

FSIS Thermal Processing- Commercially Sterile Training Course



**Student Guide
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Module 1 - Course Overview and Introduction to Thermal Processing

Purpose of the course: Provide scientific, technical, and practical information for assessing the production of canned product; provide detailed information on thermal processes and thermal processing systems; provide guidance on the application of the regulations and improve inspection program personnel job performance.

Thermal Processing is the most critical and complex food process verified by FSIS. The critical elements in operation must be strictly adhered to, or there is a great potential to affect human health.

Definition of “canning” - Placing food in a container, hermetically sealing the container so that it is airtight and impervious to the entrance of microorganisms, and then giving the container a thermal process that achieves commercial sterility.

Canned Product - A meat or poultry food product with a water activity above 0.85 which receives a thermal process either before or after being packed in a hermetically sealed container.

Commercial Sterility - The condition achieved by application of heat sufficient, alone or in combination with other ingredients and/or treatments, to render the product free of microorganisms capable of growing in the product at nonrefrigerated conditions (over 50°F or 10°C) at which the product is intended to be held during distribution and storage.

Classes of Canned Product:

- **Low acid canned foods (LACF)** - A canned product in which any component has a pH value above 4.6 (includes meat and poultry)
- **Acidified low acid foods** - A canned product which has been formulated or treated so that every component of the finished product has a pH of 4.6 or lower within 24 hours after the completion of the thermal process.
- **Acid foods** (no meat or poultry products)

Conventional Canning - Place the food in a container, hermetically seal container, thermally process container under high heat and pressure. If the pH \leq 4.6, can treat with lower heat and no pressure.

Aseptic Processing Systems - Commercially sterilize the food and container separately, plus fill and seal container in commercially sterile environment.

Canned Product Containers - Cans, glass jars, plastic containers, laminated pouches, and paperboard containers.

Types of Canned Product Containers

Cans
Glass jars
Plastic containers
Laminated pouches
Paperboard containers



Beef stew
Whole chicken
Meat sauces and gravies
Meat spreads
Soups
Entrees



Module 2 - Microbiology of Thermally Processed Foods

Microbiology - The study of small living organisms visible only by the use of a microscope..

Microorganisms of concern are molds, yeasts, and bacteria.

Bacterial spores are extremely resistant to heat, cold, and chemical agents while the vegetative cells are less resistant.

Oxygen Requirements of Bacteria:

- **Aerobes** – require oxygen to live
- **Anaerobes** – oxygen prevents growth
- **Facultative anaerobes** – tolerate presence or absence of oxygen

Moisture Requirements of Bacteria:

- The amount of moisture and its availability in a food are important factors for bacterial growth
- Measured by water activity - a_w
- Influenced by the addition of ingredients such as salt and sugar

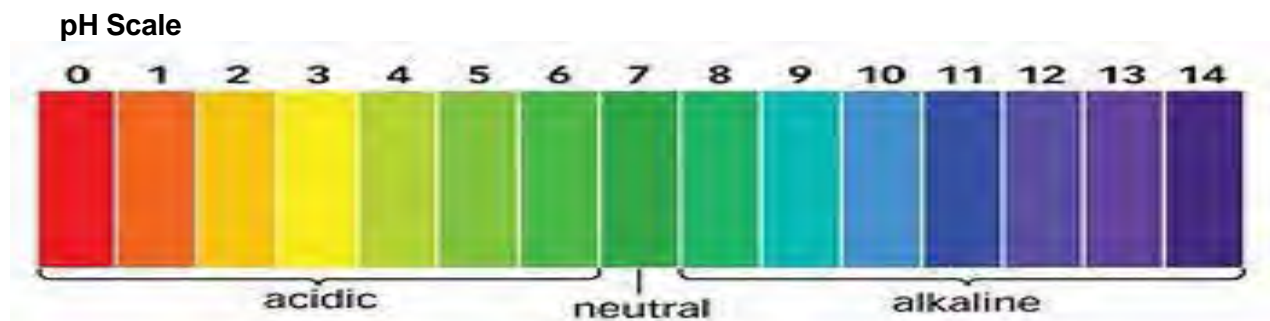
Minimum a_w requirements for Bacterial Growth:

Most molds (e.g., <i>Aspergillus</i>)	0.75
Most yeasts	0.88
<i>C. botulinum</i>	0.93
<i>Staphylococcus aureus</i>	0.85
<i>Salmonella</i>	0.93

pH requirements for Bacterial Growth:

Microbial growth is generally greater at a neutral pH

Bacteria, yeast and molds have optimum, minimum, and maximum pH for growth



Temperature Requirements for Bacterial Growth:

Bacterial group names are based on optimum temperatures for growth:

- **Psychrotrophs** - Grow best at 58°F to 68°F; can grow slowly at 40°F; only *C. botulinum* Type E and non-proteolytic strains of types B and F are of concern in canned food.
- **Mesophiles** - Grow best 86°F to 98°F; Includes all microorganisms that affect food safety; ***C. botulinum***—a spore former—is in this group
- **Thermophiles** - Optimum growth of obligate thermophiles occurs at 122°F to 150°F; spores are very heat resistant; **no human pathogens.**

***Clostridium botulinum* - Pathogen of concern for canned meat and poultry products.**

Anaerobic, mesophilic spore former. The organism produces a deadly toxin. Botulism is the disease in humans. The organism is contained in soil and water throughout the world. Spores found everywhere, but vegetative form produces toxin. Spores survive unfavorable conditions such as acid environments and heat. Certain spores survive 5 to 10 hours in boiling water—212°F (100°C). Although the spores are heat resistant, the toxin can be inactivated by boiling temperatures.

Commercially sterile foods may contain viable microorganisms

- Spores of thermophilic bacteria survive commercial sterility processes
- Not harmful
- Do not grow under normal storage conditions
- May need to be destroyed for hot-vended items

Incipient spoilage - Microbial spoilage caused by too long of a delay between container closing and retorting.

Contamination After Processing - Leaker spoilage, generally due to inadequately formed seams, container damage, or cooling water contamination.

Inadequate Heat Processing - Inadequate heat process may lead to public health hazard.

Non-Microbial Food Spoilage - Chemical action causing hydrogen swells or pinholes. Overfilling of container gives the appearance of spoilage. Zero or low vacuum cans may appear to be spoiled.

Module 3 - Principles of Food Plant Sanitation

The term “**sanitation**” is often applied to just the cleaning and sanitizing of equipment and production areas.

Sanitation has much broader applications:

- Includes activities designed to prevent product adulteration and activities designed to minimize spoilage (economic loss)
- Includes activities designed to prevent contamination with materials that may offend consumers (aesthetic senses)

Food plant sanitation addressed in federal regulations:

FDA – CGMP regulation (21 CFR 110)
Specific sanitizer formulations approved by FDA are listed in 21 CFR 178.1010
FDA – fish and fishery products (21 CFR 123)
FDA – juice and juice products (21 CFR 120)
FSIS – meat and poultry (9 CFR 416)

Thermally processed foods are safe and stable because they are given a final heat treatment designed to destroy or inactivate microorganisms. The hermetically sealed containers protect the foods against microbial recontamination before, during, and after the thermal process.

It is **important to remember** that the thermal processes are not designed to destroy an infinite number of microorganisms. Canning operations must include appropriate steps to minimize the number of microorganisms that are present on the food before those foods are placed in the container.

A comprehensive sanitation program is essential for controlling microorganisms in a food processing plant. **Chlorine** and other sanitizing agents are necessary chemicals for this purpose. Sanitizers alone cannot ensure food safety. Effective cleaning, proper operating procedures and practices, and appropriate controls are all important.

The numbers and types of microorganisms in a product depend on whether they are:

- brought into the plant on raw products
- picked up by the food as it passes through or over equipment or by employee contact
- contributed by water during washing, conveying, or preparation
- contained in ingredients added to the product
- in the cooling water for thermally processed containers

Water used for washing, conveying, and preparing food or for cooling must be of good sanitary quality (or rendered so).

Equipment **must** be cleaned frequently to minimize growth on food-contact surfaces and thereby minimizing transfer to the food.

Cleaning is especially important for **heated equipment** where a potential exists for **spore build up**, particularly thermophiles.

Wash raw product that has passed through heated equipment, preferably in cold water.

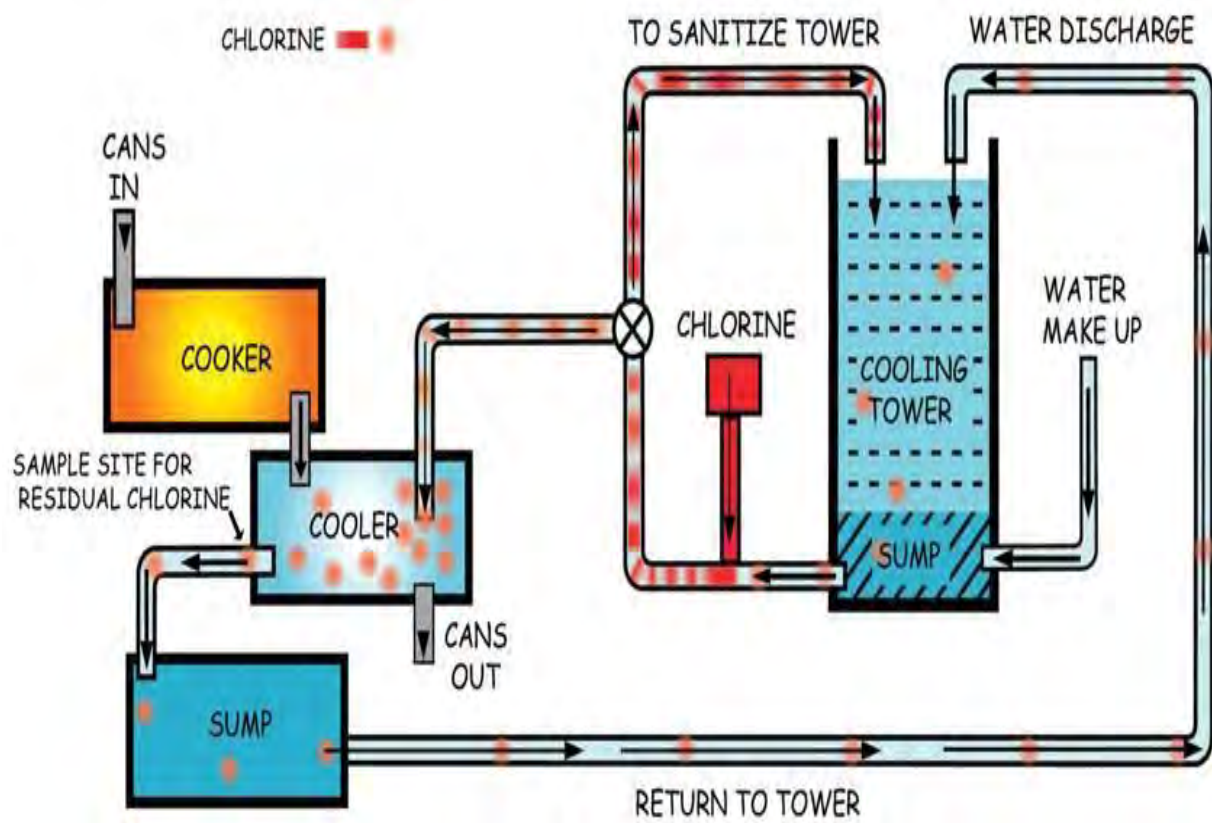
Keep temperature above 170°F.

Sanitizing treatment must not adversely affect food products or their safety for consumers.

Until recently, agents most widely used in establishments were chlorine, iodine, and quaternary ammonium compounds.

Other sanitizers have received regulatory approval and have found applications in the food industry.

Chlorine compounds are still the most widely used sanitizers in the industry.



Module 4 - Canning Regulations - An Overview

9 CFR 431.1 Definitions

- **Canned Product:** Meat or poultry food product with water activity >0.85 which receives a thermal process either before or after being packaged in a hermetically sealed container.
- **Low Acid Product:** Canned product in which any component has pH >4.6.
- **Initial Temperature (IT):** Measured in coldest container at the start of the thermal process.
- **Process Temperature (PT):** Minimum maintained temperature of the heating medium.
- **Process Time (B_b):** Intended time containers are exposed to the heating medium in a retort while at or above PT.
- **Come-up time (CUT):** Elapsed at the start of B_b until the retort reaches required PT.
- **Hermetically sealed:** Airtight; does not allow the entrance of microorganisms during and after the thermal process.
- **Commercially sterile:** free of viable microorganisms (including spores) that are capable of reproducing in the food under normal nonrefrigerated storage and distribution conditions.

All thermal processing establishments must conduct a hazard analysis for thermally processed products, assess possible outcomes, and address food safety hazards through:

1. A HACCP plan if biological, chemical and/or physical hazards are considered reasonably likely to occur (RLTO);
2. A HACCP plan or canning regulations (§318.300 - 318.311 or 381.300 - 381.311) if biological hazards are considered reasonably likely to occur (RLTO); or
3. Canning regulations or similar prerequisite program if food safety hazards are considered not reasonably likely to occur (NRLTO)

§431.2 Examination and Cleaning of Empty Containers

Visual and teardown examinations of container closure integrity must be conducted to ensure that empty containers and container materials are properly handled and free from structural damage and defects that may affect container integrity. Rigid containers (cans) are required to be cleaned prior to filling.

§431.3 Thermal Processing

All thermally processed products must be produced by the establishment in accordance with an on-file process schedule (PS) developed by a Processing Authority (PA). The establishment must provide inspectors with a list of process schedules and procedures, monitor and control all critical factors, and make available all thermal process records. Any changes to formulation, procedures, etc. must be evaluated by the PA and the PS not changed without prior written submittal of the revisions to the inspector.

§431.4 Critical Factors

Establishments must ensure that critical factors identified in the PS are measured, controlled, and recorded to ensure they are within the limits of that PS. Critical factors include maximum

pH, nitrite ppm level or % salt, water activity, product consistency, viscosity, and/or particle size, head space, heating medium flow rate, and maximum fill-in weight or drained weight.

§431.5 Operations in the Thermal Processing Room

Process schedules must be posted or made available to the retort operator and inspector. A system for product traffic control must be established. Each basket or one visible container must be marked, heat-sensitive ink applied to each container, and exposed heat sensitive indicators removed before the vehicle is refilled. Container loading systems for crateless retorts must be designed to prevent unprocessed containers from bypassing the retort.

The establishment must measure and record the I.T. of the coldest container prior to processing. Time/temperature recording devices must agree within 15 minutes. pH meters or similar electronic instruments must be used to measure maximum pH when it is a critical factor.

§431.6 Equipment and Procedures for Heat Processing Systems

Equipment and procedures used for heat processing systems must be adequate to render the product commercially sterile. Thermal processing systems must be examined at least annually, and system maintenance records must be maintained.

§431.7 Processing and Production Records

Establishments must obtain and record all data necessary to support that thermal products are prepared, processed, and handled in compliance with commercially sterile product regulations.

§431.8 Record Review and Maintenance

Establishments must prepare commercially sterile product production records when the specific event occurs. Entries must be made, and the records reviewed, signed or initialed within one working day after the process, made available to the inspector, and retained for a specified time.

§431.9 Deviations in Processing

Process deviations (PD) occur when the actual process is less than the actual PS, a critical factor does not meet the specified limit, or a thermal processing system parameter is not met. FSIS Directive 7530.1, "Handling a Process Deviation or Abnormal Container of Thermally Processed, Commercially Sterile Canned Product" provides the inspector instructions for submitting information regarding the deviation, evaluation, and product disposition.

§431.10 Finished Product Inspection

Establishments must have finished product inspection procedures in place to ensure that only normal appearing commercially sterile product is distributed into commerce.

§431.11 Personnel and Training

§431.12 Recall Procedure

Module 5 - Processing Authorities

Processing authorities are defined in 9 CFR 431.1

They include a person or persons:

- having expert knowledge of thermal process or acidification requirements
- having access to facilities for making thermal process determinations
- designated by the processor to perform certain functions
- can be employee of firm
- can be outside person or organization

FSIS does not publish a list of processing authorities; recognizes the work, not the person performing the work and is familiar with individuals and organizations performing this type of work.

Processing Authority Activities:

1. Processing authorities perform temperature distribution tests using detailed protocols.
2. Processing authorities do heat penetration tests using detailed protocols, calculate processes, and recommend process schedules.
3. Processing authorities evaluate process deviations using established protocols and provide product dispositions.

Module 6 - Principles of Thermal Processing

Canning is the process of placing food in a container and hermetically sealing it so that is airtight and impervious to the entrance of microorganisms and then giving it a thermal process; has been practiced since around 1810.

One of the **key components** that affect the sterilization of the canned products is **temperature**, which is easily regulated. Temperature is also one of the critical elements that would be included on the process schedule.

To develop the process schedule, the processing authority needs extensive knowledge of food microbiology, characteristics of the product, container, and the thermal processing system.

The processing authority must have the ability to recognize the limitations of the processor and/or the processing system.

Components of the process schedule include initial temperature of the product, process time, process temperature, product type, container type, and the thermal processing system. Critical factors may include minimum headspace, maximum thickness, and maximum pH for acidified products.

Thermal processes are developed using scientific procedures that consider: 1) the heat resistance of the microorganism to be destroyed and 2) the heat penetration into the product. The target microorganisms for LACF include ***Clostridium botulinum*** and ***C. sporogenes***. For acidified LACF, the target microorganisms are vegetative cells of pathogens and acid tolerant non-pathogenic spores.

The heat resistance of microorganisms can be dependent on several factors including growth characteristics of the target organism, media in which the organism grows, and the conditions under which the organism grows. In order to determine the heat resistance of microorganisms, thermal death time studies must be conducted. These studies can be conducted using a three-neck

flask, thermal death time tube, and numerous retorts. The microbiological parameters to determine the thermal death time study include the D value, Z value, and F value.

The **D value** refers to the time, at a constant temperature, required to 1-log_{10} of the organisms present.

The **Z value** is the change in temperature that changes the D value by a factor of 10 or the organism's heat resistance by a factor of 10.

The **F value** is the number of minutes at a given temperature necessary to destroy a given number of microorganisms.

The product heating data can be determined by conducting a heat penetration test. The heat penetration test monitors the rate of change in temperature of the food inside the container as it is being heated in a specific retort system. A temperature sensor or thermocouple is located in the product at the slowest heating region (cold spot) of the container. The slowest heating region or container cold spot depends on the product type, container size and type, the thermal processing method or system, and the heat transfer mechanism.

These heat penetration tests are used to simulate the worst-case scenario likely to occur when producing the product.

There are several potential critical factors that affect the heat penetration test such as raw or cooked meat, moisture content, clumping of the product, particle size and style, solid to liquid ratio, fill weight, etc. To determine the cold spot, the processing authority would also have to know the heat transfer mechanisms. These mechanisms include convection, conduction, convection and conduction, and induced convection. Conduction heating is defined as particle-to-particle heat transfer with no particle movement. Convection heating is defined as particle-to-particle heat transfer with particle movement. Induced convection heating involves mechanical agitation, which creates product movement to enhance convection heating of the product. A thermocouple is used to monitor the temperature inside of the container during processing.

The thermocouple must be in the slowest heating region or cold spot of the container. Mounting must place and maintain the thermocouple at the desired location. The thermocouple may need to impale the product in order to determine the cold spot.

After determining the thermal resistance data for the target organism and the heat penetration data for the product, the processing authorities can then use a scientific method to calculate the process schedule for the product. The purpose of a process schedule calculation is to demonstrate that the thermal process can deliver the required lethality consistently. It also determines how changes in the product formula preparation parameters or filling affects the lethality treatment. There are two scientific methods for determining process schedules that will achieve the sterilization value (F_0) for a given product: the general (or graphical) method and the formula method. Using the general method, lethality is calculated directly from the heat penetration time and temperature data using a Z value of 18°F and the reference temperature of 250°F. The most common formula method is the Ball formula method. The Ball formula method was developed by C. Olin Ball in 1923. After the process schedule has been developed, confirmation can be determined by an inoculated test pack.

Heat distribution (HD) and temperature distribution (TD) tests determine temperatures around containers in retort systems. Processing authorities and equipment manufacturers use HD/TD tests to develop retort operating schedules such as the venting schedule and retort come up time. Process timing must not start until the retort temperature in the process schedule is achieved and required retort operating procedures are completed.

Module 7 - Thermal Processing System Components, Instrumentation, and Equipment, and Process Room Operation

Temperature Indicating Devices - Mercury-in-glass (MIG) thermometer serves as the reference instrument for LACF; alternative devices such as thermocouples or resistance temperature devices (RTD) or digital temperature gauges (DTG) may be used; each retort is required to have at least one MIG thermometer, DTG, RTD or equivalent thermometer or electronic device (PLC).

Mercury-In-Glass/Equivalent Thermometer - Easily readable to 1°F-MIG range not to exceed 17°F/inch graduation, installed where easily read; installation location varies depending on retort type; tested for accuracy when installed and annually; defective devices **must** be repaired or replaced.

Records must specify the following information - Identification of the device (MIG/DTG/RTD); manufacturer of the device; identification of the reference device; equipment and procedures used for check; date and test results; name of person or facility performing test; date of next test (optional); each device must have a tag, seal, or other means to identify it and correlate it with the accuracy check record; a record is necessary for documenting the accuracy of the reference device; for acidified foods, no specific requirements on the type of device – should still test for accuracy.

Temperature/Time Recording Devices

Low-acid foods: Required for each retort; can be combined with the steam controller to be a recorder controller; provides a permanent record of temperature and time for the thermal process.

The temperature/time recorder should agree as close as possible with MIG/RTD but never higher; accuracy to 1°F; pen arc adjusted properly; time of day set properly; prevent unauthorized changes with a lock or notice.

Chart-Type Recorders - Use appropriate chart paper; graduations not to exceed 2°F within a range of $\pm 10^\circ\text{F}$ of the process temperature; scale not to exceed 55°F/inch within $\pm 20^\circ\text{F}$ of the process temperature.

Continuous line or multipoint plotter - Installation location of recorder bulb or sensor will vary based on the type of thermal processing system.

Each retort **must** have an automatic steam controller.

Instrument Air Supply Requires: Adequate filter system; clean, dry air at the proper pressure; independent air supply system.

Pressure Gauges - Scale should not exceed 2 psi; useful when processing with overpressure, pressure cooling and as safety device.

Timing Devices - Wristwatches are not permitted; use analog or digital clock; located where easily and accurately read.

Maintenance - The regulations require that each thermal processing system be examined at least once a year.

Steam Supply: Steam is the most common heating medium; supply of steam to thermal processing area must be adequate to bring the retort up to process temperature.

Valve Types and Uses - Gate or Ball: Used on vents for rapid discharge and are full flow; air and water lines connected to the retort must be equipped with a globe valve or other suitable valve to prevent leaking into the retort; double block and bleed configurations or three-way valves are often installed on water or air lines used for cooling.

Bleeders - Small openings on retorts used for: Circulation of steam; air removal that comes in with the steam; condensate removal. Required on external wells when the MIG/DTG and recorder probes are installed in an external well.

Mufflers - Used on vents and bleeders to reduce noise; must not reduce air removal or interfere with heat distribution; cartridges must be inspected and replaced as needed.

Posting of Thermal Processes - Operating processes and procedures **must** be posted in conspicuous place or be readily available to the operator and CSI.

A system for product traffic control **must** be established to prevent containers from bypassing the retort. Each crate, or at least one container in each crate, **must** be marked with a heat sensitive indicator.

Each container **must** be coded; codes are embossed or imprinted; may be legibly marked on a securely affixed container label.

Code Requirements: Product, unless printed on the container; year packed; day packed.

Initial Temperature (IT) - Temperature of the coldest component in the product when thermal process begins. Must be determined for coldest container in retort.

Module 8 - Steam, Batch, Still Retorts

Characteristics of these retorts:

- Pressure vessel
- Batch-type
- Non-agitating
- Vertical or horizontal
- With or without crates

Advantages of using steam:

- Excellent medium for heat transfer
- Temperature easily regulated
- Pressure can counter-balance internal can pressure
- Easy to produce and stored for instant use

Three different models:

- **Vertical** – Equipment sits vertically, loaded from the top in baskets or similar
- **Horizontal** – Equipment sits horizontally, loaded from the end in crates or similar
- **Craterless** – Equipment sits vertically but is loaded from the top using gravity with containers dropping inside the retort in no defined order (jumbled or mixed up)



Instrumentation needed:

- Temperature indicating device (Mercury-in-Glass - MIG) or equivalent device (e.g., Resistance Temperature Device – RTD or Digital Temperature Gauge-DTG)
- Temperature/time recording device

Requirements:

External well:

- Must be connected through at least a 3/4" opening
- Must have at least a 1/16" bleeder opening

Steam Inlet: Must be large enough for proper operation; must facilitate air removal; must be located opposite the vent.

Steam Spreaders – Vertical Retorts: Not required for vertical retorts. If used, usually in form of a cross, and perforations along the top or side. **All others:** Total cross-sectional area should be equal to 1.5 to 2 times the cross-sectional area of the smallest part of the steam inlet line.

Vents: Large valve-controlled openings to remove air from the retort; located opposite steam inlet; controlled by a full flow valve or equivalent; atmospheric break between vent and closed drain required.

Construction of Crates, Carts and Divider Plates: Constructed of suitable materials; perforations shall be 1" holes on 2" centers or equivalent (27% open area).

Bleeders: Small openings, normally 1/16 to 1/8 inch in diameter used to remove air from steam retorts and circulate the steam while they are in operation; open during come up and processing; bleeders must be within 1 foot of outermost containers and no more than 8 feet apart along the top of the horizontal retort.

Mufflers: Used on bleeders and vents to decrease noise; must not impede normal operation.

Module 9 - Steam, Batch, Agitating Retorts

Characteristics of these retorts:

- Uses steam as the heating medium
- Continuous container handling
- Intermittent product agitation
- At least two shells
- Configuration will vary
- Rotating reel with steps to hold containers
- Spiral T attached to shell to move containers through

Advantages of using steam:

- Excellent medium for heat transfer
- Temperature easily regulated
- Pressure can counter-balance internal can pressure
- Easy to produce and stored for instant use

Instrumentation needed:

- Temperature indicating device (Mercury-in-Glass - MIG) or equivalent device (e.g., Resistance Temperature Device – RTD or Digital Temperature Gauge-DTG)
- Temperature/time recording device

Advantages:

- Short process time
- Continuous input

Disadvantages:

- Extra critical factors
- Container size limits
- Larger investment than a still steam retort

Critical Operating Parameters: Condensate build-up; container headspace; product consistency; reel speed.

Module 10 – Continuous Rotary Retorts

Characteristics of these retorts:

- Pressure vessel
- Batch container handling
- Product agitation
- Horizontal
- Unprocessed cans are loaded, and processed cans are unloaded at the same time through air-operated gate valves
- Cans enter high on one end of the retort wall and exit low on the other end of the retort wall
- During loading/unloading, the outer reel is locked to the retort shell

Advantages of using steam:

- Excellent medium for heat transfer
- Temperature easily regulated
- Pressure can counter-balance internal can pressure
- Easy to produce and stored for instant use

Instrumentation needed:

- Temperature indicating device (Mercury-in-Glass - MIG) or equivalent device (e.g., Resistance Temperature Device – RTD or Digital Temperature Gauge-DTG)
- Temperature/time recording device

Advantages:

- Shorter process time
- Better product quality and uniformity due to shorter process times

Disadvantages:

- Batch handling
- More critical factors to measure, control, and record

Critical Operating Parameters: Headspace and/or fill-in weight; consistency/thickness; reel speed; condensate build-up in the bottom of the shell

Module 11- Retorts Processing with Overpressure

Overpressure: Pressure supplied to a retort in excess of the normal pressure exerted by the heating medium at a given temperature and is used to:

- **maintain container integrity**
- **permit adequate processing**

Overpressure requirements vary:

- Too much at the start of the process could distort containers (crush containers) or damage seals
- Too little during heating could lead to container rupture or seal damage, slow heat penetration, or interfere with water circulation patterns in the retort
- Too little during cooling could lead to container rupture or seal damage

Factors affecting overpressure requirements:

- Product fill temperature
- Container headspace
- Container vacuum
- Entrapped air
- Processing temperature

Each retort **must** have a pressure recording device.

Each retort **should** have pressure gauge.

Each retort **must** have a means of providing uniform HD/TD during processing.

The efficiency of the circulation system **must** be documented in HD/TD data or other documentation from a processing authority.

HD/TD data **must** be on file at the establishment to support the retort operating procedures.

General Characteristics of Retorts that Provide Overpressure:

- Introduced steam or air is the source of overpressure
- Batch processing, not continuous container handling
- Static (still), rotary (end-over-end), and back and forth (Shaka®process) agitation models

Factors that may Affect Heat Distribution or Processing Medium Circulation:

- Operating pressure

- Come-up procedures
- Partial loads
- Fan or pump off or not functioning properly

Retorts that Provide Overpressure

- water immersion
- cascading water
- water spray
- steam/air mixture

Module 12- Hydrostatic Retorts

Equipment and procedures for pressure processing in steam in hydrostatic retorts are covered by 9 CFR 431.6(b)(4).

Generally, the hydrostatic retort is very large and many stories high. It can be thought of as a still steam retort operated at a constant process temperature through which containers are conveyed by a continuous carrier chain at a constant rate designed to provide the correct process time.

Hydrostatic retorts are manufactured by the FMC Corporation in the U.S. and by Stork and others in Europe. Newer designs now offer end-over-end or axial agitation of the product, the use of overpressure for the maintenance of container integrity, the ability to process glass and flexible pouches, and water as a heating medium in addition to steam. The systems are often used for high volume products which need long cook times, such as condensed soups and pet foods.

Hydrostatic pressure is pressure from a body of water at rest. The weight of the water creates the pressure. The higher the water is in a vertical column, the greater the pressure. The name hydrostatic is derived from the fact that the pressure in the steam dome is counterbalanced by water in the entry and exit legs of the retort. The containers are conveyed through this steam dome. The higher the water level, the higher the pressure and temperature attained in the steam dome. They are pre-heated in a feed leg (hot water leg) prior to entering the steam dome and cooled in an exit or discharge (cooling) leg after the steam dome. Containers are carried by chain conveyors. The water is under “hydrostatic pressure” created by pressure in the water legs which seals the steam in the steam chamber.

Startup procedures for a hydrostatic retort requires venting of the retort and bringing the water in the feed legs up to temperature. This procedure takes a longer time than the venting of still steam retorts. The hydrostatic retort is normally operated for periods of up to several weeks and may be shut down and cooled only when required for maintenance or repairs.

Containers are loaded into a horizontal carrier on the continuous chain and conveyed up to the inlet leg of the sterilizer. The inlet leg is filled with water which counterbalances the pressure in the steam dome. The temperature of the water increases as the container moves from the top of the inlet leg down toward the steam-water interface at the bottom of the leg. Water temperature in the inlet leg may range from ambient to boiling. The feed leg may contribute to the process lethality by increasing the initial temperature of the product. If process lethality is claimed for the inlet leg of the retort, the water temperature in the inlet leg must be carefully controlled.

There is minimal product agitation unless specifically designed into the system. Steam is generally used as the heating medium. There are no doors and transfer valves between the processing chamber (steam dome) and the atmosphere. Process times are basically the same as a still retort. The conveyor system is used to increase the number of containers processed. Steam may enter at the top or middle of the dome.

For example, the water height in the water legs must be 37 feet high at sea level to counterbalance a processing temperature of 250° F (121° C). Operating at temperatures above 250° F will require a higher water level. The retorts can be operated below the maximum temperature if the pressure remains high enough to prevent water contact with the containers in the steam dome.

The container is conveyed through the steam-water interface into the steam dome. The number of times that the carrier passes through the steam dome as well as the speed of the carrier determines the process time. Traveling from the top of the steam dome to the bottom, and vice-versa, is referred to as one pass. Hydrostatic retorts with 2, 4, 6, and 8 passes are common. After traveling through the steam dome, the containers are conveyed into the exit water leg where the temperature decreases as the container passes up the leg. The cans leaving the steam dome are heated to a high temperature and give up their heat to the water in the discharge leg. This results in one of several possible outcomes, depending upon the design of the retort.

As the container exits the leg, it is exposed to atmospheric pressure, and it may pass through a series of water spray coolers to further cool the product. The conveyor chain carries the containers back to near the loading station where the processed product is unloaded from the continuous carrier. Because the container inlet and exit are close together, care must be taken to ensure that unprocessed containers do not become mixed with processed containers. Containers found on the floor or elsewhere whose status is questionable should be destroyed.

9 CFR 431.6(b)(4)(i) requires that the MIG thermometer be installed in the retort steam dome near the steam-water interface. This should be the coldest spot in the retort dome. There must be a steam controller.

9 CFR 431.6(b)(4)(i) requires the installation of additional temperature recorders near the top and bottom of each hydrostatic water leg if the process schedule specifies maintenance of specific temperatures in the water legs.

An automatic steam controller must be utilized for all retorts to maintain the retort temperature (**9 CFR 431.6(a)(3)**).

Before the start of operations, the steam dome must be vented just like a regular steam, batch, still, retort. The venting time and temperature must be recommended by the equipment manufacturer or the plant's processing authority.

9 CFR 431.6(b)(4)(iv) requires the hydrostatic retort to be equipped with at least one bleeder ¼ inch or larger at the top of the steam chamber or chambers at the opposite end of steam entry. In addition, all bleeders must be arranged in such a way that the operator can observe that they are functioning properly.

Control of the water levels in the feed and exit legs is essential to maintain the hydrostatic pressure in the retort. The water level is normally controlled through a differential pressure controller which adds water when it is needed and dumps excess water from the legs. Water level fluctuation in the feed and exit legs may be caused by fluctuations in the feeding and discharge of containers. As more containers are fed into the container conveyor, more water is displaced from the legs, a lack of production results in a lack of containers in the legs, and the water level falls.

The container-conveyor is driven by a variable speed motor and must be checked and recorded

at the beginning of processing and recorded at least every 4 hours. Changing container-conveyor speed changes the process time. Operating at a slower speed than in the process schedule will result in longer cook times, which affect product quality. Operating at a faster speed than outlined in the process schedule will result in shorter cook times and potentially under processed product, which could indicate a food safety issue.

Water contacting containers in the bottom loops is a serious concern. It may result in under processing. If containers contact the water, the containers **must** be segregated and evaluated by the processing authority.

The feed leg temperature cannot be lower than the minimum product initial temperature (IT), or the leg temperature becomes the IT. Critical factors must be measured and recorded in accordance with the method and frequency in the written procedure, as is true for all retorts (**9 CFR 431.4**). Records must include conveyor (chain) speed and be checked at least every 4 hours (**9 CFR 431.6(b)(v)**).

Module 13 - Acidified Low Acid Foods

An acidified food is a low acid food to which acid or acid food is added to produce a final pH of 4.6 or less. Proper acidification prevents growth of *C. botulinum*. pH is the term used to quantify the degree of acidity or basicity. The more hydrogen ions (H^+) present equates to a more acidic substance. The pH scale ranges from 0 to 14. Pure water is neutral at a pH of 7.0. Above a pH of 7.0, there are more hydroxide (OH^-) ions, whereas below a pH of 7.0 there are more H^+ ions. Buffering capacity refers to the ability of a food to resist change in pH. This varies from food to food. To determine pH of a product there are two methods: colorimetric method and electronic method.

There are several acidification procedures an establishment can use (1) acid blanched food, (2) immerse blanched foods in acid solution, (3) direct batch acidification, (4) add acid foods to low acid foods, or (5) direct acidification of food in container. Each certification method requires proper control. An establishment may utilize more than one procedure. An establishment must monitor the acidification by pH measurement as referenced in regulation 9 CFR 431.5(e).

If there is a failure to properly acidify a product to less than 4.6 pH, one of the following must occur: fully reprocess product, process as low acid food, hold for evaluation, or destroy. Establishments must maintain records showing adherence to process schedules and retain records of all process deviations.

Module 14 - Aseptic Processing and Packaging Systems

Aseptic processing is a continuous operation. The behavior of one part of the system can affect the overall performance of the entire system. In aseptic processing, packages and food product are sterilized in separate systems. The sterile package is then filled with the sterile product, closed, and sealed in the sterile chamber. The processing authority must ensure commercial sterility not only for the product but also the product sterilization system, packaging equipment, and packaging materials. Before processing can begin, the processing equipment, packaging equipment, and materials must be pre-sterilized.

Processing equipment can be pre-sterilized using steam or hot water under pressure. Packaging equipment and materials can be pre-sterilized utilizing saturated steam, superheated steam, hydrogen peroxide and heat, or other treatments. All processes must be validated. The scheduled process will include the product, product sterile zones, packaging system, and packaging materials. Formulation controls such as starches, particle size, and rehydration can change the flow rate of the product through the sterilization tubes. Flow rate must be monitored and must not be faster than the flow rate in the process schedule. Direct product heating systems include steam injection and steam infusion.

Indirect product heating systems include plate heat exchangers, tubular heat exchangers, and scraped surface heat exchangers. Hold tubes must be sloped upward at least .25 inches per foot the diameter length and slope should conform to testing. No portion of the tube is heated, but it may be insulated. Each fluid food particle may receive a different degree of sterility depending on the length of time the particle spends in the holding tube. Resident time of the fastest moving particle is determined by a processing authority. The holding tube must be designed so that every particle of food remains in the tube for the specified time in the process schedule. Other equipment and controls include temperature indicating devices and recorders. Temperature indicating devices must meet requirements must be checked for accuracy, must have calibration records and the bulb in the vicinity of the recorder. The recorder should be accurate, and the bulb should be located at the exit end of the hold tube. The process may have multiple diversion valve locations in case of a temperature drop or a pressure drop in the product-to-product regenerator. Product-to-product regenerators are used for simultaneously cooling sterilized product and heating unsterilized product.

The pressure on the sterilized product is greater than the pressure on the unsterilized product. Back pressure devices, valves, or orifices may be used to maintain pressure to prevent flashing of the product. If the pressure in the system drops, water in the product turns to steam.

Manually operated systems rely on review of production logs and recording charts to verify the process schedule was delivered. Automated systems prevent packaging of nonsterile product.

Operations should be verified at startup by following the process schedule, ensuring process monitor temperature at the coldest point downstream of the tube, and determining how the establishment prevents deviations during switchover from water to product. Operational records include temperature indicating device at the end of the hold tube, temperature recording device at the end of whole tube, temperature recorder-controller at the final heater outlet, re-generator differential pressure record, product flow rate, search tank sterile air overpressure, performance

of steaming seals, and pre-sterilization records.

Possible process deviations include temperature drop and hold tube, loss of differential pressure in regular generator, loss of sterile air pressure or other protection in the surge tank, loss of sterile air/gas to sterile zones, critical factors in the process schedule outside specification, or speed of variable speed pump too high. Aseptic processing must have written procedures for cleaning and re-sterilizing the system. If re-sterilization procedure differs from startup, verification of the procedure is from a processing authority. Factors to consider when reprocessing include previously processed product may exhibit different flow characteristics due to starch or binders. Verify whether affected lots are to be reprocessed separately, together, or blended with new product.

Packaging must also be sterilized utilizing the establishment sterilization systems. For example, cans and lids can be sterilized using superheated steam.

Aseptic systems target the same microorganisms as a typical commercial sterile low acid canned product. Aseptic systems consist of a means to heat the food, a timing pump, a hold tube, and a cooling system. Downstream from the hold tube must be brought to commercial sterility before filling. The thermal process of the food is performed in the hold tube by controlling flow rate, residence time, and temperatures. Aseptic zones of machines create and maintain a sterile zone for filling and sealing.

Sterilizing agents such as heat, chemicals, irradiation, or a combination of treatments are used to treat packaging materials or machine surfaces.

Module 15 - Records for Product Protection

Product protection for thermally processed foods involves:

- Thermal process records
- Critical factor control records
- Closure evaluation records

The main sections dealing with recordkeeping, reviewing, and maintenance requirements are in sections 431.7 and 431.8.

1. Records demonstrate compliance with regulations
2. Records provide assurance of proper and safe application of thermal processes
3. Careful review of records can give indication of problem

Automatic recordkeeping may be integrated with thermal processing control systems.

Establishments should notify FSIS prior to use.

Automatic recordkeeping systems must be validated in accordance with 9 CFR 417.4(a)(1).

Processing and container closure evaluation records **must be retained for 3 years.** FSIS permits storage at an alternate site **during the last 2 years of the retention period.**

Establishment **must** provide:

1. Process schedule development records
2. Process schedules
3. Critical factor records
4. Time/temperature recording charts
5. Processing (retort or aseptic system) records
6. Container closure specifications/guidelines
7. Container closure/integrity records
8. Retort operation documentation
9. MIG calibration/accuracy records
10. Yearly retort maintenance records
11. Information on recycled or reused container cooling water
12. A process deviation log
13. Coding for each container
14. Initial distribution records
15. Product incubation results
16. A recall procedure

FSIS requires:

- **product, day, and year**
- **establishment number on the label or container**

Computerized or automated recordkeeping systems can be used for thermal processing, critical factor monitoring, and container integrity testing, provided they meet the requirements in FSIS regulations.

Automated recordkeeping systems for retorts and aseptic systems are usually integrated with thermal processing control systems.

FSIS has encouraged the industry to work cooperatively in the development of automated recordkeeping systems.

Computerized record systems must be validated.

Module 16 - Closures for Metal Containers

Container Integrity - Primary Intent of Part 9 CFR 431.2

- To prevent product adulteration due to leakage during cooling and handling after retorting.

Kinds of metal cans:

Sanitary (Open Top) Can

- **3-piece soldered**
- **3-piece welded**
- **2-piece drawn**
- **Half-size seam table tray**

Double Seam:

- Formed by joining body of can with end
- Body flange interlocked with end curl
- Formed in two operations

The most critical measurements to a can's double seam are:

- Overlap: The degree of interlock between the body hook and cover hook
- Tightness: Degree of cover hook wrinkle after double seaming. Tightness rating indicates relative freedom from wrinkles.

Juncture Area - Location where double seam crosses welded side seam

Can Seam Defects:

First Operation Too Loose	Cutover & Fracture	Can Body Buckling
Loose First/Normal Second Operation	Double Seam Skip	Misassembly
First Operation Too Tight	Broken Chuck	Cut Seam
Tight First/Loose Second Operation	Excessively Tight Second Operation	Swollen Can
Excessive Countersink Depth	Insufficient Overlap	Corrosion
Short Cover Hook	Double Seam Skip	Damaged Coating
Long Cover Hook	False Seam	Open Seam at Side Seam
Mushroomed Flange	Damaged Flange & End Curl	Dents
Loose Second Operation Seam	Knock Down Flange	Jumped Seam or "Jump-over"
Loose Seam	Droop	Fractured Embossed Code
Vee, Lip, or Spur	Cocked Body	Paneling
Sharp Seam	Deadhead(Spinner)	Internal Can Corrosion (Pinhole Development)

Visual Inspection Requirements

- For double-seam cans, each can should be examined for gross defects such as cutover or sharpness, skidding (deadheading), false seam, droop at the crossover or lap, and condition of the inside of countersink wall for evidence of broken chuck.
- Must record the observations made and any corrective action taken.
- Additional visual closure inspections must be made immediately following a jam in a closing machine, after closing machine adjustment, or after start-up of a machine following a prolonged shutdown.
- All pertinent observations must be recorded.
- When irregularities are found, the corrective action must be recorded.

Immediate Corrective Action Required When:

- Sharp cutovers/fractures
- Heavy cut-over at crossover
- Severe droop at cross-over
- Vees or lips
- False seam
- Distorted seam
- Skidding or deadheading
- Fractured code

Should Perform Teardown Examinations:

- At the beginning of production
- Immediately after severe jam
- After adjustment or changes to seaming machine

Module 17 - Closures of Glass Containers:

Container Structure:

Glass container:

There are 3 basic parts to a glass container:

1. **Finish:** The finish is the very top part of the jar that contains threads or lugs that contact and hold the cap or closure. Specific areas identified in the "finish" are sealing surface, glass lug, continuous thread, transfer bead, vertical neck ring seam and the neck ring parting line.
2. **Body:** The body of the container is that portion which is made in the "body mold". It is the largest part of the container and lies between the finish and the bottom. The characteristic parts of the "body" are the shoulder, heel, side wall, and mold seam.
3. **Bottom:** The bottom of the container is made in the "bottom plate" part of the glass-container mold. The designated parts of the bottom area are normally the bottom plate parting line and the bearing surface.

Glass closures:

Among the terms commonly used for describing parts of metal vacuum closures are the following:

Panel: The flat center area in the top of the cap.

Radius/Shoulder: The rounded area at the outer edge of the panel connecting the panel and skirt.

Skirt: The flat side of the cap. The skirt may be smooth, knurled, or fluted and serves as the gripping surface.

Face: The outside of the cap.

Reverse: The inside of the cap.

Curl: The rounded portion at the bottom of the skirt that adds rigidity to the cap and serves to protect the cut edge of the metal.

Lug: A horizontal inward protrusion from the curl that seat under the thread or lug on the finish of the glass container and holds the cap in position.

Coatings: Coatings and inks used on the inner and outer surfaces of the cap to protect the metal from attack, adhere gasket materials, and decorate the closure.

Gasket: The actual sealing member of the cap which must make intimate contact with the glass finish at the proper point to form an effective seal. Gaskets are made of either rubber or plastisols.

Safety Button or Flip Panel: A raised, circular area in the center of the panel which is used only for vacuum packed products and serves two principal purposes which are detection of low or no vacuum packages and an indicator to the consumer of a properly sealed package.

Vacuum Formation:

Almost all low acid foods packaged in glass containers are sealed with vacuum-type closures. The vacuum within the package and the overpressure in the retort on the outside of the cap play an important role in forming and maintaining a good seal. There are two basic types of cappers which apply caps while forming a vacuum in the container:

1. **Mechanical Vacuum Capper**: applies the cap to the jar in an evacuated chamber (usually used on dry products and rarely on low-acid processed foods).
2. **Steam Flow Capper**: the container is subjected to a controlled steam flow that displaces the headspace gases from the jar by a flushing action. The steam is trapped in the headspace as the cap is applied, then condenses to form a vacuum which helps hold the closure in place.

The method of cold-water vacuum check requires a series of jars to be filled with cold tap water to the approximate headspace that will be maintained with the product to be run. A series means 4 to 6 containers for a straight-line capper, and 1 container for each capping head on a rotary capper. The capper is allowed to warm up to operating temperature and normal steam setting and these jars are then sealed in the capper. The jars are then opened and re-run through the capper and then checked for vacuum. By running the jars through the capper, the first time the water is de-aerated, and thus a truer vacuum reading is obtained after the second run. Vacuum is measured using a standard vacuum gage. The range of vacuum is recommended by the container manufacturer, but typically should be 22 inches or more.

Vacuum Closures:

There are four primary factors that affect vacuum formation (however, 1-3 are considered critical factors only if designated critical by the process authority):

1. **Headspace**: There must be sufficient void or headspace at the top of the container to allow adequate steam to be trapped in the container for forming a vacuum, and to accommodate product expansion during retorting. The correct amount of headspace varies with products, processes, and package design, but a rule-of-thumb in the industry is that it should be not less than 6% of the container volume. Inadequate headspace can result in displacement or deformation of the closure during retorting.
2. **Product fill/sealing temperature**: Product filling temperature affects the final vacuum in the container (due to product contraction upon cooling). The higher the product temperature at the time of sealing, the higher the final package vacuum. Higher filling temperatures also result in less air being entrapped in the product.
3. **Residual air in the product**: Air can have a direct effect on the final package vacuum and should be kept at a minimum for good sealing. The more air that is trapped in the product, the lower the vacuum. Expansion of residual air in the container during processing can exert pressure against the closure and adversely affect seal integrity. Air in the container can also impede heat penetration into the container during retorting.
4. **Capper vacuum efficiency**: Capper vacuum efficiency refers to the ability of a steam flow capper to produce a vacuum in sealed glass containers. The most convenient, routine check on the vacuum efficiency of a steam-flow capper is the "cold-water vacuum check." Currently, two primary types of vacuum closures are used on low-acid food products:

1. **Lug type closure:** This closure is the predominate vacuum-cap type. It is a convenient closure because it can be removed without a tool and forms a good reseal for storage. Structurally, the lug cap consists of a steel shell and can have four, six, or eight metal lugs depending on its diameter. Normally it contains a flowed-in plastisol gasket. During closure application the headspace is swept by steam and lug caps are secured to the glass finish by turning or twisting the cap onto the finish to seat the lugs of the cap under the threads on the glass finish.

With this lug type of closure, the top of the glass finish makes contact with the gasket on the inside of the lid. In most instances the lids are heated with steam to soften the compound and facilitate sealing. Both the lugs and vacuum hold the cap in place on the glass finish, but vacuum is the most important.

2. **Press on-Twist off (PT) closures:** This closure is in widespread use on baby foods as well as other products. Structurally, the PT cap consists of a steel shell with no lugs. The gasket is molded plastisol on the inside vertical wall and covers a sealing area extending from the outer edge of the top panel to the curl of the cap. These closures typically have a safety button or flip panel.

The cap is first heated to soften the plastisol. It is then pushed directly down on the glass finish after air is swept from the headspace with steam. The glass threads form impressions in the skirt of the cap gasket and allow the cap to be cammed-off and on. The PT closure is held in place on the finish primarily by vacuum, with some assistance from the thread impressions in the gasket wall when the cap is cooled.

3. **Plastisol-Lined Continuous Thread (PLCT) Cap:** The PLCT cap consists of a metal shell with a threaded skirt curled at the end. It contains a flowed-in plastisol gasket on the inside that makes intimate contact with the top of the finish when the cap is screwed onto the jar finish. The PLCT cap may be used in both steam and non-steam applications. Security measurements on this type of container closure can be performed. However, pull-up cannot be determined. An example would be the “mason jar.”

Closure Evaluation Requirements:

Generally, closure application inspections are performed either visually (non-destructive), or by cap removal (destructive). It is important to know the tests and observations on the different types of closures as well as the defects that can occur.

Visual Examinations (Non-Destructive):

As with metal cans, requirements for visual examination of closures for glass containers include regular observations for gross closure defects of at least one container from each capper head by a closure technician. According to 9 CFR 431.2(c)(1), a closure technician must visually assess the adequacy of the closures formed by each closing machine. Visual examinations must be done at sufficient frequency to ensure proper closure and must be performed at least every 30 minutes of continuous closing machine operation. The entire container must also be examined for defects. When there are defects, corrective actions must be taken. All these procedures must be documented.

Additional visual examination must be performed at the beginning of production, immediately following a container jam, and after every machine adjustment. This includes when there is a

change in container size, per 9 CFR 431.2(c)(1). At least one container from each closure machine must be examined during each regular examination period, either before or after thermal processing at intervals of at least every 4 hours of continuous machine operation.

Equipment can assist in non-destructive examinations, including mechanical headspacers (which control headspace limits in the container) cocked cap detectors and ejectors, and dud detectors (which detect low vacuums) are commonly found on glass container closing lines and can affect sealing of the container. For example, if a headspacer is incorporated in the processing line, it is imperative that it is set properly. A headspacer can contribute to product overhanging the finish by dripping liquid and product on the glass finish, which may affect good sealing. Cocked-cap detectors/ejectors and dud detectors, if used, maintained, and set properly, can serve as useful tools in the evaluation of defective seals and sealing problems.

Physical Examination (Destructive):

The canning regulations require that physical or destructive testing be performed by a trained closure technician at intervals of sufficient frequency to ensure proper closure and in a manner provided as guidance by the manufacturer. Sufficient frequency is defined as either before or after thermal processing at intervals not to exceed 4 hours of continuous closing machine operation. Specification guidelines for closure integrity must be on file and available for review, per 9 CFR 431.2(c)(2). Additional visual examination should be performed at the beginning of production, immediately following a container jam, and after every machine adjustment.

Security: Security values (lug tension of an applied closure) are the most reliable measurement of proper lug cap application. Security value ranges are supplied by the closure manufacturer to the processor. Generally, if measured values are always higher than the range specified, it indicates a secure package with some degree of over-application. If measured values are always lower than the range specified, that usually indicates under-application. Some factors that may affect the measured values are type of plate, compound, and glass surface treatment applied by the container manufacturer.

Security measurement is a destructive test. There is no requirement as to the number of containers that should be tested; however, being a destructive test, there are practical limits to the number of containers that one would test. A security test is performed as follows:

- Mark a vertical line on the cap and a corresponding line on the container.
- Turn cap counter-clockwise until the vacuum is broken.
- Reapply the cap until the closure is finger-tight.
- Measure the distance between the marked vertical lines in 1/16-inch increments.

Security is considered positive if the line on the cap is to the right of the line on the container and negative if the line on the cap is to the left of the line on the container. A high positive security can indicate under-application; a negative security value can indicate over-application. The cause of negative security should be determined and corrective action taken immediately.

Security can be measured at the capper and after processing and cooling. The range of measurement, however, should be lower after processing due to compound sink that occurs with heat and high pressure.

Module 18 - Flexible/Semi-Rigid Containers

- Not significantly affected by enclosed product at atmospheric temperature/pressure but can be deformed by external pressure less than 10 psi

Semi-Rigid Plastic

- Co-extruded, multi-layer body
- Multi-layer laminated lid fusion sealed to body flange
- Metal lid double seamed to a co-extruded, multi-layer body
- Retortable or aseptic filled

Package Terminology

Retortable/microwaveable bowl: Semi-rigid container made of plastic and adhesive blends

Height: Distance from base of bowl to body flange

Width: Diameter of opening

EZO end: Scored metal end with pull-tab

Stacking ring: Curved area below body flange

Double seam: Interlocking and compression of end curl and body flange

Critical Defects – Plastic Containers with Double Seamed Metal Ends

Cuts
Damaged flanges
Short height
Swollen package

Major and Minor Defects – Plastic Containers with Double Seamed Metal Ends

Major

Abrasion
Foreign matter inclusion
Load damage
Malformed

Minor

Abrasion
Delamination
Foreign matter inclusion
Gels
Malformed

Frequency of Testing: Inspections must be conducted at frequencies sufficient to ensure proper closure. Recommend every 30 minutes for visual inspections.
Recommend every 4 hours for tear down examinations.

Paperboard Cartons/Flexible Container/Retortable Plastic Tray/Aseptic Cups, Bowls, and Bottles

- Container body comprised of oxygen barrier sandwiched between polypropylene layers
- Flexible container lids comprised of oxygen layer sandwiched between polypropylene and/or other layers of polymer materials

Container Forming Methods

- Thermoforming - Pressing plastic roll stock into die molds
- Blow molding - Molten plastic air blown into mold to shape of container

Critical Defects - Semi-Rigid Containers with Heat-Sealed Lid

Channel leaker
Cut
Fracture
Incomplete seal
Swollen package
Puncture

Major Defects – Semi-Rigid Containers with Heat-Sealed Lids

Contaminated seal
Abrasion
Crushed
Seal width variation
Uneven seal impression

Minor Defects - Semi-Rigid Containers with Heat-Sealed Lids

Foreign matter inclusion	Gels
Label foldover	Malformed
Wrinkle	Abrasion
Burnt seal	Crushed
Delamination	Flex cracks

Critical Defects – Flexible Containers with Heat-Sealed Lids

Channel leaker	Cut
Fracture	Incomplete seal
Swollen package	Puncture

Destructive Tests

Burst test	Peel test
Dye test	Electro-conductivity test
Residual gas	

Non-destructive Examination

Visual test

Pressure differential test

Squeeze test

Vacuum (bubble) test

Frequency of Testing

▪ **Visual Examinations:**

- Seals must be examined from each sealing machine
- Necessary corrective actions must be taken and recorded
- The entire container must be examined
- Must be performed before and after the thermal process operations
- Must be done at sufficient frequency
- Should be based on a statistical sampling plan

▪ **Physical Tests:**

- Must be conducted with sufficient frequency
- Must be performed after the thermal process and should be made at least every 2 hours of continuous production
- Guidelines for test procedures must be on file and made available to the CSI
- Results and corrective actions must be recorded

Module 19 - Container Handling

Container integrity is easily taken for granted. Container integrity is the ability of a packaged, sealed food container to withstand processing and distribution and to prevent entry of microorganisms.

Before processing, containers, lids, and flexible roll stock must be handled in a manner that prevents defects and damage that could affect the hermetic condition of the sealed container. After processing, it is important to prevent entry into a food container of both spoilage organisms and organisms of public health significance, such as *Clostridium botulinum*.

The integrity of a food container is influenced by its design, quality of seal formation, and care in handling.

Containers must remain hermetically sealed under commercial operating conditions. According to 9 CFR 431.2(a), empty containers, closures, and flexible pouch roll stock must be evaluated by the establishment to ensure that they are free of structural defects and damage that may affect product container integrity. This requirement applies to all commercial containers. The hermetic seal must prevent entry of microorganisms during and after thermal processing. Gentle handling is especially important with plastic pouches, paperboard boxes, and semi-rigid bowls and trays, because these containers are not as strong as the rigid containers.

There are three requirements to keep canned product commercially sterile: 1) the hermetically sealed container which prevents microorganism re-entry, 2) the heat process to ensure product commercial sterility, and 3) post-process handling that protects container integrity.

Rough handling can cause metal cans with good double seams to lose their double seam integrity and possibly leak post-process. Glass jar closures can fail even if made well. Untrained employees may be inclined to use whatever containers are available for use, including damaged boxes of pouches, lids, etc. IPP should be examining product in empty container storage areas. Pre-production container handling includes examining empty containers, determining methods for cleaning, minimizing rough handling, and looking for handling procedures that may damage containers prior to filling.

Rigid containers must be cleaned before filling to prevent incorporation of foreign matter into the finished product. Closures, semi-rigid containers, preformed flexible pouches, and flexible pouch roll stock contained in original wrappings do not need to be cleaned before use. All empty containers, closures, and flexible pouch roll stock must be stored, handled, and conveyed in such a manner that will prevent soiling and damage that could affect the hermetic condition of the finished product container.

There are steps in the processing of canned product that may be of particular concern as it relates to container integrity. The way establishments blanch product and fill containers is an important consideration. "Blanching" is when raw vegetables are cooked in hot water or exposed to steam, usually prior to thermal processing. Blanching may affect container integrity, the thermal process, and product quality. Blanching shrinks product to assist in the proper filling of container but can expel cellular gases that can cause strain on the container during thermal processing. In other words, blanching food drives the air out of it. The presence of air reduces the vacuum in the container, which can lead to container damage. Residual air in pouches can create small cold spots that affect heat penetration. Residual air in metal cans expand during heating and may create internal pressure leading to buckling. Containers can be filled by hand or

mechanically filled, depending upon the container and product. The filling of the container must be controlled to ensure that any filling requirements are met. Even if headspace is not a critical factor in the process schedule (agitating process), headspace is important for the formation of a vacuum. Establishments must prevent overfilling.

The steps closer to the retort are the more critical. The seams are mostly formed by the time they arrive at the warehouse. The establishment needs to handle the containers carefully through labelling, palletizing, casing, and warehousing.

The container vacuum may draw bacteria in through a less-than-secure seal, causing leaker spoilage due to bacterial contamination after processing.

Module 20 - Processing Deviations

9 CFR 431.1 - Process Schedule

A process schedule (PS) is the thermal process and any specified critical factor for given canned product required to achieve shelf stability. The PS is established by a processing authority (PA) and addresses critical factors (CF), or characteristics, conditions, or aspects of thermal processing procedures, containers, and products that could affect the PS. The process schedule includes a minimum initial temperature (I.T.), minimum process time (Bb), minimum process retort temperature (RT), and, when established as critical factors, minimum container headspace and maximum product consistency.

§431.9(a) - Processing Deviations

A processing deviation (PD) occurs when the actual applied process is less than the minimum requirements of the process schedule or when any critical factor does not comply with the requirements for that factor. A PD may be detected on the production floor (in-process) or through records review (after process) and is not the same as a HACCP deviation, which is a failure to meet an established critical limit at a CCP.

To prevent the distribution of under-processed product, the establishment may utilize an operating process that equals or exceeds the minimum requirements set in the PS. The operating process must be conspicuously posted near thermal processing equipment or available to the thermal processing system operator and the inspector.

§431.9(b) - Handling Processing Deviations

Processors must handle processing deviations according to:

1. A HACCP plan that addresses food safety hazards associated with microbial contamination for canned product, or
2. An alternative documented procedure that ensures only safe and stable product is shipped in commerce, or
3. Meet §431.9(c) requirements.

§431.9(c)(1) - Options for Handling In-process Processing Deviations

The processor has 3 options for handling PDs when there is no HACCP plan that addresses food safety hazards associated with microbial contamination, no approved total quality control system, or no alternative documented procedures:

- (i) Immediately reprocess product using a full process schedule, or
- (ii) Use an appropriate alternative process schedule approved by a PA, or
- (iii) Hold product until the PD is evaluated by a PA to assess product safety and stability. Upon completion of the evaluation, the processor must provide the inspector the complete deviation description and all necessary supporting documentation, a copy of the evaluation report, and a description of any taken or proposed product disposition actions.

§431.9(c)(1)(iv) - Product handled under §431.9(c)(1)(iii) must not be shipped from the establishment until FSIS Policy Development Staff (PDS) has reviewed all information submitted and approved product disposition actions.

§431.9(c)(1)(v) – If an alternate process schedule used is not on file with the inspector or if an alternate process schedule is immediately calculated and used, the establishment must set product aside for further evaluation by both the PA and PDS in accordance with §431.9(c)(1)(iii) and (iv).

§431.9(c)(1)(vi) – Processing deviations in a continuous rotary (agitating) retort caused by emergency reel stops and temperature drops must be either be evaluated by a PA and PDS, all containers must be given an emergency process developed by a PA before the retort is restarted or cooled, or all containers must be removed or prevented entry into retort and either reprocessed, repacked and reprocessed, or destroyed.

§431.9(c)(2) - Handling Processing Deviations Identified in Record Reviews

Whenever plant management or the inspector identify a PD during reviews of processing and production records, the deviation must be reviewed and evaluated by a PA and PDS before the product is shipped from the establishment. All PDs found during records review must be maintained.

§431.9(d) - Documented Handling of Process Deviations

Processors must maintain complete records regarding the handling of each PD, including appropriate processing and production records, a full description of any corrective actions taken, the procedures and results of PD evaluations, and the disposition of affected product. Full records containing the appropriate information must be maintained in a separate file or in a log and made available to FSIS employees upon request.

Processing Deviation Options

Processing deviations can occur from mechanical failures or from product formulation errors or changes. If the PD cannot be corrected in progress, the plant has 3 options:

1. **Rework:** The plant can open the containers and rework the product back into another batch of product to be commercially sterilized or rework the product into another process such as frozen foods if proper precautions (e.g., cooling) were taken. Rework can change product properties and affect heat penetration.
2. **PA Evaluation:** The establishment may hold product and submit the PD information (e.g., processing records) to the designated PA for evaluation and review.
3. **Destroy the product:** The District Office has the responsibility to determine how FSIS will observe or accept necessary documentation demonstrating product destruction.

Process Deviation Verification

The inspector will verify that the plant implements its HACCP plan or alternative procedures for handling PDs as written, including reviews of the plant's corrective actions, the cause of the PD, and product disposition.

Module 21 - Canning HAV and HACCP Plan Verification

All establishments must conduct a Hazard Analysis (HA).

Some establishments may decide microbial (biological) hazards in thermally processed products are RLTO and address them in a HACCP plan.

Other establishments may choose to use the regulatory exemption and omit microbial hazards from HACCP plan. In this case the decision in the HA is that microbial hazards are NRLTO because the product is produced in accordance with the canning regulations. The ongoing support for this decision is that the product is produced in compliance with the canning regulations. So, compliance with the canning regulations is a prerequisite for the decision in the HA.

When operating under the exemption, failure to meet any canning regulation is noncompliance with 9 CFR 417.5(a)(1), and all noncompliances with canning regulations are to be associated. When there are repetitive noncompliances or a failure to prevent microbial hazards, the establishment does not have support for the decision in the HA that microbial hazards are NRLTO.

Notice that this exemption only applies to microbial hazards. Any chemical or physical hazards deemed RLTO during the HA must be addressed in the HACCP plan.

IPP will conduct the HAV task per FSIS Directive 5000.6.

Because compliance with the regulations is a prerequisite for products under the exemption, IPP are to verify compliance with all canning regulations during the HAV task. To do this, they will review records and make observations. In the absence of existing documentation supporting compliance, IPP must gather additional information. For example, if a canning regulation has not been verified recently enough to determine compliance, IPP must verify that regulation.

Once the additional information has been gathered, IPP will assess the information and determine whether it provides overall support for the decision in the HA that microbial hazards are NRLTO.

Concerns about the adequacy of the food safety system should be discussed with the Supervisor. An EIAO may be assigned to conduct an FSA.

The HACCP Verification task is performed the same way for products produced under the exemption (i.e., not under a HACCP plan but through compliance with the canning regulations).

Expectation: Verify all canning regulations at least once during the year. If no changes, Recall Training would probably be done only once. Other regulations could be verified much more often, depending on the situation. Focus on regulations with the greatest potential public health impact.

If on patrol, IPP may not have time to verify more than one requirement before going to other plants. Have a tracking system for regulations verified—for example, use Inspector Notes in PHIS.

Specifications, procedures, and criteria for venting and I.T. must be met.

Process times and temperatures are typical CLs at the retort CCP. Time-temperature data is obtained from monitoring the CCP. Other canning regulations can be verified during processing, such as simultaneous readings of the MIG and the chart temperatures.

All canning regulations must be met in HACCP facilities. Many other regulations must be Verified, such as recall plan, training, container closure examinations, posting processes, annual audits, etc.

EIAOs have critical roles in canning establishments. They perform in-depth food safety assessments to determine the adequacy of the plant's food safety system, especially in response to illness outbreaks or spoilage incidents.

Module 22 - Investigation of Canned Food Spoilage Incidents

SPOILAGE: the process of decaying

The **primary reasoning** behind spoilage diagnosis is to distinguish between post-process contamination and insufficient thermal processing.

Spoilage diagnosis can **only be completed** with both inspectional and analytical evidence.

Complementary:

- Laboratory evidence may assist the CSI in determining the cause of spoilage.
- Investigative evidence can provide assistance to the laboratory in determining the type of tests to perform.

Analytical evidence includes identification of:

- Gross container defects
- Container seam/seal defects
- Product appearance
- Product chemical characteristics
 - pH, water activity
- Product microbiological test results
 - Identification of organism(s) and their growth characteristics

Normal and abnormal container appearances may help to diagnose the type of spoilage.

- An abnormal container is a container with any signs of swelling or product leakage or any evidence that the contents of the unopened container may be spoiled
- Defective containers are severe dents near seams, gross seam defects, severe rust, etc.
- Need to separate to determine % in lot

Reference Material for examinations:

- FSIS Canning Reference Manual
 - FDA, Bacteriological Analytical Manual Chapter – Examination of Container Integrity (Glossary and References)
 - Examination of Containers
 - Canned Foods
 - Glass
 - Flexible and Semi-rigid Containers
 - FSIS Microbiological Laboratory Guidebook

Sample Submission to the FSIS Laboratory

- CSIs are to follow the specific instructions provided by the Western Laboratory from the initial call.
- If the affected product is reprocessed or retained pending disposition by a PA, IPP still submit samples to the lab.
- If the establishment decides to destroy the product, no further action is required by the CSI, except verifying the establishment properly documents and disposes of the product.
- CSIs are to complete and submit the following original forms with the product samples:
 - FSIS Form 10,000-2, Laboratory Report.
 - FSIS Form 10,000-3, Canned Foods--Abnormal Containers; and
 - FSIS Form 7500-1, Canned Food Sample Reporting Form.
- CSIs send one copy of each form, and any additional information requested, to:
 - The DO
 - The PDS canning team
- CSIs retain one copy of each form in the government office file
 - Number of containers in the lot
 - Total number of containers examined
 - Product information, e.g., product name, container type, and code(s) lot breakdown
 - Processing information, e.g., type of retort, process schedule, deviation noted, etc.
 - Storage temperature
 - Location where abnormalities were found, e.g., incubator, warehouse, in distribution
- The type and number of each type of container abnormality found
- Correlate with samples (lab must confirm inspectors' observations). **Swollen cans can change over time.**
- Possible explanation for abnormal containers
- Location of each type of defect noted
- Use side seam as a marker, or mark 12 o'clock position on container
- Location in lot where sampled container was taken

Affected Lot Disposition -

- Under-processing:
 - Reprocess or destroy
- Process less than commercially sterile - above minimum health
 - Incubate and sort, determine pH
- Post-processing contamination; non-health hazard
 - Sort out swells/defects
 - Dud detection (sort out cans with little or no vacuum)

Module 23 - Process Verification and Assessment

As part of evaluating the adequacy of the establishment's food safety system, the EIAO/CSIs will be reviewing/observing parts of the system.

EIAOs follow instructions/FSA methodology in FSIS Directive 5100.1.

This directive prescribes the general technique for how to perform an FSA in a canning establishment and what CSIs should do upon being assigned to a canning establishment. After the EIAO meets with management, he/she should request the most recent 60 days of production records prior to conducting the walkthrough.

The EIAO/CSI should review the HACCP system to prepare for the tour.

The EIAO should amend observations or do addendums to observations before he/she leaves (the establishment may have made corrections before the FSA is complete).

The best way to familiarize yourself with thermal processing is to follow the process from start to finish. Ask establishment management questions during the walkthrough.

During the initial or entrance meeting, the EIAO or CSI should ask management how the establishment handles process deviations and abnormal container incidents and the location of the processing deviation file.

IPP should have:

- Stopwatch for continuous retort reel timing and hydrostat chain timing
- Accurate thermometer

for CF measurements-(Establishment will have)

- Caliper for measuring outside pipe diameter
- Dividers to confirm process timing on recording charts
- A method to test sanitizers

Reminders: CSIs and EIAO cannot physically do can seam teardowns or go into confined spaces.

In addition to the specific instructions in FSIS Directive 5100.1, it is a good idea to:

Pick a product line and review/evaluate a couple of retorts if it appears they are all plumbed the same. Do not try to evaluate each retort system if more than one is being used for meat and poultry products. Pick one retort system for the FSA. For instance, if the establishment has hydrostat, continuous rotary, and still retorts, choose only one system. If time permits, choose an additional type of retorting system.

Four basic areas of concern:

Note: The CSI verifies these during each HACCP Verification task.

Establishment of the process
Delivery of the process
Documentation of the process
Container integrity

Module 24 - Electronic Records and Signatures

Electronic records and signatures are considered the **legal equivalents of paper records** and handwritten signatures executed on paper.

A **predicate rule** is any regulation or law that includes a requirement to keep a record. Look to the predicate rule for:

- what records to keep
- how long to maintain records
- what signatures are required

An **electronic record** is any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system.

An **electronic signature** is a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.

System Requirements:

- **Validation**
- **Qualification:**
 - **Installation qualification**
 - **Operational qualification**
 - **Performance qualification—test**

Electronic signature mechanisms may be based on:

- ***Biometrics, such as scan of retina, face, or fingerprint, or voice recognition***
- ***two distinct components, such as identification code or card and password***

Closed system means an environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system.

Open system means an environment in which system access is not controlled by persons who are responsible for the content of electronic records that are on the system.

Standard Operating Procedure (SOP) For Supervisors –
Virtual Thermal Processing (VTP) Course - On-the-Job Training (OJT) Checklist

Target Audience: Supervisors of Inspection Program Personnel (IPP) who recently completed the Virtual Thermal Processing course and are assigned to a Thermal Processing establishment.

Objective of this SOP: Ensure that supervisors provide necessary guidance and time to IPP who recently participated in the VTP course to complete the OJT checklist.

Instructions: Supervisors should review the OJT checklist and coach/mentor the IPP while they are working on checklist items. The Center for Learning (CFL) recommends completing the checklist within the first week after finishing the VTP course training. However, following completion of the VTP course, IPP have 3 weeks to complete the checklist.

Upon IPP completion of the OJT checklist, the supervisor or designee should sign and date the checklist. Participants should keep a copy of the list for their records and certify the completion by sending an email to: FSISAgLearn@usda.gov. The email should contain the participant's name, the Virtual Thermal Processing course number, and date of completion of the OJT and a statement attesting that they completed the OJT list. The participant should attach the signed list to the email.

NOTE: The VTP – OJT checklist only applies to IPP that recently completed the Virtual Thermal Processing Course and are assigned to a Thermal Processing (canning) establishment.

If you have any questions, please contact Dr. Hala Bessyoung at hala.bessyoung@usda.gov.

Virtual Thermal Processing (VTP) Inspection Course - On-the-Job Training (OJT) Checklist

The objective of this OJT Checklist is to verify that the VTP Course participants that recently completed the Virtual Thermal Processing Course and are assigned to a Thermal Processing(canning) establishment can successfully apply the knowledge they gained during training.

After completing the VTP Inspection course training, participants must complete OJT. Participants will have up to three weeks following completion of the VTP Inspection training course to complete the training. The participant must conduct each part of the tasks, as soon as practicable and if applicable. The tasks can be performed at any of the establishments in their assignment that produce thermally processed, commercially sterile (TPCS) products.

The participant should collaborate with their supervisor while working on the OJT list. Upon completion of the OJT, the participant and supervisor should sign the list attesting for the participant's successful completion of the OJT list. Participants should keep a copy of the list for their records and certify the completion by sending an email to: FSISAgLearn@usda.gov. The email should contain the participant's name, the VTP Inspection course number, and date of completion of OJT and a statement attesting that they completed the OJT list. The participant should attach the signed list to the email.

If you have any questions, please contact Dr. Hala Bessyoung at hala.bessyoung@usda.gov.

Student Name			
VTP Course Number			
Tasks *Applies to thermally processed product	Estimated Time	Date	Participant Initials
• HAV Task - Please review documentation from an open or completed task	180 minutes		
• HACCP Verification Task	60 minutes		
• Big 8 Formulation Verification task -	60 minutes		
• Sanitation SOPs <ul style="list-style-type: none">◦ Pre – Operational◦ Operational	60 minutes		
• SPS Task	60 minutes		
• Supervisor signature and date			

Resources:

[Verifying an Establishment's Food Safety System](#)

[Performing The Pre-Operational Sanitation Standard Operating Procedures Verification Task
Procedure Verification Task](#)

[Performance of the Hazard Analysis Verification Task](#)

[Ongoing Verification of Product Formulation and Labeling Targeting the Nine Most Common \("Big 9"\)
Food Allergens](#)

[Generic HACCP Model for Thermally Processed Product](#)

[Procedures for Domestic Condition of Canned Product Container Examination](#)

[Handling a Process Deviation or Abnormal Container of TP, CS Canned Product](#)

[Import Reinspection of Meat, Poultry, and Egg Products](#)

[Inspection & Mission Training](#)

Notes

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