atmosphere at least two times the diameter of the largest inlet above the maximum overflow point of the CLT
	6. **Level Control Device**
		1. This device is required to control the flow of milk to the constant level tank and therefore provide constant head pressure to the product leaving the tank.
		2. The constant level tank shall be equipped with an automatic device of sanitary design and construction to control the raw product level.
2. **Feed Pump**

The feed pump is used to improve flow through the raw regenerator, and to supply the flow control device with milk from the constant level tank to prevent starving, especially if the flow control device is a homogenizer. It also helps to remove negative pressure and subsequent **flashing** or vaporization in the raw regenerator section. In aseptic processing and packaging systems, the feed pump normally operates in both forward and diverts flow, as long as the flow control device is in operation.

* 1. **General Conditions**
		1. A feed pump must be of sanitary design. The pump must be clean and in good mechanical condition.
		2. The raw product side of the regenerator may be by-passed at start up. Entrapment of the product in the by-pass line during periods when the feed pump is in operation shall be precluded by: Close-coupled by-pass connections (i.e. as close as possible: approximately 2.5 times the pipe diameter).
		3. Design of the manually or automatically controlled valve which will permit a slight movement of product through the by-pass line
		4. Other equally effective system
	2. **Location**
		1. The feed pump shall be located between the constant level tank and the inlet to the raw product side of the regenerator.
		2. **Inter-wiring**

Where a feed pump is used a pressure differential controller-recorder is required and shall be inter-wired in such a way that it can only operate when the flow control device is **allowed to run**; i.e. the FCD has been turned on by the operator or operating system and safety interlocks that may be installed on the aseptic processing and packaging system are not preventing the FCD from operating.

1. **Regeneration**

The regenerator section on aseptic systems may either be of milk-to-milk or milk-to-heat transfer medium-to-milk type. The cold raw product is warmed by hot sterilized product flowing in a counter current direction on the opposite sides of thin stainless-steel plates or tubes. The sterilized product will in turn, be partially cooled.

The basic requirements for the regeneration section are:

* That it is installed and operated in such a way that the proper pressure relationship exists between the raw product or media and sterilized product in forward and divert flow conditions
* Proper sanitary design and construction
* Clean and in good condition, with no cracks, pinholes or leaks
	1. **General Conditions**

 Since the physical distance between the various liquids in the sterilization plates or tubes is extremely small, the liquids have the potential to move through the plates or tubes and cross-contaminate the product if pin holes, cracks or leaks exist.

 The plates or tubes shall be of sanitary design, constructed of stainless steel or other corrosion resistant material, and must be without pin holes, cracks or leaks. The plates or tubes must be clean with no presence of milk remnants, milk-stone, mineral scale build-up, or foreign materials. If plates are used, the plate gaskets must be equipped with leakage grooves and must not be compressed or otherwise show signs of wear.

 A routine program to monitor the condition of plates and tubes (pin holes, gasket condition, cracks, etc.) must be established by plants, taking into consideration the design specifications, operating conditions and hours of operation, wear and the history of the plates and gaskets. The integrity of all food contact heat exchange surfaces must be checked at least once per year by an acceptable method (e.g. dye recirculation, dye check, pressure retention, Helium Testing etc.). However, if the plant has experienced problems with heat exchanger integrity (plate or gasket issues), a more frequent inspection program must be implemented to verify that the problem has been remedied. Appropriate records must be kept showing proper testing has occurred. These records should also document the cause of any failure (e.g. age, compression, metal fatigue, etc.). If pin holes are found in any plate in any section, then all plates in the same section should be checked.

* 1. **Pressure Differentials**

 This task will only assess the differential pressure. The equipment used to monitor pressure (PDC recorder and gauges) will be assessed under the task **Pressure differential recorder controllers (PDC recorder**).

 As previously discussed, raw milk or media and sterilized milk are separated in the regenerator section only by thin metal plates or tubes and a system of gaskets. In milk-to-milk type regenerators, the raw side of the regenerator must, at all times, be under lower pressure (at least 14 kPa or 2 psi) than the sterilized milk.

 In milk-to-heat transfer medium-to-milk type regenerators, the sterilized milk section must always be under greater pressure by at least 14 kPa (2 psi) than the heat transfer medium. The protection is on the sterilized milk side of the system and is engineered to allow sterilized product to leak into the heat transfer medium in case of regenerator plate (or tubular) failures. In this type of system, the heat transfer medium (e.g. hot water) must be from a safe source. Locations of the pressure sensors for these controls are a) at the heat transfer medium inlet on the aseptic side of the regenerator and, b) at the sterilized product outlet of the regenerator.  Failure to maintain the required pressure differential in the sterilized milk section of the regenerator shall cause the FDD to assume the divert flow position.

 **12.0** **Flow Control Device**

 This task governs the uniform rate of flow through the holding tube so that every particle of product is held for the required period of time, as specified in the **scheduled process**. This device is a positive displacement type pump or homogenizer. Other equally effective mechanisms such as a Meter Based Timing System (MBTS) with proper components (centrifugal pump, flow control device or variable speed motor, meter head, relays, alarms and flow recorder-controller, etc.) may also be used as a flow control device.

 **12.1 General Conditions**

The flow control device must be constructed of stainless steel and be in good mechanical and sanitary condition. The driving mechanism shall be designed so that in the case of wear, belt stretch, etc. the capacity will not increase. The flow control device cannot be excluded from the system during operation of the aseptic processing and packaging system. The device must be located upstream from the holding tube and normally it is located between the outlet of the raw regeneration section and the inlet of the heating section of the aseptic processing and packaging system.

 **12.2 Set and Seal**

 The maximum operating capacity of the flow control device shall be set to ensure appropriate **flow rate** to give the proper **holding time**, in accordance with the calculations done in the **scheduled process**, as evaluated under **Holding Verification and Records.**

 When homogenizers are located within the aseptic system, flow rate evaluations shall be made with these pieces of equipment operating (with no valve pressure on the homogenizer) and by-passed to determine the fastest flow rate (minimum holding time). When flow promoters are located downstream from the flow control device, the flow rate shall be determined with the flow control device operating at maximum capacity, and the flow promoters in operation.

 If maximum speed gives legal holding time a seal is not necessary. If the device is of the variable speed type or a single speed capable of being altered with different belts and pulleys, it must be sealed at an established flow rate to prevent operation at a greater capacity than that which gives the proper holding time. Alarm settings determining the flow diversion set points on magnetic flowmeter systems must also be sealed.

 Any change in the line resistance of the system after maximum speed of the pump has been set, will alter the flow rate and corresponding hold time. Increasing the line resistance by the addition of plates or piping will decrease the flow rate, increasing holding time. This increase in flow resistance in effect reduces the efficiency of the sterilizer. Decreasing the line resistance by the removal of plates, pipes, or auxiliary units will increase the flow rate, decreasing the holding time. Wear of the drive belts and pump impellers due to normal operation will gradually decrease the rate of flow through the system, thereby increasing the holding time.

 The flow control device is to be evaluated and sealed (if necessary) upon installation and annually thereafter, and in addition, whenever the seal on speed setting is broken, whenever any alteration is made affecting the holding time, the velocity of the flow (such addition or removal in the number of plates, pipes or auxiliary units) or the capacity of the holding tube or whenever a check of the capacity indicates a speed up. Records of alteration and re-evaluation of the system must be kept in the plant's file.

**12.3 Fail Safe Capability**

There must not be a by-pass (recirculation line) around the flow control device during processing. A by-pass may be present for CIP purposes, but must be dismantled and removed during processing. To ensure that no by-pass is present during processing a proximity switch should be utilized so that the FDD will not operate in forward flow.

A Meter Based Timing System must have the appropriate controls and instrumentation in place. When a Meter Based Timing System replaces the positive displacement flow control device, it must be evaluated upon installation and at least once every 6 months thereafter, whenever seal on the flow alarm is broken, whenever any alteration is made affecting the holding time, the velocity of the flow or the capacity of the holding tube or whenever a check of the capacity indicates a speed-up. Appropriate records must be kept showing proper testing has occurred.

**13.0 Heating Section**

The heating section of the aseptic system provides rapid, uniform and controlled heating of the product up to sterilization temperature. The raw product is usually forced through this section by the flow control device. Heating may be by direct injection or infusion of steam, or indirect heating through tubes, plates, or scraped-surface heat exchangers.

**13.1 General Conditions**

 For indirect heating, the heating equipment shall be clean and in good condition. It shall be of sanitary design and constructed of stainless steel or other corrosion resistant material. During operation, the heating section must not leak at gaskets, seals, joints or connections.

 With direct heating, it must be noted that the steam injection process is an inherently unstable process. When steam is injected into a fluid, condensation of the steam may not be completed inside the injector unless proper design criteria are satisfied. Lack of complete condensation would cause temperature variations in the holding tube that could lead to some milk particles being processed below the required temperature.

**13.2 Heating Medium**

 Steam used as a heating medium shall be free of harmful substances or extraneous matter. Only culinary steam may be used for direct steam injection or infusion.

 Steam should be as free as possible from non-condensable gases. Any vapours in the holding tube would displace product, resulting in shorter holding times. A de-aerator installed on the boiler will aid in keeping the holding tube free of non-condensable gases.

 Boiler and water treatment chemicals and other additives used must be dairy safe and approved for dairy plant purposes.

1. **Pressure Limit Recorder Controllers**

For both direct and indirect heating systems, product pressures in the holding tube and across the steam injector must be monitored and controlled to keep the product in a liquid phase and to ensure adequate isolation of the injection chamber.

A pressure limit recorder controller must be in systems that can operate with less than 518 kPa (75 psi) pressure in the holding tube. This instrument is used to monitor product pressure in the holding tube. This instrument has a pressure switch that causes the FDD to move to the divert position if the product pressure falls below a prescribed value, e.g. If the operating temperature is 100°C (212°F), the pressure switch must be set at 69 kPa (10 psi); If the operating temperature is 116°C (240 °F), the switch must be set at 140 kPa (20 psi). The pressure switch settings are determined during the set up and testing procedures (See Test 30 in Chapter 18 – Critical Process Test Procedures).

On direct heating systems with steam injection only, a differential pressure limit indicator is needed to ensure adequate isolation (supplementary orifices) of the injection chamber so that product is uniformly heated in the chamber. This instrument must have a differential pressure switch so that the FDD will move to the divert position if the pressure drop across the injectors is below 69 kPa (10 psi).

Records shall indicate the holding tube operational pressures, the pressure switch settings, the results of required tests, and satisfactory follow up on out of specification findings.

* 1. **Controllers/ Settings Sealed**

Once the required tests have been completed, the controllers and settings must be sealed to prevent unauthorized adjustments.

* 1. **Ratio Controller (Direct Heating Systems)**

A ratio controller is required for systems applying direct heat to product to prevent water adulteration of the product being processed. The ratio controller is 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. This is accomplished by constantly monitoring the product temperatures at the inlet and outlet of the vacuum chamber.

One sensor is located immediately prior to the point of steam injection (incoming product), and the other is located immediately after the product exits the vacuum chamber (outgoing product). The optimum temperature differential between the incoming and outgoing product shall be determined by total solids analysis and such differential set on the ratio controller. The ratio controller automatically controls the pre-heat steam supply or the flash chamber vacuum to prevent water adulteration of the product.

When a water feed line is connected to a vacuum condenser, and the vacuum chamber is not physically separated from the vacuum condenser, satisfactory methods must be installed to prevent adulteration of the product with water in the condenser.

1. **Holding**

This is the part of the aseptic processing and packaging system in which heated product is held for the specified time required in the **scheduled process**. This section is located after the final heating section of the Aseptic system and may include the sensing chamber at the end. The sensing chamber is that portion which houses both the official indicating thermometer and the STLR hot milk temperature sensors.

* 1. **General Conditions**

The holding tube and all connections shall be of sanitary design and construction and shall be clean and in good mechanical condition. The holding section shall be located after the FCD with no intervening flow promoters, and after the final heating section, but before the FDD or any cooling section.

No device shall be permitted for short circuiting a portion of the tube or for the removal of a section of the tube such that the holding time is reduced below that specified by the scheduled process. No portion of the holding section between the inlet and the sensing chamber shall be heated.

* 1. **Slope and Support**

When the holding section is comprised of a holding tube, it is required to have a continuous upward slope (including elbows) of at least 2% (2 cm per 100 cm). The slope is required to eliminate any air entrapment in the holding tube, which would displace product and reduce the holding time. To prevent variance in the slope, the holding tube shall be permanently fixed by mechanical supports.

* 1. **Holding Verification and Records**

The holding time is determined by calculation and is specified in the scheduled process. The calculations must include the extra condensate volume from steam added, if direct heating from steam is used. Results determined will dictate the length of the holding tube needed to provide the proper holding time, based on the flow rate used.

The actual length of the holding tube installed may be compared to the measurement determined by calculation in the scheduled process. Records shall indicate the measured flow rate of the system under the conditions outlined in Set and Sealed. This measured value must be the same or lower than the value used in the calculation for the scheduled process.

Re-calculation of the holding tube length may be necessary if changes are made to the system that could alter the flow rate, or if the process itself is changed in any manner.

Verification of proper holding tube length and flow rate shall be done upon installation, annually, or whenever the seal on the FCD is broken, and after any change is made to the system that could affect the holding time. The appropriate records shall be kept on the plant's file, including all supporting calculations.

* Product pressures in the holding tube shall be monitored as per- Pressure Limit Recorder Controllers.
* The holding tube length must be such that the fastest flowing particle of any milk or milk product will not leave the holding tube in less than the required holding time of min 15 sec. 3.2.3 Particle movement laminar flow turbulent flow are detailed in Refer Table 1(a) for Holding Loop Calculation for Dairy Products whose Flow Rate type is Turbulent (Re >2100) and Table 1(b) for Holding Loop Calculation for Dairy Products whose Flow Rate type is Streamline/ Laminar (Re <2100)



Laminar/ Streamline flow pattern when the Reynolds number, Re is < 2100

Turbulent flow pattern when the Reynolds number, Re is > 2100

**Figure 1: Particle movement laminar flow turbulent flow**

* Calculation of type of flow is detailed in the article namely “Residence time distribution in aseptic processing of particulate foods”.
* Radial velocity & temperature profile in tube is shown below



**Figure 2: Radial velocity & temperature profile in tube**

* Velocity profiles are also influenced by the radial distance in the holding tube in addition to the rheological properties (specifically the flow behaviour index, n) as illustrated in below.



**Figure 3: Velocity and Radial distance profile in tube**

* Any piping from the outlet of the heater to the flow diversion device that has less than the required slope shall not be considered part of the holding tube.
* The length of the holding tube shall be the length of tube from the heating section outlet to the diversion temperature sensing device.
* Hence Holding Coil length shall be the distance between T1 & T2 as per the Figure 3
* The holding time for HHST systems must be determined from the pumping rate rather than by the salt conductivity test, because of the short holding tube. The holding tube length must be such that the fastest flowing particle, of any milk or milk product, will not traverse the holding tube in less than the required holding time. Since laminar flow, the fastest flowing particle travels twice as fast as the average flowing particle, can occur in the holding tube during pasteurization of high-viscosity milk or milk products, holding tube lengths are calculated as twice the length required to hold the average flow for the time standard
* The holding tube shall be so designed that the simultaneous temperature difference between the hottest and coldest product in any cross-section of flow at any time during the holding period will not be greater than 1° F (0.5°C),
* The average velocity through the holding tube shall not be less than 1.0 feet per sec (30.5 mm per sec),
* Minimum CIP velocity through the holding tube and other pipelines shall be minimum 5.0 feet per sec (1.5 m /sec)
* Minimum velocities during CIP and product in holding tubes are captured in Table 1

**Table 1: Minimum velocities during CIP and product in holding tubes**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 16 GA O.D. Tube Size | Length Equiv. Std.90° Tube Bend | Minimum Recommended CIP Flow Rate (5 feet/sec) | Area of Tube I.D. (A) | Minimum Average Velocity at 1 feet/sec |
| in. | in. | GPM | sq. in. | GPM |
| 1 | 3.48 | 10 | 0.594 | 2.0 |
| 1 ½ | 4.94 | 24 | 1.485 | 4.8 |
| 2 | 6.83 | 43 | 2.761 | 8.6 |
| 2 ½ | 8.65 | 70 | 6.491 | 20.4 |
| 3 | 10.48 | 102 | 6.491 | 20.4 |
| 4 | 13.68 | 180 | 11.545 | 36.0 |

NOTE: The Length Equivalence of a standard 90° tube bend can be deducted from the Linear Length calculation based on the number of 90° tube bends incorporated into a single or multi-loop holding tube design

1. **Flow Diversion Device (FDD)**

The FDD is set up to control the direction of product flow according to the establishment of safe conditions within the processing system. It is located after the cooling section and before the filler or aseptic surge tank and is designed to divert flow away from the filler or aseptic surge tank automatically.

* 1. **General Conditions**

The FDD must be of a design that permits sterile operations, and that can positively and effectively prevent potentially unsterilized product from contaminating the fillers or aseptic surge tank(s). Since there are many possible valve designs, numbers and arrangements, acceptance should be determined by the responsible agency.

FDDs must be equipped with a proper control panel where the control functions and relays are installed. This control panel may be part of a universal panel unit. This panel shall be free of any device or switches that may override the control functions and jeopardize the safety of sterilized product. On valves that have external solenoids, the airlines must not have quick release couplings.

Installations on aseptic processing and packaging systems often have complex operating parameters for the FDD that can only be handled by a micro-processor or programmable logic controller (PLC). A PLC or micro-processor control used strictly for FDD function is not required to meet the standards of **Program Logic Controllers and Computers**, but all valve functions must pass the required tests.

The FDD and the return lines shall be constructed of stainless steel and must be clean and in good mechanical condition. Valves, plunger seals and O-rings must also be clean and in good mechanical condition. Stem length of the valves shall be non-adjustable to ensure that proper seating of the valves is not disturbed. If the stem has a threaded attachment, a locking pin or other equivalent locking mechanisms shall be used to prevent any misalignment. Air to the FDD must be clean and unrestricted.

* 1. **Return Line**

The FDD shall have a pipeline that directs the flow of potentially unsterile product safely away from fillers and /or aseptic surge tanks. Any subsequent valves installed on this line must be configured in all positions to allow free flow from the FDD, without blocking the flow or creating excessive back pressure on the FDD. A flash cooler may be installed on the return line to prevent injury to bystanders during divert events when pre-sterilizing the system.

* 1. **Location**

The FDD must be located after the final cooling section and before the fillers or aseptic surge tanks.

* 1. **Fail Safe Divert Capability**

The FDD shall automatically assume the divert position (so product will not go to aseptic surge tanks or fillers) under at least one of the following conditions for **indirect**heating systems:

* + 1. The product temperature in the sensing chamber drops below the specification in the scheduled process
		2. The differential pressure between sterilized product and unsterilized product or heat transfer media is less than 14 kPa (2 psi) in the regenerator
		3. Adequate product pressure is not maintained in the holding tube to prevent boiling (less than 69 kPa (10 psi) above the boiling pressure of the product in the holding tube)
		4. Loss of electrical power or compressed air to the FDD solenoids
		5. Excessive flow rate is detected for systems utilizing a magnetic flow meter as a flow control device
		6. Pressure in the surge tank drops below the value specified in the scheduled process, in systems where there is only one surge tank or no capability to send product directly to a filler (prevents sterile product from entering unsterile tank). Note: In systems where more than one surge tank exists, product would not need to be diverted but could be directed to the sterile surge tank

The FDD shall automatically assume the divert position (so product will not go to aseptic surge tanks or fillers) under at least one of the following conditions for **direct**heating systems:

* + 1. The product temperature in the holding tube drops below the specification in the scheduled process
		2. The differential pressure between sterilized product and unsterilized product or heat transfer media is less than 14 kPa (2 psi) in the regenerator
		3. Adequate product pressure is not maintained in the holding tube to prevent boiling (less than 69 kPa (10 psi) above the boiling pressure of the product in the holding tube)
		4. Loss of electrical power or compressed air to the FDD solenoids
		5. For steam infusion systems, loss of pre-determined parameters (temperature, pressure level, etc. as determined by the qualified authority) at the steam infusion chamber exits
		6. For steam injector systems, improper differential pressures across the steam injectors at the holding tube (a 69 kPa (10 psi) drop across the injector is required)
		7. Excessive flow rate is detected for systems utilizing a magnetic flow meter as a flow control device
		8. Pressure in the surge tank drops below the value specified in the scheduled process, in systems where there is only one surge tank or no capability to send product directly to a filler (prevents sterile product from entering unsterile tank). Note: In systems where more than one surge tank exists, product would not need to be diverted but could be directed to the sterile surge tank

The FDD shall be installed with position detection capabilities to provide an electrical signal to the STLR flow indicating lights and event pen.

After an event causing a flow diversion, all product contact surfaces downstream from the holding tube shall be re-sterilized, as outlined in the **scheduled process** (see also Thermal Limit Controller Sequence Logic). The re-sterilization process must include the fillers and aseptic surge tanks, unless there is a properly designed aseptic barrier to act as a leakage barrier.

Plant records shall indicate the test results for valve operation at the required intervals and must show satisfactory follow-up on out of specification findings.

* 1. **Leak Detect**

Aseptic processing and packaging systems where the filler continues to operate from an aseptic surge tank while the FDD is in the divert position, must use a properly designed aseptic barrier to separate sterile product from potentially non-sterile product.

The aseptic barrier shall be located between the FDD and the blocking valve for the aseptic surge tank.

The barrier(s) may include one or more steam blocks but must include a resistance thermal device (RTD) or other acceptable temperature sensor at the lowest level of the barrier to detect barrier failure due to steam loss or fluid leakage into the barrier. Barrier failure detected by the temperature sensing device must trigger an alarm system to alert the operator to the alarm condition, immediately initiating a **shut down sequence** for the processing system as specified in the scheduled process.

After a barrier failure condition, the fillers, aseptic surge tanks and lines, and aseptic processing system must be completely drained of product and all equipment must be re-sterilized before processing and filling may resume. Implicated product should be placed on "**hold**" until its sterility is assessed. This failure must be noted in the operator's log book and a process deviation report must be completed, which includes the date and time of the process deviation, investigation into the cause of the process deviation and action taken both on product and other corrective measures.

1. **Device/Panel Sealed**

The FDD control panel and valve position detector cover(s) must be sealed to prevent unauthorized tampering or adjustments. The valve position sensing detectors, valve actuating solenoids and relays shall be sealed. If a PLC or micro-processor is used to control valve functions, access to programming functions shall be sealed.

1. **Indicating Thermometer**

The indicating thermometer provides the official processing temperature of the product, which is a critical factor in the **scheduled process**. This is to prevent situations where aseptic processing may be operated with a defective or damaged unit while waiting for a replacement thermometer.

* 1. **General Conditions**

This thermometer is required for all aseptic processing and packaging systems. It must be clean and in good operating condition. The thermometer shall be mercury actuated or an accepted equivalent, or an approved resistance thermal device (RTD).

Mercury actuated or accepted equivalent thermometers shall be direct reading and contained in a corrosion resistant case which permits easy observation of column and scale. The filling above the mercury is to be nitrogen or equally suitable gas. The bulb shall be Corning normal or equivalent.

The RTD type must be fail-safe, utilizing two separate RTDs. It must meet the scale and thermometric response specifications. The criteria in Design Requirements for Digital Thermometers shall be used to evaluate RTDs when used as alternatives to mercury actuated direct reading thermometers.

* 1. **Location/Accessibility**

The official indicating thermometer shall be located in the sensing chamber, along with the probe for the STLR. The indicating thermometer probe should be located after the probe for the STLR. The distance between the 2 probes should not be more than 30cm (12 inches). The indicating thermometer must be easily and safely accessible by the operator, to allow accurate reading of the processing temperature.

* 1. **Specifications**

The scale shall be graduated in 0.5°C (1°F) divisions with not more than 9.4°C (17°F) per 25 mm (1 inch) of graduated scale.

The stem fitting shall be pressure-tight against the inside wall of the fitting, with no threads exposed to product.

* 1. **Calibration/Records**

Records of tests performed to determine the thermometer's calibration shall be maintained in the plant's files. Tests must include temperature accuracy and thermometric response, upon installation and at an interval of at least every 6 months. The frequency of testing should be increased if the calibration is consistently found to be out of adjustment. If the calibration is consistently found to be out of adjustment, the reason for the calibration problems should be immediately identified and rectified.

Testing methods shall comply with the required standards and must show satisfactory follow-up on out of specification findings. Plant management must investigate the safety of the product produced with out of calibration equipment (e.g. if the indicating thermometer at the outlet of the holding tube is reading higher than the calibration standard, the product may have been under processed).

* 1. **Sealed**

The access to calibration adjustments must be sealed once the thermometer has been calibrated. The cover or scale plate on mercury in glass (MiG) thermometers should have a seal attached to indicate tampering. The thermometer panel and the RTD sensor housing should be sealed on resistance thermal devices.

1. **Safety Thermal Limit Recorder**

**19.1 The function of this device is to**

* + 1. Automatically record the temperature of the product in the sensing chamber on a chart that also indicates the time of day, and provides a record of the process
		2. Indicate and record the position of FDD (i.e. forward or divert flow)
		3. Supply a temperature cut out signal input to the thermal limit controller unit

The evaluation of this task could include the review of documents such as:

* + 1. Plant records
		2. Testing/calibration documents
		3. Scheduled process
		4. Ladder logic
	1. **General Conditions**

The STLR must meet the criteria established by the manufacturer of the APPS systems (industry to supply). Units must be manufactured for STLR usage and any modifications must be performed by or authorized by the manufacturer.

The STLR shall be housed in a case that is moisture-proof under normal operating conditions. The STLR must be maintained in good condition and operated as specified by the manufacturer. Any covers preventing access to public health adjustments, such as the divert set-point, must be maintained in place.

The single probe which senses the temperature for both the temperature recording pen and the cut-in /cut-out control shall be installed with a pressure-tight seal against the inside wall of the pipe with no threads exposed to milk or milk products.

The STLR must be serviced at least once per year and maintained on a continual basis so that the instrument functions according to specifications. Records of service and maintenance must be available in the plant's files.

All switches on the STLR and any controls associated with the operation of the aseptic unit shall be clearly identified. There shall be no switches or devices that could jeopardize the safety of the product by by-passing or overriding any public health controls.

1. **Location**

The single probe which senses the temperature for both the temperature recording pen and the cut-out control shall be installed in the sensing chamber, before the indicating thermometer probe. The distance between the 2 probes should not be more than 30 cm (12 inches).

* 1. **Specifications**

A circular chart shall make one revolution in not more than 12 hours and shall be graduated for a maximum record of 12 hours. If operations extend beyond 12 hours, a 24-hour chart can be used if it can provide an equivalent level of accuracy and clarity.

The chart positive drive mechanism shall be equipped with a system to prevent slippage or manual rotation (e.g. pin to puncture the chart paper). The chart used shall correspond with the chart number displayed on the identification plate of the STLR

The chart graduations shall not exceed 1°C (2°F) within a range of 5.5°C (10°F) of the processing temperature. The chart temperature scale shall not exceed 30°C (55°F) per 25 mm (1 inch) within a range of 11°C (20°F) of the processing temperature.

The STLR must have a functioning temperature recording pen.

All units must also have a functioning frequency pen. This pen, also called the event or divert pen, records the position of the FDD with a line on the outer edge of the chart. The frequency pen is energized by a position detector in the FDD as the FDD moves into forward position. The frequency pen is de-energized during diverted flow and it moves down to indicate a divert.**Some systems may be designed so that the event pen indicates the critical factors required to enable forward or diverted flow. In such cases, the event pen will be de-energized when at least one of those pre-determined critical factors is not met.**

These two pens must track together or follow the same timeline. On certain models, a reference arc is used to align these two pens.

If the STLR requires a third pen, as with a multiple temperature divert unit, this third pen cannot track with the other two. It must be adjusted to lead or follow the other pens by a specified time factor. This value shall be displayed on the STLR unit. This ink used in this set-point recording pen should be differentiated from the other two.

1. **Thermal Limit Controller Sequence Logic**

Since the FDD is located downstream from the cooling section on aseptic systems, forward flow cannot occur until all product contact surfaces from the holding tube to the FDD have been held at or above the required system sterilization temperature for the time specified in the scheduled process.

The thermal limit controller unit utilizes a sequence of electrical inputs and timers to ensure the Aseptic processing and packaging system is sterilized before allowing the FDD to assume the forward flow position.

For indirect heating systems, forward flow commences only after sensors at the FDD and at the holding tube have reached the required temperature for the length of time specified for system sterilization as per the scheduled process.

In direct heating systems, forward flow may commence only after the sensors located at the holding tube, the coolest part of the vacuum chamber, and at the FDD have reached the required temperature for the time period specified for system sterilization as per the scheduled process.

This assures that all parts of the system have been properly sterilized before allowing the FDD to move into the forward flow position. Once the minimum times and temperatures have been satisfied for system sterilization, the two auxiliary controllers (see Auxiliary Thermal Recorder / Controller- General Condition-at the FDD, and at the vacuum chamber on direct heating systems) then drop out of the control loop, and the primary recorder-controller (STLR) at the holding tube outlet (sensing chamber) resumes its function for normal product processing temperature control.

Failure to meet any safe forward flow condition, such as temperature below cut out, improper regenerator pressure differential, improper holding tube pressure, loss of predetermined liquid levels at steam infusion chamber exits or loss of differential pressure across the injector, shall cause the FDD to immediately move into the divert flow position, unimpeded by the thermal limit controller unit.

After a diversion event, the FDD shall not resume forward flow until the system is re-sterilized and the thermal limit sequence logic is again satisfied.

The settings and adjustments for the thermal limit controller unit must be enclosed and sealed to prevent unauthorized tampering.

* 1. **Calibration /Records**

The performance accuracy of the STLR and thermal limit controller shall be performed upon installation, verified at least once every six months and whenever a seal has been broken. Records of tests to determine accuracy shall be maintained in the plant's files. Tests which should be performed include the following:

1. Recorder temperature accuracy
2. Recorder time accuracy
3. Cut in/Cut out
4. Thermal limit controller sequence logic
5. Recording thermometer check against indicating thermometer: (Daily) The recording thermometer shall not read higher than the corresponding indicating thermometer. However, should the recording temperature differ from that of the indicating, necessary measures must be taken and documented to correct the situation.
	1. **Sealed**

Access to STLR cut in/cut out adjustments shall be sealed. The sealing device should provide an indication of tampering or unauthorized adjustment.

The enclosure for the settings and adjustments for the thermal limit controller sequence logic must be sealed to prevent unauthorized adjustment.

1. **Programmable Logic Controllers and Computers**

Programmable logic controllers or computers installed on an aseptic processing and packaging system for operational convenience and not public health control must meet certain safeguards and tests. The computer may not control any public health function when the system is in processing mode. When in CIP mode, the computer may control any functions when CIP mode is first selected. Non-public health controls, such as product pumps or valves, may be controlled at any time by the computer. The vendor is responsible for providing a testing protocol to verify that public health safeguards are not under the control of the computer during the production cycle.

Computers for the operation of public health controls on aseptic processors have additional considerations. Computers are different from hard-wired controls in three major areas. To provide adequate public health protection, the design of computerized public health controls must address these three major differences.

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

Second, in a computerized system, the control logic is easily changed because the computer program is easily changed. A few keystrokes at the keyboard will completely change the control logic of the computer program. Conversely, hard-wired systems require tools and a technician to make wiring changes. Once the hard-wired system is properly installed and working, it does not change. The problem can be solved by sealing the I/O access to the computer, but some procedure is needed to ensure that the computer has the correct program installed when it is re-sealed.

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

If the design of computerized public health controls does address the above-mentioned differences, they can be effectively interfaced with conventional hard-wired operating controls and instrumentation. When computers or programmable logic controllers are used in pasteurizing or sterilizing systems, they must be installed in such a manner that public health controls are not circumvented by the computer or programmable logic controller during the product run operations, except as provided for under

The vendor is responsible for ensuring that their PLC or computer installation complies with the requirements, through documentation and testing.

The responsible regulatory agency shall evaluate the complete documentation of interconnecting wiring, pneumatic controls, applicable programming logic and ladder logic, and results of the testing procedures. This will help to verify compliance with the criteria in.

1. **Pressure Differential Recorder Controllers (PDC recorder)**

Proper pressure relationships must exist across all media to prevent contamination of the sterilized product by raw product, heating medium and cooling medium. Pressure relationships under the following conditions must be considered:

1. Forward flow
2. Divert flow
3. Shutdown

Proper pressure relationships must exist between raw milk or media and sterilized milk to prevent contamination of the sterilized product. In aseptic processing and packaging systems, failure to maintain a 14 kPa (2 psi) differential between the raw side of the regenerator and the sterilized side will cause the FDD to assume the divert position. The feed pump normally operates in both forward flow and divert flow, as long as the FCD is allowed to run. This is because the sterilized side of the regenerator and cooling section are always full, since the FDD is located after the cooling section. Aseptic systems require a pressure differential recorder to monitor and record pressures to ensure that proper pressure differential has been maintained in the regenerator.

This task will assess the actual pressure devices used. The appropriate pressure differential is assessed under Regeneration and Cooling Section.

Tests are performed upon installation and at least once every 6 months thereafter. Appropriate records must be kept showing proper testing has occurred.

* 1. **General Conditions**

The sensors of pressure differential controllers must be clean and in good mechanical condition. The design should allow easily dismantling of the sensors for inspection, and the indicating / recording unit must be housed in an appropriate moisture proof enclosure.

The pressure differential recorder controller shall be inter-wired with FDD such that divert occurs when the sterilized product pressure in the regenerator is not exceeding, by 14 kPa (2 psi) or greater, the pressure on the raw side of the regenerator. It is considered acceptable to use a legal PLC to control the pressure differential in lieu of a pressure differential controller as long as the same control conditions are respected such as inter-wiring with FDD, pressure indicating and recording capabilities, set-point indication.

In milk-to-heat transfer medium-to-milk type regenerators, in the sterilized milk section the heat transfer medium must always be under lower pressure by at least 14 kPa (2 psi) than the sterilized milk.

Pressure gauges may be used to verify the pressure display for the pressure differential recorder controller. Gauges shall be clean and in good condition.

* 1. **Location**

Two types of regeneration are used in aseptic systems, product-to-product regenerators, and product-to-water-to-product regeneration systems. The latter system is often preferred for some products, because it allows more even heat transfer and prevents burn-on.

Product-to-product regenerators shall have the raw product sensor between the feed pump and the raw product inlet to the regenerator. The sterilized product sensor shall be installed at, or downstream from, the sterilized product outlet of the regenerator.

Product-to-heat transfer medium-to-product regenerators shall have the raw side pressure sensor in the water loop after the water pump (location of highest media pressure in the loop). The sterilized side pressure sensor shall be in the product line at the sterilized side outlet of the regenerator (location of lowest sterilized product pressure).

* 1. **Specifications**

A circular chart shall make one revolution in not more than 12 hours and shall be graduated for a maximum record of 12 hours. If operations extend beyond 12 hours, a 24-hour chart can be used if it can provide an equivalent level of accuracy and clarity.

The chart positive drive mechanism shall be equipped with a system to prevent slippage or manual rotation (e.g. pin to puncture the chart paper). The chart used shall correspond with the chart number displayed on the identification plate of the pressure differential recorder controller.

The pressure recording unit shall have chart scale divisions not to exceed 14 kPa (2 psi) on the working scale of not more than 140 kPa (20 psi) per 25 mm (1 inch). Pens may be used to record the raw side pressure and the sterilized side pressure or the pressure differential.

Electronic data collection, storage and reporting of pressure differentials, with or without hard copy printouts, may be acceptable provided the electronically generated records are readily available at the establishment for review by the regulatory agency and meet minimum criteria required for STLR charts.

* 1. **Calibration / Records**

The accuracy of the pressure display and recorder, and the differential controller divert function, shall be validated at least every six months, and whenever the controller is adjusted or repaired. Pressure gauges, if used, must be checked for accuracy at least once per year.

Records shall be easily available and must indicate testing results and satisfactory corrective action. Tests must be completed according to the required methods.

* 1. **Sealed**

The pressure differential recorder-controller adjustments/legal panel must be sealed.

1. **Auxiliary Temperature Recorders/Controllers**

These instruments may be used in several locations on the aseptic processing and packaging system, to provide a record of start-up pre-sterilization and product processing temperature, and to provide temperature signals to the thermal limit controller unit or other processing controls. Two common installation points would be at the final heater outlet (to provide better feedback and control of the heating process), and at the inlet to the FDD (to provide a record and control of the pre-sterilization process).

* 1. **General Conditions**

The temperature recorder / controller unit shall be clean and in good mechanical condition. It should be moisture-proof under normal operating conditions. The chart positive drive mechanism shall be equipped with a system to prevent slippage and manual rotation (e.g. pin to puncture chart paper). It must also be equipped to produce a continuous permanent record of all pertinent information (i.e. time of day and temperature). The processor is responsible to indicate on the chart recorder the chart part number to be used. Pens should be operational and easily calibrated. The unit should be serviced at least once a year, and records of the servicing kept in the plant's file.

1. **Cooling Section**

This section of the sterilizer uses chilled water and /or glycol to cool the hot product down to packaging and filling temperature. Since the FDD is located downstream from this section, the cooling section may become contaminated with potentially unsterile product during divert and must be re-sterilized as part of the thermal limit controller sequence logic after a divert event.

Flash coolers are sometimes installed on the divert line to prevent injury to by-standers if a divert event occurs during the re-sterilizing of the holding tube and cooling section, when there is no cooling turned on.

* 1. **General Conditions**

The cooling sections must be clean and in good condition. They must be constructed of stainless steel or other corrosion resistant and easily cleanable material. The design should allow easy cleaning, and should not entrap product in crevices, joints, seams or openings. During operation, there should not be any leaks at gaskets, seals, or connections.

A routine program to monitor the condition of plates and tubes (pin holes in plates, gasket condition, cracks, tube clamps, etc.) must be established by plants. The integrity of all food contact heat exchange surfaces must be checked at least once per year by an acceptable method (e.g. dye penetration, permanganate recirculation, pressure retention, Helium testing, etc.). However, if the plant has experienced problems with heat exchanger integrity, a more frequent inspection program must be implemented to verify that the problem has been remedied. Appropriate records must be kept showing proper testing has occurred. These records should also document the age of all the plates and which ones are replaced, the cause of the holes (e.g. age, compression, metal fatigue, etc.). If pin holes are found in any plate, then all plates of the same age should be checked.

* 1. **Pressure Differentials**

This task will only assess the actual differential of pressure. The equipment used to monitor (gauges) will be assessed under Pressure Differential Controllers.

In the cooling section, the system must be designed to maintain pressure on the sterilized product side of the plates at least 14 kPa (2 psi) higher than on the cooling medium side of the plates during forward flow. 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. This reduces the possibility of chemical contamination in the event a pinhole leak develops in the plates.

An automated mechanism is the only way to achieve the correct pressure relationship in the cooling section during forward flow, divert and shutdown conditions so that the pressure on the sterilized product side is greater than the cooling media side.

Pressure gauges, if used, must be checked for accuracy upon installation and at least once per year. Gauges shall be clean and in good condition. Pressure differential controller sensors, and pressure gauges, shall be located at the cooling media inlet and at the sterilized product outlet.

* 1. **Cooling Medium**

Cooling medium (usually sweet water or water-glycol mixture) must be checked at least monthly for microorganisms (e.g., coliforms, psychrotrophs).

Records shall document the safety of any cooling water additives and cooling media products used, as well the microbial testing results.

1. **Homogenizer**

The homogenizer is a high-pressure pump that produces a homogenized product by reducing the size of fat globules as they are forced through a small orifice under high pressure. Since the homogenizer is a positive pump, it can be utilized as a flow control device. If the homogenizer is utilized as a flow control device, its compliance requirements are to be rated under the **Flow Control Device.**

* 1. **General Conditions**

Filters, homogenization valves, pistons, seat valves, pressure gauges and dead ends must be clean and in good mechanical condition. All product contact surfaces must be stainless steel or other food grade, non-corrosive material. All homogenizers should be equipped with appropriate gauges.

Homogenizers installed downstream from the holding tube in the aseptic zone shall be of an aseptic design, to prevent contamination of the sterilized product.

* 1. **Homogenizer Larger Than FCD**

This homogenizer must be designed and installed so that the flow rate is not affected. The manufacturer must be able to demonstrate that any homogenizer located downstream does not affect the flow rate (e.g. physical break, pressure sensors in holding tube, FCD is a MBTS, etc.) If a homogenizer located downstream from the flow control device has a capacity greater than the flow control device, then the homogenizer must not be a flow promoter.

One way to achieve this is to have a recirculation line between the inlet (suction line) and the outlet (pressure line) of the homogenizer installed to prevent the homogenizer from starving. This line shall be unrestricted and shall not contain a shut-off valve but may contain a check valve allowing flow only from the outlet back to the inlet. The diameter of the recirculation line including the check valve shall be equal or greater than the supply line to the homogenizer. Other acceptable systems could also achieve this requirement.

The homogenizer must not reduce the holding time and must not reduce the pressure required in the holding tube to keep the product in the liquid phase.

1. **Aseptic Surge Tank**

The aseptic surge tank acts as a sterilized product balance tank for the fillers. This allows both the fillers and the aseptic processor to operate independently at their own flow rate.

The aseptic surge tank is installed downstream from the FDD. If the surge tank is protected by one or more aseptic barriers at the FDD, filling operations may continue from the tank while the Aseptic processor is in divert. Otherwise, the fillers and aseptic surge tank must also be emptied and re-sterilized after a divert event.

The cleanliness and operation of the aseptic surge tank are important to prevent contamination of the sterilized product. Air over the product in the tank must be sterile.

* 1. **General Conditions**

The aseptic surge tank and associated valves, thermometers, etc. must be clean and in good condition. Instrumentation (temperature recording chart) must be installed to record and verify pre-sterilization of the tank before production commences.

* 1. **Sterile Air**

As product is withdrawn from the surge tank, negative pressure could develop in the tank, which could cause unsterile air and bacteria to be drawn in through joints, gaskets, etc. For this reason, the sterile air must be pressurized to prevent the development of negative pressure inside the aseptic surge tank.

In general, a processing authority establishes a venting or air purge schedule for the surge tank. Sterile air over-pressure must be maintained on aseptic surge tanks to ensure proper operation (i.e., product flow to the filler).

Sterile air is produced by incineration and/or filtration. Attention must be paid to how the establishment monitors sterile air over-pressure and the method of achieving sterility. If incineration is used, a temperature sensing device monitoring system is generally the easiest means. If a sterile filter is used, the specifications of the filter, 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 on the processing records.

A sterile air pressure controller or transmitter shall be used to monitor the sterile air pressure in the tank. Records of tests performed to determine the controller's/transmitter's calibration shall be maintained in the plant's files. Tests must include accuracy, upon installation and at an interval of at least every 6 months. The frequency of testing should be increased if the calibration is consistently found to be out of adjustment. If the calibration is consistently found to be out of adjustment, the reason for the calibration problems should be immediately identified and rectified.

Testing methods shall comply with the required standards. Follow-up on out of specification findings must be satisfactory.

If the sterile air pressure drops below the value specified in the scheduled process, the filler(s) shall cease operation, and the aseptic barrier located at the inlet of the unsterile tank shall be activated to protect the sterile product in the processing system from entering the unsterile tank. Filling operations may not resume until the aseptic surge tank, fillers and valves have been emptied and re-sterilized. If multiple aseptic surge tanks and fillers are used and the sterility of these is maintained, this requirement may not apply.

1. **Stuffing Pump**

Stuffing pumps may be used to improve the efficiency of other devices, such as homogenizers.

* 1. **General Conditions**

Stuffing pumps are usually centrifugal pumps. They must be constructed of stainless steel or a suitable corrosion resistant material and must be clean and in good mechanical condition. Painted exterior surfaces must also be clean and in good condition, free of flaking paint and rust.

All pumps not specifically designed for CIP use must be disassembled for cleaning. This includes removal of impellers and back plates for cleaning.

All pumps installed in the sterile zone must be of an aseptic design.

* 1. **Proper Installation/Operation**

Product stuffing pumps must be inter-wired with the flow control device electrical operating signal. When the flow control device is prevented from operating, either by the operator or operating system and /or by safety interlocks installed on the system, the stuffing pump and other flow-promoting devices must stop. Stuffing pumps may be configured to start prior to starting the homogenizer, but the FCD must be in an**allowed to run**condition.

When a stuffing pump is used in an aseptic processing and packaging system it must be installed and operated in such a way that it will not influence the proper pressure relationship within the regeneration section, and it must not reduce the holding time below the required minimum.

If the homogenizer is used as a flow control device, a centrifugal type stuffing pump may be installed between the raw product outlet of the regenerator and the inlet manifold of the homogenizer to supply the desired pressure to the homogenizer.

Tests are performed upon installation, at least once every 6 months thereafter and when micro-switch is re-set or replaced. Appropriate records must be kept showing proper testing has occurred.

1. **Aseptic Packaging**

Aseptic packaging has been defined as a procedure consisting of sterilization of the packaging material or container, filling with a commercially sterile product in a sterile environment and producing containers that are tight enough to prevent recontamination. which are hermetically sealed.

UHT of product

* Aseptic transfer
* sterilization of packaging material, sterile surroundings during packaging
* tight containers

Aseptically packaged UHT milk must also give almost complete protection against light and atmospheric oxygen. The package must therefore be of barrier type or similar.

The term **aseptic** implies the absence of any unwanted organisms from the product, package or other specific areas. The term **hermetic** is used to indicate suitable mechanical properties to exclude the entry of bacteria into the package or, more specifically, to prevent the passage of microorganisms and gas or vapour into or from the container.

1. **Packaging Conditions**
	1. **Packaging Material**

An appropriate program must be established by the processor to ensure that the packaging materials received are in compliance with the requirements identified in the scheduled process. These procedures should include visual examination of the packaging material to identify damage and defects. All packaging material shall be stored in a clean and sanitary manner to minimize the risk of contamination and physically damaging the materials.

* 1. **Sterilant**

The aseptic packaging machine must ensure the sterilization of the container and provide a sterile environment for filling. The most commonly used sterilants, depending on the application, are hydrogen peroxide (H2O2) or a combination of H2O2 and peracetic acid. During the sterilization of the packaging material by H2O2 or other sterilants, a residue of these sterilants may be left on the material. Testing of the residue must be performed at an appropriate frequency and must be at or below the level specified by the scheduled process. Sterilants used to sterilize the package shall be dairy safe and approved for dairy plant purposes. If dilution is required, sterilants must be diluted as per manufacturer's recommendation.

Two important factors must be considered when using sterilants, these are (Long-Life Products: Heat-Treated Aseptically Packed - A Guide to Quality. Von Bockelmann et. al. 1998):

1. Microbiological efficiency of the sterilization process
2. Elimination of chemical residues from the package which can subsequently contaminate the filled product

Depending on the type of packaging equipment, different means of applying the sterilants can be used e.g., spray, vapour, roller system, immersion bath etc. Other systems may be acceptable if the Process Authority proves that these sterilants meet Health Canada's requirements for commercial sterility.

Plastic bottle sterilization: in general, plastic bottles are sterilized using a solution of H2O2 and peracetic acid. The bottles are filled with the solution of chemical sterilant while passing on a conveyor for a pre-determined contact time, then they are inverted to empty the solution followed by a sterile water rinse to eliminate any chemical residual in the package prior to filling.

* 1. **Headspace Gas**

Some processors use nitrogen gas or other media to create a headspace in the formed package. The nitrogen gas or any other media used must be filtered or treated in other ways to remove or destroy microorganisms.

* 1. **Packaging/Filling Room Air Quality**

In order to minimize contamination from other areas of the processing plant, the packaging/filling aseptic zone must be under positive pressure, relative to the rest of the plant. However, the room must be under negative pressure relative to the aseptic zone of the packaging machine. Microbial analysis of air quality should be conducted on a specified time frame adequate to substantiate the air quality is acceptable and records of results are kept in the plant's file.

* 1. **Packaging and Filling Controls**

The aseptic packaging stage is the most delicate operation of producing aseptic product, both in terms of control and preventative measures required. The processing plant must have well trained personnel to carry out the operations and to maintain the equipment.

For packaging and filling equipment, the critical controls which attain and maintain commercial sterility within the aseptic zone must be identified. These critical controls include sterile air supply systems and sterile product contact surfaces of the filler and packaging material. The packaging and filling critical controls become the basis of the scheduled process for aseptic packaging.

* 1. **Calibration of Controls**

The packaging and filling critical controls must be calibrated on a regular basis. When they function properly, they will be fail-safe. If the critical controls are not met, the machine must stop and preclude the packaging of sterile product into non-sterile containers. Records of calibration must be kept indicating the date of testing, method(s) used, and the name of the individual performing the calibrations.

* 1. **Setting of Controls**

In order to have a **commercially sterile** finished product, the identified critical controls must be set and adhere to the specifications identified in the scheduled process during container formation and filling. These critical controls may include but are not limited to, for example:

1. positive sterile air/inert gas pressure in the filling and sealing area of the machine
2. hydrogen peroxide concentration and temperature
3. drying section temperature

Although these systems usually operate in an automatic mode, most, if not all, will be equipped with a capability of manual over-ride of the automatic controls. This manual over-ride must be protected from unauthorized personnel access.

**30.8 Setting Deviation**

Acceptable variations from the specified setting of critical controls must be described in the scheduled process and in the operator's packaging and filling production log. In the event of a critical deviation from the setting, the packaging system shall be shut down, non-sterilized product must be segregated, and the system must be re-sterilized before resuming operation.

**30.9 Quality Control**

Each processing establishment must have a quality control program of the processes used as well as the products packaged. The tests and frequency of this program may vary with the food product as well as the needs of the regulator and establishment but must be done in such a manner and at a statistically valid frequency that provides a high level of assurance that the finished product is commercially sterile.

1. **Finished Product Testing**

**Sampling Plan:** Statistically valid samples of the production must be taken to assess the safety and quality of the product. The quantity of containers to be taken, the tests to be performed and the standards to be met should be determined for each plan of the sampling program, based upon specifications supplied by the processing authority.

**Inspection of heat seals:**Appropriate inspections and tests must be conducted by trained personnel before production starts and during production, after jam-ups and as per manufacturer's recommendation. Inspection of seals must be done at intervals of sufficient frequency to ensure consistent and reliable hermetic sealing as per manufacturer's recommendation.

In general, tests can be divided into two main types:

1. Non-destructive testing: visual inspection of seals for absence of voids, wrinkles, pleats. Other important checks to be performed include seal alignment, overlap, product contamination in seals, de-lamination, etc.
2. Destructive testing: activation pattern using a polarisation filter, vacuum bubble test, conductivity/electrolytic test, dye penetration test, microbial challenge test, storage and distribution test, burst test, removal torque test, seal security/seal strength tests, etc.

The methods used for these inspections must be those specified by the packaging material supplier.

**Incubation:**Incubation tests must be done at a statistically valid frequency to verify the "commercial sterility" of the finished product. Samples are generally incubated at a specified temperature for a specific period of time to detect mesophilic growth. Incubated packages are observed for any sign of gas production (puffers), product changes such as odour, pH, oxygen content, viscosity and other indicators of spoilage, such as separation or curdling.

**Microbial Evaluation:** Microbial analysis for commercial sterility must be conducted on a statistically valid number of containers from each lot (from each filling head) regardless of the absence of signs of non-sterility following incubation.

Microbial growth from unsterile containers must be further investigated and the action taken recorded. Pending the outcome of the investigation, the lot must be detained.

**Product Release:** All package integrity, incubation testing, processing record review and the investigation of any process deviations must be satisfactory before the product is released for distribution.

1. **Record Keeping**

It is important that the scheduled process be properly established, correctly applied, sufficiently supervised and documented to provide assurance that the requirements have been met. Production records must consist of the operator's packaging/filling production log and the operator's on-line record of critical parameter testing. These records must be maintained on file for at least 3 years or the shelf-life of the product if longer than 3 years.

1. **Packaging Records**

A trained operator is responsible for verifying that all critical controls are recorded and meet specifications. Review of records by the responsible individual should be completed before the product is released.

The operator's packaging/filling production log should contain the following information:

* date
* batch
* packaging machine number
* product being filled and packaged
* source of product (i.e. from surge tank or sterilizer)
* preparations taken to bring equipment into packaging readiness, e.g. inspection/repairs/replacements of valves, gaskets, gauges, warning lamps etc.; cleaning, preheating and sterilization steps; pressure and temperature checks

To ensure product safety and to provide a historical record of the process, the following information should be recorded:

* Date
* Hourly filling code
* Machine number
* Packaging start time
* Packaging stop time
* Machine downtime and reason, corrective action taken to restart
* Intervals at which teardowns conducted
* Types of teardowns conducted, classification of defects observed, corrective action taken
* Hydrogen peroxide concentration
* Production volume
* Unusual occurrences
* Operator's signature
* Signature of individual responsible for review

**Table 2a: Holding Loop Calculation for Dairy Products whose Flow Rate type is Turbulent (Re >2100)**

|  |  |  |
| --- | --- | --- |
| **Holding coil length-Calculations** |  | **38 mm Dia Holding pipe** |
| Flow rate | **5000** | LPH |
| Pipe OD | **0.038** | Meters |
| Thickness | **0.0016** | Meters |
| ID | **0.0348** | Meters |
| Area | 0.00095 | sq.m |
| Velocity | 1.46 | m/s |
| Density | 1027 | kg/m3 |
| Dynamic viscosity | 0.0021 | Ns/m2 |
| Reynolds no. |   |   |
|   | **24863.93** | **Turbulent flow** |
| Max Velocity in holding loop (Vmax) | 1.75 |   |
| Holding coil length to achieve 4 sec holding | 7.00 | M |
| Volume at Maxflow and holding time | 0.007 | m3 |
| Time needed for Temperature Sensor Response to PLC / HMI for reprocess | 1.00 | Secs |
| Holding Time in sec | **4** | **Secs** |
| Min Distance to be provided between Temp Sensor and Diversion Valve  | 1.8 |   |
|   |  |  |  |
| Holding loop length in meters to achieve 4 seconds Holding Time | **7.0** |
| Min Distance to be provided Temperature Sensor Response to PLC / HMI for reprocess | **1.8** |
| Total Length of the holding loop in meters till FDV  | **8.8** |

**Table 2b: Holding Loop Calculation for Dairy Products whose Flow Rate type is Streamline/ Laminar (Re <2100)**

|  |  |  |
| --- | --- | --- |
| **Holding coil length-Calculations** |  | **38 mm Dia Holding pipe** |
| Flow rate | **5000** | LPH |
| Pipe OD | **0.038** | meters |
| thickness | **0.0016** | meters |
| ID | **0.0348** | meters |
| Area | 0.00095 | sq.m |
| Velocity | 1.46 | m/s |
| Density | 1027 | kg/m3 |
| Dynamic viscosity | 0.03 | Ns/m2 |
| Reynolds no. |   |   |
|   | **1740.48** | **Streamline Flow** |
| Max Velocity in holding loop (Vmax) | 2.92 |   |
| Holding coil length to achieve 4 sec holding | 12.00 | m |
| Volume at Maxflow and holding time | 0.011 | m3 |
| Time needed for Temperature Sensor Response to PLC / HMI for reprocess | 1.00 | secs |
| Holding Time in sec | **4.1** | **secs** |
| Min Distance to be provided between Temp Sensor and Diversion Valve  | 2.9 |   |
|   |  |  |  |
| Holding loop length in meters to achieve 4 seconds Holding Time | **12.0** |
| Min Distance to be provided Temperature Sensor Response to PLC / HMI for reprocess | **2.9** |
| Total Length of the holding loop in meters till FDV  | **14.9** |