

Commercial Sterility Processing

Implementation and Management of Commercial Sterility Processes

Development

To define detail, scope and purpose.

Development

This information can be used to develop food safety and quality programs that meet the requirements of modern Regulatory, Customer and Industry Standards:

- We take the time to explain the expectations and requirements of food safety and quality compliance as these relate to your food safety and quality programs.
- You may choose to use our Premium Resources to build, enhance or upgrade your food safety and quality program.
- We encourage you to share this webpage with any food compliance associates and peers you believe may benefit from our commitment to providing our users with user-friendly information and resources to achieve a superior Food Compliance Culture.
- We welcome your suggestions for additions of general or specific content through the haccp.com Contact Page.

Key Definitions for Commercial Sterility Processing

- **Acidified Food:** A low-acid food to which acid or acid foods are added to bring the finished equilibrium pH to 4.6 or below.
- **Anaerobic Environment:** An environment in which no oxygen is present. Microorganisms that live within this environment do not require oxygen for survival.
- **Aseptic:** Free from septic matter or disease-producing bacteria. In food processing and packaging, this word describes the system used to package food in a sterile manner.
- **Bacterial Spores:** A dormant, resistant form of certain bacteria that, because of its thick outer wall, is able to survive in hostile environments in which bacterial survival, growth and reproduction would otherwise not be possible.
- **Clostridium botulinum:** A spore-forming, anaerobic bacterium that produces botulinum toxin and is the primary target organism of thermal processes for low-acid foods.
- **Come-Up Time:** The time taken for a retort to reach the required processing temperature after heating begins.
- **Commercial Sterility:** The absence of microorganisms capable of growing in the food under the normal non-refrigerated conditions in which the food is likely to be held during manufacture, distribution and storage.
- **Continuous Flow Techniques:** Techniques in which food items, usually liquids, are heated rapidly and held at designated temperatures for a short time before being hot-filled and sealed into their packaging.
- **D-value or Decimal Reduction Time:** The time in minutes required to achieve the inactivation of 90% of the target microorganisms under stated exposure conditions.
- **Double Seam:** The interlocked fold that joins a can end to the can body and forms the hermetic seal.
- **F0 (F-value):** A measure of the lethality delivered by a thermal process, expressed as the equivalent minutes at 121.1°C (250°F).
- **Heat Exchanger:** Equipment that transfers heat between a heating or cooling medium and the product without the two mixing.
- **Hermetically Sealed:** With a hermetic seal; airtight.
- **Hot Fill:** A technique in which containers are filled at high temperatures to ensure continued sterility of the container and product during and after the filling process.
- **Incubation:** Maintaining an item at the most favourable temperature for the growth of microorganisms. Other environmental factors, such as humidity and light exposure, may also be controlled for optimum growth.
- **Kill Step:** A process step at which bacteria are killed. This is most commonly achieved by a process involving

temperature and time.

- **Log Reduction or Logarithmic Reduction:** A measure of how effective a process step, such as the application of time and temperature, is in controlling the target microorganism.
- **Low-Acid Food:** A food with a finished equilibrium pH above 4.6 and a water activity above 0.85, which can support the growth of *Clostridium botulinum* if it is not adequately processed.
- **Mercury in Glass or MIG Thermometer:** An accurate, vacuum-sealed, glass-cased temperature measuring device often used for processes involving a retort.
- **Microbiological Pathogens:** Any microbiological entity, including viruses, bacteria or other microorganisms, that can cause foodborne illness in humans.
- **Pressure Vessel:** A closed container designed to hold gases or liquids at a pressure substantially different from the ambient pressure.
- **Process Authority:** A person or organisation with expert knowledge of thermal processing who establishes and validates scheduled processes.
- **Retort:** The application of time and temperature processing to sealed packaged items within a pressure vessel.
- **Static Aseptic Techniques:** Techniques in which food items are filled at very high temperatures into packaging and sealed. The high temperature at which the product is filled will not permit bacterial growth if the package has not been opened. This process relies on a heat-based kill step before packaging.
- **Ultra Heat Treatment or UHT:** A treatment involving a continuous flow of heat at a high temperature for a short time, such that there are no viable microorganisms or spores capable of growing in the treated product when kept in an aseptic container at ambient temperature.
- **Vegetative Bacteria:** Bacteria that are in the growth and reproductive phase, as opposed to spores.
- **Viscosity:** A measure of a fluid's resistance to deformation by shear stress or tensile stress. Interpreting viscosity as thickness, water is thin and has a low viscosity, while honey is thick and has a high viscosity.
- **Z-value:** The temperature change, in degrees Celsius or Fahrenheit, required for the thermal destruction curve to move one log cycle.

Commercial Sterility Processing Development

When considering the development, documentation, and implementation of Commercial Sterility Processing within food safety and quality management systems, the following information should be considered to ensure effective outcomes:

Commercial Sterility



Commercially sterile foods are protected by hermetically sealed packaging.

Commercial sterility techniques have been used since the early 19th century to preserve foods. Early techniques involved sealing foods into glass bottles and boiling the bottles in water for extended timeframes. By the mid-19th century, tin-coated steel containers were being used in what would become one of the most prevalent food preservation techniques used throughout the world.

Commercial sterility techniques are well suited to preserving foods as they kill and deactivate microorganisms and their spores through structured process controls involving the creation of an anaerobic environment and time and

temperature treatments.

Microorganisms, many of which are harmful to humans, are also responsible for the spoilage of foods. Applying a suitable temperature to foods over a defined period denatures proteins and enzymes, which are essential components of living cells. This damage kills vegetative bacteria, which is the simpler part of the commercial sterility process. The challenge is to kill bacterial spores, which are more robust than vegetative bacteria. Bacterial spores are difficult to kill because they have thick protective walls which increase their resistance to heat, drying, freezing, chemicals, and radiation. The 'kill step' for bacterial spores widely defines the modern parameters for Commercial Sterility.

Modern Commercial Sterility techniques include retorting, static aseptic, and continuous flow applications:

- Retorting includes techniques such as canning and pouch retorting. This is where food items are hermetically sealed into appropriate packaging and subjected to specified controlled time and temperature to achieve Commercial Sterility;
- Static aseptic includes techniques such as hot fill packaging. This is where food items are filled at very high temperatures into packaging and sealed. The high temperature at which the product is filled will not permit bacterial growth if the package has not been opened. This process relies on a heat-based kill step before packaging;
- Continuous flow includes techniques such as UHT. This is where food items, usually liquids, are heated rapidly and held at designated temperatures for a short time before being hot-filled and sealed into their packaging.

The goal of all variants of Commercial Sterility is to produce foods that remain sterile whilst their packaging remains intact.

Low-Acid and Acidified Foods

The pH of a food determines how much heat processing is required. Low-acid foods have a finished equilibrium pH above 4.6 and a water activity above 0.85, which allows *Clostridium botulinum* spores to germinate and produce toxin in the anaerobic, non-refrigerated conditions inside a sealed container. For this reason, low-acid canned foods are given a severe heat treatment, commonly expressed as an F0 value (equivalent minutes at 121.1°C (250°F)), which delivers a very high reduction in *Clostridium botulinum* spores.

Acidified foods are low-acid foods to which acid is added to bring the finished equilibrium pH to 4.6 or below. Acidic conditions prevent spore germination, so a milder heat treatment is typically used, and control of pH becomes a critical parameter. Naturally acidic foods, such as many fruits, are also commonly processed using a milder heat treatment.

Scheduled processes for low-acid and acidified foods should be established by a process authority and supported by heat penetration studies for each product, container size and retort type.

How Does Commercial Sterility Work?

A D-value is the specific time required at a specific temperature to kill, for example, 90% of bacterial spores, which is the same as reducing their number by one logarithm unit. In short, the D-value is a measure of the heat resistance of a specified type of bacteria. The D-value depends on the species of bacterial spores involved.

The outcome of any heat sterilisation process depends heavily on the following factors:

- The initial number of microorganisms in the items being subjected to the heat sterilisation process;
- The D-value of relevant microorganisms;
- The temperature of heat exposure;
- The time of heat exposure.

Commercial Sterility Processing relies on one or more steps at which microorganisms are killed and their spores destroyed. When applying a sterilisation procedure such as heat, not all bacterial spores are killed at the same time. A certain proportion of spores is killed within any given period at a suitable temperature, but not all of them.

This is where the most important factor of Commercial Sterility Processing comes to the forefront: lethality depends on both temperature and time. At a given temperature, the time required to achieve the target reduction is what the process is designed around, and a higher temperature shortens that time.

The process through which time and temperature are used to kill bacteria is commonly known as logarithmic reduction. Because each log reduction removes a fixed proportion of the remaining spores, the count can approach zero but never reach it, so it is never possible to guarantee absolute sterility. In this context, the efficiency of sterilisation is expressed by the number of decimal reductions in the count of bacterial spores. The D-value, or Decimal Reduction Time, is commonly used to indicate the killing rate of bacterial spores.

In some applications, more than one temperature and time combination is applied to achieve the required sterilisation, increasingly to maintain product quality. In such instances, the required change in temperature is described by the Z-value, which is defined as the change in temperature required to alter the D-value by a factor of one logarithmic unit.

Commercial Sterility Sampling Procedures

As absolute sterility is not achievable, sampling plans with nominated acceptable tolerances are commonly defined for displaying conformance with the method of Commercial Sterility Processing employed.

A common example of a sampling plan applied for Commercial Sterility Processing is a maximum acceptable defect rate of 1 in 10,000 samples. To determine the effectiveness of the Commercial Sterility Processing methods employed, and to ensure the number of defects does not exceed the nominated target, sampling procedures are implemented.

It is common for a defined sample percentage of finished products from each batch to undergo an 'incubation' process to ascertain the absence of microorganisms within finished products. This supports the effectiveness of the time and temperature controls of each processed batch of product. Incubations are commonly conducted at 37°C (99°F), a temperature favourable to the growth of any potential microorganisms contained within the processed product. Incubation temperatures and durations for mesophilic and thermophilic organisms are defined by the applicable regulation, customer requirement or process authority. Generally, if the incubated products do not show any signs of bloating or loss of vacuum, it is assumed that the Commercial Sterility process has been successful.

As the methods and techniques used for Commercial Sterility Processing are long-established, and have a strong validated and verified history of achieving their intended food safety goals under controlled conditions, products are commonly not required to be microbiologically tested on a scheduled basis. Though the Commercial Sterility process should always achieve consistent results when conducted in a controlled and verified manner, it is important to consider that analytical microbiological testing can provide substantial evidence of product conformance to Commercial Sterility standards. In this context, it is of utmost importance for the analytical microbiological testing of commercially sterile products, when conducted, to ensure that the product within its original packaging is not contaminated as an element of the sampling or testing process.

Condition of Cans



Rust and corrosion on cans can indicate poor storage and a risk of leakage.

Packaging materials used in the canning process are made from a thin steel strip coated with a thin layer of tin on the internal and external surfaces. In many cases, the interior of cans is lined with an organic compound to separate the food from the tin lining and prevent any chemical reaction. A rubber-like compound helps to form a hermetic seal when the bottom and lid are seamed onto the body of the can.

Once canned food is produced, poor transportation or storage practices might cause denting or damage to the can seams. Leaks resulting from damage can allow contamination to enter the can, which may allow spoilage to occur. Poor handling and storage conditions over time may also result in rusting of the outside of the can. Rusting commonly occurs when cans are stored in high humidity conditions, and is normally just unsightly, but can cause leakage over extended periods.

Badly dented cans, particularly those with damage to the double seam, should be rejected or placed on hold, and the cause investigated. Bulging can ends may indicate microbial growth and a significant risk to consumers, so affected cans should be isolated unopened and returned to the supplier or managed as non-conforming product. Cans with stained labels may indicate poor storage practices and a possible leak, and should also be rejected if identified. Consumers who find damaged cans should return them unopened to the store of purchase.

Using Canned Foods

The hermetically sealed contents of canned food are uncontaminated before opening, so great care should be taken to ensure contaminants are not introduced when the can is opened. It is considered best practice for the top of the can to be washed before opening. This will ensure that any dust or dirt on the can top will not enter the food during the opening process.

When opening canned food, a clean, sharp can opener should be used. Because the metals used in the construction of the can are relatively soft, the use of a blunt can opener can introduce small pieces of metal into the food contained within the can. Blunt can openers also leave jagged edges, which can provide health and safety risks. Can openers should ideally be washed after each use to further avoid the risk of contamination.

Once opened, canned foods should be treated as fresh foods. After opening, foods should be immediately removed from their can, placed into a non-reactive container with a tight-fitting lid, and stored within a refrigerator. Opened canned foods should be used within a suitable timeframe, as they will spoil after the hermetic seal on the can has been breached.

Aseptic Packaging



Aseptic processing relies on sterile equipment, product and packaging.

Aseptic processing and packaging is a complex technique as it relies on a minimum of three different sterilisation techniques to be effective.

As elements of aseptic processing and packaging methods, sterilisation is conducted:

- On the processing and packaging equipment before production;
- On the food product to be packaged;
- On the food contact surface of the packaging being used.

Failure of any one of these three techniques may result in an unsafe end product. Sterilisation of equipment must also be supported by effective cleaning and sanitation before it begins. In this context, potential microbiological contamination points within an aseptic packaging facility must be addressed in a holistic sense.

For example, in a canning operation, if the product or package is contaminated before the retorting process, all bacteria and spores will be destroyed through the time and temperature process for the sealed can. In a similar instance within aseptic packaging, where the product or packaging was not sanitary, the result would be an unsafe product, as there are no further kill steps after the product has been packaged.

Flexible Commercially Sterile Packaging



Flexible pouches are increasingly used for commercially sterile foods.

Flexible packaging for commercially sterile food products is becoming increasingly popular due to its versatility and shorter processing times, which can be reduced dramatically compared to rigid packaging such as cans. Additional advantages for manufacturers include reduced shipping costs and storage space for empty flexible packaging, such as pouches. Whilst flexible commercially sterile packaging has advantages, challenges include seal integrity and the need for more complex filling systems. Its thin profile also allows heat to penetrate faster than in cans, which shortens the heat processing time required to achieve commercial sterility.

A typical commercially sterile pouch is a heat-resistant bag made of laminated plastic films or foil, commonly consisting of an outer layer of polyester or nylon for printing, coding and protection, a middle aluminium foil layer that functions as the principal oxygen and water vapour barrier, and an inner or food contact layer of a heat sealant material such as polypropylene. Products are filled aseptically and sealed, or sealed and sterilised by pressure cooking in a retort, to produce commercially sterile finished products.

UHT Processing



Stainless steel vessels and pipework in a food processing facility.

There are two main modern UHT processing methods used within food industries: direct heating and indirect heating. Both methods apply heat to the product at a high temperature for a short time. The method selected relies on the nature and volume of the product being treated.

Direct heating usually involves subjecting the product to steam under controlled conditions until a nominated temperature is achieved for a nominated timeframe, after which the product is rapidly cooled within a vacuum vessel. Rapid heating and cooling gives a minimal sustained heat load on the product, which results in a high-quality end product.

Indirect heating involves circulating the product around partitions that are themselves heated or cooled according to the relevant process. The heating or cooling medium on the non-product contact side of the partition transfers its heat or chill to the product without physically contacting it. The equipment used to heat the product within this method is commonly referred to as a heat exchanger.

Heat exchangers are commonly available in three different types:

- Plate heat exchangers, which are commonly used for smooth liquids of low viscosity;
- Tubular heat exchangers, which can handle the treatment of smaller particles and offer longer treatment times depending on the size of the tubes available;
- Scraped surface heat exchangers, which are specially designed for the UHT of viscous products with or without particulates.

Cooling Process



Water used to cool processed containers must be chlorinated or otherwise treated.

Water is commonly used in the initial cooling of commercially sterile products. Any water used for product cooling must be chlorinated or otherwise treated so that it will not introduce microbiological pathogens into foods during the cooling process.

This is particularly important for canned products, as cans expand and contract during temperature and pressure variations, and contamination may enter at the can seams or ends. If water used to cool retorted items is

adequately treated, it will not contaminate the product inside the can. The Codex Code of Hygienic Practice for Low and Acidified Low Acid Canned Foods considers a residual free chlorine content of 0.5 to 2 parts per million (ppm) to be usually adequate for cooling water.

Additional cooling is commonly facilitated after the items have been removed from the retort within a well-ventilated area. Containers remain wet and vulnerable to seam contamination until dry, so handling of wet containers should be minimised and equipment that contacts them kept clean.

If your food business supplies foodstuffs manufactured to a customer's specifications, it is important to consider any specific Commercial Sterility Processing Development requirements in relation to their items.

Regulatory and Industry References

Commercial sterility requirements vary by market, and the following references may assist in the development of your program:

- 21 CFR Part 113, Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers (United States Food and Drug Administration);
- Code of Hygienic Practice for Low and Acidified Low Acid Canned Foods (CXC 23-1979) (Codex Alimentarius);
- Australia New Zealand Food Standards Code (Food Standards Australia New Zealand).

Customer requirements and the advice of your process authority may also apply to your Commercial Sterility Processing program.

Commercial Sterility Processing Development Key Points

- Commercial Sterility Processing programs must be developed to meet relevant Regulatory, Industry, and Customer standards and requirements;
- The Senior Management of your business is committed to providing adequate resources for the development of your Commercial Sterility Processing program;
- Should you require additional resources for the development of Commercial Sterility Processing program elements, please discuss this with the relevant Senior Management representative;
- A properly developed Commercial Sterility Processing program will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- A poorly developed Commercial Sterility Processing program will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.

Documentation

To establish the developed detail in a viewable format to facilitate information.

Documentation

Document: A document provides guidance and/or direction for performing work, making decisions, or rendering judgments that affect the safety or quality of the products or services that customers receive.

Documented policies, procedures, work instructions, and schedules form the basis of any food safety and quality management system. The following documentation formats may be considered to ensure ongoing compliance with specified requirements for Commercial Sterility Processing:

- Commercial Sterility Processing policy;
- Commercial Sterility Processing development procedures;
- Commercial Sterility Processing implementation procedures and work instructions;
- Commercial Sterility Processing monitoring procedures;
- Commercial Sterility Processing corrective and preventative action procedures;
- Commercial Sterility Processing verification schedule;
- Commercial Sterility Processing verification procedures;

- Commercial Sterility Processing validation schedule;
- Commercial Sterility Processing validation procedures;
- Commercial Sterility Processing training procedures.

If your food business supplies foodstuffs manufactured to a customer's specifications, it is important to consider any specific Commercial Sterility Processing Documentation requirements in relation to their items.

You may wish to visit the Commercial Sterility Processing Templates section of haccp.com for examples of Commercial Sterility Processing documentation, record, and resource formats commonly applied within food safety and quality systems.

Commercial Sterility Processing Documentation Key Points

- Commercial Sterility Processing programs must be documented to meet relevant Regulatory, Industry, and Customer standards and requirements;
- All documented Commercial Sterility Processing program elements must be controlled to ensure compliance;
- Key documented Commercial Sterility Processing program elements should be available to your business team at all times to ensure they can facilitate required tasks;
- A properly documented Commercial Sterility Processing program will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- A poorly documented Commercial Sterility Processing program will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.

Implementation

To facilitate the application of the documentation.

Implementation

Implementation: Implementation is the application of documented food safety and quality system elements into the actual business operation.

The implementation of Commercial Sterility Processing within any food business requires genuine commitment from senior management, staff, and visitors to ensure the nominated goals of implementation are achievable on an ongoing basis. It is a step that requires significant planning and consideration of general and specific food business circumstances to ensure the outcome of Commercial Sterility Processing does not negatively impact the safety and quality of the food items dispatched from the business.

Implementation of Commercial Sterility Processing must include a clear definition of responsibilities and authorities for all levels of participation by senior management, staff, and visitors to the site.

When implementing Commercial Sterility Processing within a food safety and quality system, you may wish to consider the following requirements before completion:

- Communication and display of the Commercial Sterility Processing policy;
- Completion of Verification and Validation of Commercial Sterility Processing development procedures;
- Availability of Commercial Sterility Processing implementation procedures and work instructions;
- Availability of Commercial Sterility Processing monitoring procedures and record templates where applicable;
- Availability of Commercial Sterility Processing corrective and preventative action procedures and record templates where applicable;
- Availability of the Commercial Sterility Processing verification schedule;
- Availability of Commercial Sterility Processing verification procedures;
- Availability of the Commercial Sterility Processing validation schedule;
- Availability of Commercial Sterility Processing validation procedures;
- Completion of Commercial Sterility Processing training procedures;

- Completion of product design and development requirements related to Commercial Sterility Processing;
- Completion of process design and development requirements related to Commercial Sterility Processing;
- Completion of training for team members who have responsibilities and involvement within Commercial Sterility Processing;
- Completion of competency approval for team members who have responsibilities and involvement within Commercial Sterility Processing.

If your food business supplies foodstuffs manufactured to a customer's specifications, it is important to consider any specific Commercial Sterility Processing Implementation requirements in relation to their items.

Commercial Sterility Processing Implementation Key Points

- Commercial Sterility Processing programs must be implemented to meet relevant Regulatory, Industry, and Customer standards and requirements;
- Your Commercial Sterility Processing program must be fully implemented as per relevant documented Policies, Procedures, and Work Instructions;
- The implementation of Commercial Sterility Processing requires a commitment to the provision of resources by the Senior Management of your business;
- A properly implemented Commercial Sterility Processing program will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- A poorly implemented Commercial Sterility Processing program will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.

Monitoring

To review, confirm and document evidence of the implementation against documented limits.

Monitor

Monitoring: Monitoring is the act of reviewing and confirming measurable parameters of a defined process or product status.

Monitoring requirements within food industry sectors are generally identified against limits of acceptability defined within HACCP plans, implementation procedures, and work instructions. Monitoring usually includes some element of record-keeping, which may be maintained manually or through digital systems. It is important to consider that advancements in technology have produced many systems and processes that are self-monitored or self-adjusted when variances are identified. Regardless of the system used, the goal of any monitoring activity is to provide sufficient evidence that any limit of acceptability has been met.

Traditional Commercial Sterility Processing monitoring requirements include manual recording and the application of corrective actions when the results of monitoring are found to be outside acceptable limits. Corrective Actions should also generally be strongly linked to the monitoring process where applied to ensure full traceability of the applied actions.

The following examples of monitoring activities and record formats may apply to Commercial Sterility Processing:

- Commercial Sterility packaging confirmation records: Confirmation assessments are often conducted on packaging used within products processed to achieve Commercial Sterility. The condition and conformance of packaging, whether rigid, such as cans, or flexible, such as pouches or formed cartons, is of utmost importance to ensure finished products will be microbiologically safe. It is common for Commercial Sterility packaging confirmation assessments to be conducted upon receipt, for raw materials, and during processing, for work in progress;
- Commercial Sterility processing records: Records are maintained to show that the nominated time and temperature requirements for Commercial Sterility Processing have been met. Other process parameters, such as retort pressure and the chlorine content and pH of cooling water, are also commonly monitored;
- Commercial Sterility retort operating records: Records of venting, come-up time, and cross-checks between the

mercury in glass (MIG) thermometer and the temperature recorder.

If your food business supplies foodstuffs manufactured to a customer's specifications, it is important to consider any specific Commercial Sterility Processing Monitoring requirements in relation to their items.

You may wish to visit the Commercial Sterility Processing Templates section of haccp.com for examples of Commercial Sterility Processing documentation, record, and resource formats commonly applied within food safety and quality systems.

Commercial Sterility Processing Monitoring Key Points

- Monitoring provides real-time confirmation and evidence that your risk-based FS&Q Controls are effectively implemented;
- Commercial Sterility Processing programs must be monitored to meet relevant Regulatory, Industry, and Customer standards and requirements;
- Monitoring of Commercial Sterility Processing must be facilitated as per relevant documented Policies, Procedures, and Work Instructions;
- Nominated monitoring records for Commercial Sterility Processing must be maintained as per relevant documented Policies, Procedures, and Work Instructions;
- A properly monitored Commercial Sterility Processing program will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- A poorly monitored Commercial Sterility Processing program will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.

Corrective Action and Preventative Action

To apply "real time" interventions to documented monitoring limits.

Corrective Action

Corrective Action: Corrective action is mandatory action to be taken when a deviation from the Quality System occurs, particularly in relation to a Critical Control Point.

Preventative Action: At any step in the process where a hazard has been identified, preventative action must be put into place to prevent re-occurrence.

Corrective Action and Preventative Action are implemented to ensure identified non-conformance issues are documented, investigated, and rectified within appropriate timeframes.

Corrective action is any action applied to regain control over a product, process, policy, or procedure that has been identified as being non-conforming or outside nominated limits of acceptability.

Preventative action is any action applied to prevent any identified non-conformance from reoccurring.

The outcome of corrective and preventative actions should result in regained process control after effective application. Specified corrective actions are commonly linked to the HACCP Plans and the food business certification process.

Below are Corrective Action and Preventative Action examples which may be associated with Commercial Sterility Processing related non-conformance:

- Review of the Commercial Sterility Processing policy;
- Review of Commercial Sterility Processing development procedures;
- Review of Commercial Sterility Processing implementation procedures and work instructions;
- Review of Commercial Sterility Processing monitoring procedures;
- Review of Commercial Sterility Processing corrective and preventative action procedures;
- Review of the Commercial Sterility Processing verification schedule;
- Review of Commercial Sterility Processing verification procedures;

- Review of the Commercial Sterility Processing validation schedule;
- Review of Commercial Sterility Processing validation procedures;
- Review of Commercial Sterility Processing training procedures;
- Re-training in Commercial Sterility Processing;
- Review of management review activities to include Commercial Sterility Processing as an agenda item;
- Initiation of product hold procedures where safety or quality may be compromised;
- Initiation of a product recall or product withdrawal procedures where investigations show that there is a substantial safety or quality risk to the released product;
- Contacting stakeholders including customers regarding any confirmed or potential Commercial Sterility Processing concerns involving their product.

If your food business supplies foodstuffs manufactured to a customer's specifications, it is important to consider any specific Commercial Sterility Processing Corrective Action requirements in relation to their items.

You may wish to visit the Corrective Action and Preventative Action section of haccp.com for examples of best practice applications for this food safety and quality system element.

Commercial Sterility Processing Corrective Action and Preventative Action Key Points

- The implementation of Corrective Action and Preventative Action provides confidence that your FS&Q Program is effectively implemented and that FS&Q criteria are being met;
- Where deviations or variations are observed, Corrective Action and Preventative Action must be facilitated to meet relevant Regulatory, Industry, and Customer standards and requirements;
- Corrective Action and Preventative Action of Commercial Sterility Processing must be facilitated as per relevant documented Policies, Procedures, and Work Instructions;
- Records of Corrective Action and Preventative Action for Commercial Sterility Processing must be maintained as per relevant documented Policies, Procedures, and Work Instructions;
- Proper application of Corrective Action and Preventative Action for your Commercial Sterility Processing program will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- Poor application of Corrective Action and Preventative Action for your Commercial Sterility Processing program will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.

Verification

To review and confirm documented monitoring and corrective actions against documented parameters.

Verify

Verification: The act of reviewing, inspecting, testing, checking, auditing, or otherwise establishing and documenting whether items, processes, services, or documents conform to specified requirements.

Verification is the detailed review of all food safety and quality system elements to confirm that they are effectively developed, documented, implemented, monitored, and reviewed. All food safety and quality system elements, including documented policies, procedures, training, HACCP plans, and their operational applications must be verified on an ongoing scheduled basis. The verification process commonly includes a defined schedule for which verification activities are required, how often they are conducted, who is responsible, and detailed documented procedures for each nominated verification activity.

The general goal of an established verification process is to ensure any systemic non-conformance issues are identified and rectified within an appropriate timeframe. When non-conformance issues are identified through the verification process, Corrective Actions and Preventative Actions should be implemented to ensure they do not impact the effectiveness of the food safety and quality system.

The following examples of verification activities may apply to Commercial Sterility Processing:

- Review of the Commercial Sterility Processing policy;
- Review of Commercial Sterility Processing development procedures;
- Review of Commercial Sterility Processing implementation procedures and work instructions;
- Review of Commercial Sterility Processing monitoring procedures;
- Review of Commercial Sterility Processing monitoring records;
- Review of Commercial Sterility Processing corrective and preventative action procedures;
- Review of the Commercial Sterility Processing verification schedule;
- Review of Commercial Sterility Processing verification procedures;
- Review of the Commercial Sterility Processing validation schedule;
- Review of Commercial Sterility Processing validation procedures;
- Review of Commercial Sterility Processing training procedures;
- Review of Commercial Sterility Processing performance since the last review and historically;
- Analytical testing of product or process to ensure the effectiveness of Commercial Sterility Processing;
- Seam inspection, seam teardown and container integrity checks on a scheduled basis;
- Retort temperature distribution checks and calibration of temperature measuring devices, such as MIG thermometers;
- Inclusion of Commercial Sterility Processing as an agenda item within the Management Review Process.

If your food business supplies foodstuffs manufactured to a customer's specifications, it is important to consider any specific Commercial Sterility Processing Verification requirements in relation to their items.

You may wish to visit the Verification Activities section of haccp.com for examples of best practice applications for this food safety and quality system element.

Commercial Sterility Processing Verification Key Points

- Your verification program provides evidence that your FS&Q Controls have worked;
- Commercial Sterility Processing programs must be verified to meet relevant Regulatory, Industry, and Customer standards and requirements;
- The verification of Commercial Sterility Processing must be facilitated as per relevant documented Policies, Procedures, and Work Instructions;
- Nominated verification records for Commercial Sterility Processing must be maintained as per relevant documented Policies, Procedures, and Work Instructions;
- A properly verified Commercial Sterility Processing program will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- A poorly verified Commercial Sterility Processing program will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.

Validation

To confirm the documented monitoring or procedural limits.

Validate

Validation: The process of gathering evidence to provide a scientific basis for the documented act of demonstrating that a procedure, process, and activity will consistently lead to the expected results. It often includes the qualification of systems and equipment.

Validation is the provision of evidence to support the limits of control or acceptability for food safety or quality parameters nominated within systemic elements. Limits of control or acceptability are commonly included within documented food safety and quality system elements such as procedures, HACCP plans, and specifications.

Common sources of validation include regulatory and legislative standards, finished product specifications and

customer requirements, industry codes of practice and guidelines, verified and validated research, historical product, and process control outcomes, and analytical testing.

The general goal of an established validation process is to ensure any inappropriate limits of control or acceptability are identified and rectified within an appropriate timeframe. When non-conformance issues are identified through the validation process, Corrective Actions and Preventative Actions should be implemented to ensure they do not impact the effectiveness of the food safety and quality system.

Validation activities are commonly defined within the verification schedules and procedures of established food safety and quality management systems.

The following examples may apply to validation of the limits of control or acceptability for Commercial Sterility Processing:

- Confirmation of nominated food safety and food quality control limits for Commercial Sterility Processing. These limits may be applicable to regulatory, industry, customer, or finished product specifications;
- Confirmation of scheduled processes through heat penetration studies and review by a process authority;
- Confirmation of analytical testing methods being used to confirm the effectiveness of Commercial Sterility Processing and ensure the accuracy of outcomes.

If your food business supplies foodstuffs manufactured to a customer's specifications, it is important to consider any specific Commercial Sterility Processing Validation requirements in relation to their items.

You may wish to visit the Validation Activities section of haccp.com for examples of best practice applications for this food safety and quality system element.

Commercial Sterility Processing Validation Key Points

- Your validation program provides evidence that your FS&Q Controls will work;
- Commercial Sterility Processing programs must be validated to meet relevant Regulatory, Industry, and Customer standards and requirements;
- The validation of Commercial Sterility Processing must be facilitated as per relevant documented Policies, Procedures, and Work Instructions;
- Nominated validation records and supporting documentation for Commercial Sterility Processing must be maintained as per relevant documented Policies, Procedures, and Work Instructions;
- A properly validated Commercial Sterility Processing program will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- A poorly validated Commercial Sterility Processing program will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.

Training, Competency and Resources

Skills, knowledge and competency requirements to facilitate development, documentation, implementation, monitoring, corrective action, verification and validation of every Food Safety and Quality System Element.

Skills and Knowledge

Skills and Knowledge: Skills and knowledge are attributes of human interactions commonly linked to competency within any specific job-related task.

Training and competency requirements for Commercial Sterility Processing must be ongoing, including regularly scheduled reviews to ensure the effectiveness of training and competency outcomes.

Team members who have defined responsibilities regarding Commercial Sterility Processing should have knowledge including:

- Basic Commercial Sterility Processing requirements;
- Positive outcomes of Commercial Sterility Processing;
- Negative outcomes of a lack of Commercial Sterility Processing;

- Current Commercial Sterility Processing procedures, methods, and techniques;
- General operational, corporate, and social awareness regarding Commercial Sterility Processing;
- Regulatory, industry, and customer requirements regarding Commercial Sterility Processing.

Team members who have defined responsibilities regarding Commercial Sterility Processing should have skills including:

- Competency in basic Commercial Sterility Processing;
- Effective application of current Commercial Sterility Processing procedures, methods, and techniques;
- The basic development, documentation, and implementation of HACCP and Prerequisite Programs within the food industry sector.

Team members who have defined responsibilities regarding Commercial Sterility Processing should have access to resources including:

- Commercial Sterility Processing training;
- Commercial Sterility Processing associations and events;
- Regulatory standards, industry and customer information, and updates regarding Commercial Sterility Processing;
- Incidents within the food industry sector regarding Commercial Sterility Processing;
- Commitment to Commercial Sterility Processing by senior management;
- Suitably qualified food industry professionals with verified experience in Commercial Sterility Processing;
- Effective communication systems including email, internet, and phone through which Commercial Sterility Processing information can be sent and received within suitable timeframes.

If your food business supplies foodstuffs manufactured to a customer's specifications, it is important to consider any specific Commercial Sterility Processing Training, Competency, and Resources requirements in relation to their items.

You may wish to visit the Training, Competency, and Resources section of haccp.com for examples of best practice applications for this food safety and quality system element.

Commercial Sterility Processing Training, Skills, and Knowledge Key Points

- Your Training, Skills, and Knowledge program ensures all participating personnel, visitors, and contractors have the required skills and knowledge to effectively facilitate the requirements of your FS&Q Program;
- Training, Skills, and Knowledge programs for Commercial Sterility Processing must be facilitated to meet relevant Regulatory, Industry, and Customer standards and requirements;
- Training, Skills, and Knowledge programs for Commercial Sterility Processing must be facilitated as per relevant documented Policies, Procedures, and Work Instructions;
- Training, Skills, and Knowledge records for Commercial Sterility Processing must be maintained as per relevant documented Policies, Procedures, and Work Instructions;
- Properly applied Training, Skills, and Knowledge programs for Commercial Sterility Processing will provide a strong framework for your business to maintain compliance with relevant Regulatory, Industry, and Customer standards and requirements;
- Poorly applied Training, Skills, and Knowledge programs for Commercial Sterility Processing will not fully support your business and may contribute to significant non-compliance against Regulatory, Industry, and Customer standards and requirements.



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