HACCP For Shelf-Stable Processes

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Abbreviations Used in this Module

§ - Section
01 procedure - verification procedure performed by CSI in 03 HACCP ISP Activity
02 procedure - verification procedure performed by CSI in 03 HACCP ISP Activity
03D – Thermally Processed/Commercially Sterile
03E – Not Heat Treated/Shelf-stable
03F – Heat Treated/Shelf-stable
9 CFR – Title 9 Code of Federal Regulations
a_w – water activity
CCP – Critical Control Point
CL – Critical Limit
CSI – Consumer Safety Inspector
DO – District Office
E. coli – *Escherichia coli*
EIAO – Enforcement, Investigations and Analysis Officer (formerly known as CSO)
EPA – Environmental Protection Agency
FDA – Food and Drug Administration
FIFRA - Federal Insecticide, Fungicide, and Rodenticide Act
FLS – Frontline Supervisor (formerly know as Circuit Supervisor)
FSIS – Food Safety Inspection Service
GMP – Good Manufacturing Practice
HA - Hazard analysis
HACCP-Hazard Analysis and Critical Control Point system
ISP – Inspection System Procedure Guide
Lm – *Listeria monocytogenes*
NACMCF-The National Advisory Committee on Microbiological Criteria for Food
NOIE – Notice of Intended Enforcement action
NRTE – not ready-to-eat
NSS – not shelf-stable
pH – a measure of acidity, technically “power of Hydrogen” but always stated as “pH”
PHV – Public Health Veterinarian
RTE – ready-to-eat
SHI – Safe-handling Instructions
SOP – Standard Operating Procedure
SS – shelf-stable
SSOP – Sanitation Standard Operating Procedures
USDA – United States Department of Agriculture

Objectives for this Module

To demonstrate mastery of this module, the Consumer Safety Inspector will

1. Identify the regulatory processing categories.
2. Determine which of the regulatory processing categories are covered in the shelf-stable products.
3. Identify the significance of performing the hazard analysis.
4. Identify the components of a HACCP plan and HACCP system.
5. Describe monitoring and verification activities.
6. State the difference between a HACCP noncompliance and a deviation from a critical limit in the HACCP plan.
7. Describe the plant's responsibility concerning a HACCP noncompliance and a deviation from a critical limit in the HACCP plan.
8. State where FSIS HACCP verification responsibilities are outlined.
9. List the 4 responsibilities for the CSI under the FSIS HACCP methodology.
10. Describe noncompliance linkages and to what they may lead.
11. Describe the two components of a HACCP 01 and 02 procedure.
12. Describe a HACCP 01 and 02 procedure in relationship to the five regulatory requirements that will be verified.
13. Describe the difference between validation, verification, and pre-shipment review.
14. Identify the regulatory requirements for monitoring.
15. Identify the regulatory requirements for verification.
16. Identify the regulatory requirement for corrective action.
17. Identify the regulatory requirement for reassessment.
18. Identify the recordkeeping regulatory requirements.
19. Explain the regulatory requirements for pre-shipment record review.
20. Describe the canning establishment's responsibility to address microbiological hazards.
21. Using the FSIS canning regulations, identify the regulatory requirements in a canning establishment.
22. Describe a HACCP 01 and 02 procedure in relationship to the regulatory requirements that will be verified in a canning operation.

Definitions Used in This Module

Shelf-Stable

Shelf-stable products are those that do not spoil under ordinary unrefrigerated temperature and humidity conditions, if the package integrity is maintained. These products are free of microorganisms capable of growing in or on the product at non-refrigerated conditions (over 50°F) at which the product is intended to be held during distribution and storage. This could include dried, salt-cured, fermented, and acidified products, which would fall under either the heat-treated shelf-stable, or not heat treated shelf-stable processing categories. Example products may include meat or poultry jerky, Lebanon bologna, pepperoni, and hard salami.

Thermally Processed, Commercially Sterile - "Canned"

Thermally processed, commercially sterile meat and poultry products are packaged in hermetically sealed containers and remain shelf-stable under unrefrigerated conditions. "Canned product" is defined in §318/381.300(d) as a meat or poultry product with a water activity above 0.85 which receives a thermal process either before or after being packed in a hermetically sealed container. Example products may include canned spaghetti with meatballs, canned corned beef hash, and canned soups with meat or poultry.

Ready-to-Eat (RTE) Product

A meat or poultry product that is in a form that is edible without additional preparation to achieve food safety and may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes. Since safe-handling instructions (SHI) are only required on labels of Not Ready-to-Eat product (per §317.2(l) and 381.125(b)), labels for RTE product are not supposed to bear a safe-handling instruction or other labeling that directs that the product must be cooked or otherwise treated for safety. RTE product can include frozen meat and poultry products.

Heat Treated

Heat treated product has received some degree of heat treatment. The heat applied by the process produces a product primarily recognized as a cooked product.

- For the HACCP process 03E the process will deliver a product in which its primary, product-defining lethality is attained via a non-heat treatment such as drying, but of which some heat may also have been applied but is not the primary lethal treatment that defines the overall process. For example, in a dry salami process the fermentation and drying steps overwhelmingly define the process by which pathogens are controlled and the product is identified. Although some heat may or may not be applied in the process, it doesn't define the process or the product.
- For the HACCP process 03F the process will deliver a product in which its primary, product-defining lethality is attained via heat. For example, in a popped pork skin process the heat caused the significant lethal treatment and the product is recognized as being a cooked product.

Rules of Practice

The Rules of Practice, 9 CFR 500, are FSIS's enforcement regulations. The Constitution guarantees that the government cannot take away a person's basic rights to 'life, liberty or property, without due process of law.' "***Due process rights***" means that a fair "*process*" or proceeding, must take place before the government interferes with an individual's property or actions. Plants have a right to expect that FSIS will be fair and consistent, provide details about enforcement concerns, promptly respond to appeals, and provide the opportunity for correction.

Sec. 500.1 Definitions.

- Regulatory control action
- Withholding actions
- Suspension

Sec. 500.2 Regulatory control action.

Regulatory control actions are taken when there is danger of adulterated, contaminated, misbranded, or hazardous product leaving the plant. These are situations that require immediate correction. Examples of such circumstances include insanitary conditions, product adulteration, or conditions in the plant that prevent an inspector from deciding that product is not adulterated. Once the regulatory control action is taken, the Rules of Practice regulations require that the inspection personnel taking the action immediately notify plant management. This can be done orally or in writing. The written notification will be a noncompliance record (NR). The NR documents the noncompliance, and the description should include any FSIS reject/retain tag numbers issued.

Sec. 500.3 Withholding action or suspension without prior notification.

The Rules of Practice regulation also identifies situations where FSIS may take withholding or suspension actions without giving the plant prior notification. Withholding the marks of inspection and suspending inspection services are significant enforcement actions and are taken only after careful evaluation of the facts and circumstances. In most cases, in-plant personnel take these enforcement actions because the situation involves an imminent threat to public health. FSIS can immediately take a withholding action or suspension without giving the plant prior notification in order to protect the public health, but inspection program personnel must be able to document the imminent threat to public health. The establishment must be notified orally and then, as promptly as the circumstances permit, in writing. The decision to take a withholding action can be made by the IIC or designee, the frontline supervisor, or the DO, whereas the decision to suspend is made only at the DO level or higher.

Sec. 500.4 Withholding action or suspension with prior notification.

If a withholding or suspension action is based on any reason other than those listed in §500.3, FSIS must provide the plant written notice (NOIE) before taking the action. This gives the establishment an opportunity to provide a response to the notification. Often these enforcement actions are based on repetitive noncompliance, such as systemic problems with the SSOP or HACCP systems.

Sec. 500.5 Notification, appeals, and actions held in abeyance.

A Notice of Intended Enforcement action (NOIE) is issued for noncompliances that do not pose an imminent threat to public health, but, that may warrant a withholding or suspension if not corrected. The NOIE will be issued to the plant by the District Manager (DM). The NOIE must contain specific information including the action FSIS intends to take and the effective date of the action, the reason for the proposed action, and the operations, products, or processes affected. The NOIE provides the establishment an opportunity to present immediate corrective action and further planned preventive action. The NOIE also notifies the establishment that it has three business days to contest the basis for the proposed enforcement action or to demonstrate how compliance has been or will be achieved.

Sec. 500.6 Withdrawal of inspection.

Withdrawal of the grant of inspection terminates the grant of inspection. Once that happens, no portion of the plant can operate as an FSIS federally inspected establishment.

Sec. 500.7 Refusal to grant inspection.

FSIS has the authority to refuse to approve a grant of inspection. When FSIS decides not to approve a grant of inspection, the establishment cannot operate as a Federal meat, poultry, or egg products processing facility.

Sanitation

Inspected establishments must meet two sets of regulations concerning sanitation: the Sanitation Performance Standards (SPS) and the Sanitation Standard Operating Procedures (SSOP) requirements.

The Sanitation Performance Standards regulations set the results to be achieved, but they don't prescribe the step-by-step procedures to produce safe meat and poultry products. Establishments aren't required to develop, generate, or maintain daily records that document compliance with SPS.

To verify that establishments are operating in accordance with the SPS regulations, you perform Inspection System Procedure (ISP) 06D01 when it is scheduled by the Performance Based Inspection System (PBIS) or as an unscheduled procedure when you suspect noncompliance with any of the sanitation performance standards. Most of the time, you will verify compliance with the SPS regulations by directly observing the conditions in the establishment.

You must assess the situation in the establishment and then make the determination whether or not the situation creates insanitary conditions, causes adulteration of product, or prevents FSIS from performing inspection. When you determine that the plant has failed to meet the SPS, you also evaluate what is known for a fact and determine if the plant has also failed to meet the SSOP and/or HACCP requirements.

Sanitation Standard Operating Procedures (SSOPs) are written procedures that an establishment develops and implements to prevent direct contamination or adulteration of product. The establishment must also maintain daily records sufficient to document the implementation and monitoring of the SSOPs and any corrective action taken. The establishment is required to maintain these written procedures on file, and they must be available to FSIS upon request. It is the establishment's responsibility to implement the procedures as they are written in the SSOPs. If the establishment or FSIS determines that the SSOPs fail to prevent direct contamination or adulteration of product, the establishment must implement corrective actions that include the appropriate disposition of product, restoration of sanitary conditions, and measures to prevent recurrence. It is also required that SSOPs should describe the procedures that the establishment will take to prevent direct contamination or adulteration of product.

There are SSOP procedures for pre-operational sanitation verification (01B) and SSOP procedures for operational sanitation verification (01C). You perform these procedures to verify that the establishment is meeting the SSOP regulatory requirements. Regardless of whether you are performing the recordkeeping procedures (01B01 & 01C01) or the review and observation procedures (01B02 & 01C02), you are verifying that the same regulatory requirements are met. Those requirements are

- Implementation of SSOP (monitoring) (§416.13);
- Maintenance of SSOP (effectiveness) (§416.14);
- SSOP corrective actions (§416.15); and
- SSOP recordkeeping (§416.16).

Ready-to-Eat Product Sanitation

Some shelf stable products are ready to eat. ***Ready-to-eat* (RTE)** products have received a ***lethality*** treatment. The lethality treatment, generally a cooking procedure, must be designed to kill all of the pathogens, or harmful bacteria. This lethality treatment makes the product safe to eat by the consumer without any further treatment, and we normally refer to these products as "ready-to-eat."

Many RTE processes involve handling the product after it has received its lethality treatment (***post-lethality***). When the product is ***directly exposed*** to the environment it can become cross-contaminated. ***Cross-contamination*** is the transfer of bacteria and possibly pathogens to the exposed RTE product after the lethality treatment. These bacteria can come from the environment, from the employees, or from the equipment. They can be transferred directly, such as when an exposed RTE product is placed on a table top which has bacteria on it. Often they are transferred indirectly, such as when a pallet placed on the floor in the raw area is subsequently used in the RTE area, or when an employee handles a pallet and then touches exposed product.

Many RTE products are taken right from the package and consumed as they are, with little or no heat treatment. If any pathogens are present, they will be consumed along with the product. Thus the risk of these products producing foodborne illness is increased. Because of this, establishments producing these products have an increased responsibility for sanitation of the RTE production area.

There are important considerations in the layout of the plant and the location of post-lethality processing. Cross-contamination can be avoided by separating raw meat and poultry from RTE products. Cross-contamination may also occur when raw unprepared vegetables contact ready-to-eat foods.

Air flow is another important concern. Air will flow from areas of high pressure to lower pressure. Air flow can be influenced by the location and operation of refrigeration units and other types of ventilation equipment. Air flow from a raw area into a cooked area could possibly carry *Lm* and contaminate the RTE product or product-contact surfaces.

An effective plant design will include sufficient **ventilation** to prevent the formation of condensation and control humidity.

Many different types of **plant layout** exist. It is the establishment's responsibility to control the processing procedures in whatever environment exists in its particular plant in order to ensure that only safe product is produced.

Examples of plant design considerations:

- Traffic between raw and RTE areas
- Physical proximity between RTE and raw products
- Air supply and flow between raw and RTE areas
- Humidity
- Overhead fixtures that harbor dirt or moisture
- Condensation
- Plumbing from drip pans

***Listeria monocytogenes* and Construction**

Another consideration to be aware of related to RTE product is contamination of product from *Listeria monocytogenes (Lm)* that can be traced to construction in the establishment. *Lm* contamination has been linked with disruptions in the production process or environment. In particular, disruptive construction (e.g., breaking out walls or other activities that can generate dust) has been shown to have a clear association with *Lm* contamination of both product and the surrounding environment. *Lm* can survive in moist, enclosed areas of the environments, such as cracks in walls and floors, and in crevices around drains; often these areas are disturbed during construction.

Dust generated by construction and other disruptive activities can establish contamination on food contact and other environmental surfaces. For example, dust can travel throughout the plant on air currents or be transferred by people or equipment traveling through the construction area into other areas of the establishment. Dust from construction can be difficult to detect and control. Therefore, increased monitoring of product, food-contact surfaces, and the environment is recommended **during and after** these disruptive events.

Some examples of disruptive construction activities include:

- Removal of drains
- Removal of floor coatings
- Removal of a wall or ceiling that has absorbed moisture
- Movement through an RTE area of potentially contaminated materials
- Exposure of an area typically not accessible for cleaning

Establishments have the responsibility to control establishment activities during construction in order to ensure that only safe food is produced. When construction is necessary, there are several solutions that establishments may employ. Establishments may establish negative air pressure in the construction area in order to ensure that air does not flow from the construction area into the plant. Temporary partitions can be established to protect the undisturbed areas of the plant from construction dust and debris. Intense cleaning is also a control method used by establishments following the disruptive construction.

Processing Categories

9 CFR 417.2(b) requires establishments to develop and implement a written HACCP plan covering each product produced by that establishment whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur. The regulation lists processing categories that group products by major processing parameters.

We will be discussing the three processing categories that deal with shelf-stable products. They correspond to the procedures in the Inspection System Procedures Guide (ISP).

- **Thermally Processed, Commercially Sterile (canned), 03D**
- **Not Heat Treated Shelf-Stable, 03E**
- **Heat Treated Shelf-Stable, 03F**

A single HACCP plan may be written for **multiple products** within a single processing category, as long as the hazards, critical control points, critical limits, and other HACCP regulatory requirements are essentially the same. Some products can fall into more than one processing category. The important focus is not what processing category, but whether all of the regulatory requirements have been met.

Examples of Products In Each Process Category		
Thermally Processed, Commercially Sterile (canned) 03D	**Not Heat Treated Shelf-Stable 03E**	**Heat Treated Shelf-Stable 03F**
Canned Corned Beef Hash	Pepperoni	Summer Sausage
Spaghetti with Meat Sauce		Beef Jerky
Beef Vegetable Soup		Beef stew, freeze dried

You are required to enter the appropriate processing categories into PBIS in order to get an accurate Procedure Schedule. Since you determine the process category, it is important that you understand the categories and the plants' procedures.

Determining Process Category Workshop

It is important to be aware that there is a wide variety of shelf-stable products produced. Determining the process category and procedure code for many products is obvious. For other products, you will have to look at the product name, labeling, the processing steps, hazard analysis, and HACCP plan.

For each of these products, using the information given, list the procedure code for the process category where you think each product belongs.

1. Beef chili, canned, retorted
2. Potted meat food product, canned, retorted
3. Beef broth, aseptically processed, packed in fiberboard container
4. Dried beef, cured and sliced, packed in glass jar
5. Summer sausage, fermented, fully cooked and dried in smokehouse
6. Pepperoni, fermented and dried
7. Pepperoni, fermented, heat is applied as primary lethality treatment and then dried
8. Beef jerky, heated and dried in smokehouse
9. Salted beef, cured with salt brine and dried to MPR 2:1
10. Lard
11. Popped pork skins
12. Bacon bits in glass jar
13. Country cured ham
14. Ham, in metal can, labeled “keep refrigerated”

15. You rotate into a new assignment. One small establishment processes a product called Chinese style sausage. The meat ingredients are ground and mixed with vinegar and soy sauce. The mixture is stuffed into small diameter natural casings. The sausages are hung on trees and put into a drying room. After drying, the sausages are individually vacuum packaged, labeled and shipped without refrigeration. The label does not have a handling statement or safe handling instructions. The plant manager says the MPR of the final product is 1.9:1.

Based on what you have observed, is it likely that this product is shelf-stable?

Based on what you have observed, is it likely that this product is ready-to-eat?

What information would you need to gather in order to answer these questions?

What processing category might this product be in?

Listeria Monocytogenes Verification

FSIS Directive 10,240.4, Rev.2, Verification Procedures for Consumer Safety Inspectors for the *Listeria monocytogenes (Lm)* Regulation and *Lm* Sampling Programs, provides the CSI with:

- Instructions for verifying whether establishments are complying with the regulations in 9 CFR 430, Requirements for Specific Classes of Product,
- Collection responsibilities under the ALLRTE and RTE001 sampling projects, and
- Instructions for Ready-to-Eat (RTE) products when establishment product disposition occurs off-site.

Introduction

On June 6, 2003, FSIS published an interim final rule that requires establishments that produce certain RTE products prevent product adulteration by the pathogenic environmental contaminant *Listeria monocytogenes*. The regulation, 9 CFR 430.4(a), states that *L. monocytogenes* is a hazard that an establishment producing post-lethality exposed RTE products (including RTE shelf-stable products) must control or prevent. It also states that RTE product is adulterated if it contains *L. monocytogenes* or if it comes into direct contact with a food contact surface that is contaminated with *L. monocytogenes*. 9 CFR 430.4(b) sets out three alternatives that establishments producing post-lethality exposed RTE product are to choose from in order to meet the requirements of 9 CFR 430.4(a). You are responsible for verifying that establishments are in compliance with the 9 CFR 430.4(b).

Definitions

Antimicrobial agent. A substance in or added to an RTE product that has the effect of reducing or eliminating a microorganism, including a pathogen such as *L. monocytogenes*, or that has the effect of suppressing or limiting growth of *L. monocytogenes* in the product throughout the shelf life of the product. Examples of antimicrobial agents added to RTE products are potassium lactate and sodium diacetate.

Antimicrobial process. An operation, such as freezing, applied to an RTE product that has the effect of suppressing or limiting the growth of a microorganism, such as *L. monocytogenes*, in the product throughout the shelf life of the product.

Deli product. A ready-to-eat meat or poultry product that is typically sliced, either in an official establishment or after distribution from an official establishment, and assembled in a sandwich for consumption.

Hot dog product. A ready-to-eat meat or poultry frank, frankfurter, wiener, or other product such as defined in 9 CFR 319.180 and 319.181.

Indicator organisms. These are bacteria used to determine objectionable microbial conditions of food, such as the presence of potential pathogens, as well as the sanitary

conditions of food processing, production or storage areas. *Listeria spp*. are such indicators for *Listeria monocytogenes*.

Lethality treatment. A process, including the application of an antimicrobial agent, that eliminates or reduces the number of pathogenic microorganisms on or in a product to make the product safe for human consumption. Examples of lethality treatments are cooking or the application of an antimicrobial agent or process that eliminates or reduces pathogenic microorganisms.

Post-lethality exposed product. Ready-to-eat product that comes into direct contact with a food contact surface after the lethality treatment in a post-lethality processing environment.

Post-lethality processing environment. The area of an establishment into which product is routed after having been subjected to an initial lethality treatment. The product may be exposed to the environment in this area as a result of slicing, peeling, re-bagging, cooling semi-permeable encased product with a brine solution, or other procedures.

Post-lethality treatment. A lethality treatment that is applied or is effective after post-lethality exposure. It is applied to the final product or sealed package of product in order to reduce or eliminate the level of pathogens resulting from contamination from post-lethality exposure.

Prerequisite program. A procedure or set of procedures that is designed to provide basic environmental or operating conditions necessary for the production of safe, wholesome food. It is called “prerequisite" because it is considered by scientific experts to be prerequisite to a HACCP plan.

Ready-to-eat (RTE) product. A meat or poultry product that is in a form that is edible without additional preparation to achieve food safety and may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes. RTE product is not required to bear a safe-handling instruction (as required for non-RTE products by 9 CFR 317.2(l) and 381.125(b)) or other labeling that directs that the product must be cooked or otherwise treated for safety, and can include frozen meat and poultry products.

CSI Responsibilities for Verifying Compliance with 9 CFR Part 430.4

You must be familiar with the establishment products and processes that must comply with Part 430.4 in order to verify compliance. If necessary, you can ask establishment management whether they produce any RTE product that is exposed to the environment after the initial lethality step. The establishment is required to comply with Part 430.4 if the RTE products produced are exposed to the environment after the lethality step. The establishment is **not** required to comply with Part 430.4 if the RTE products produced are **not exposed** to the environment after the lethality step.

Examples

- Beef jerky exposed to the environment before packaging
  -Required to comply with Part 430, must choose one of the 3 alternatives

- Country Cured Ham, sliced and film wrapped in retail packages
  -Required to comply with Part 430, must choose one of the 3 alternatives

- Summer Sausage, cooked in impervious casings which is not removed prior to packing
  -Not required to comply with Part 430

- Canned Chicken, hermetically sealed commercially sterile shelf-stable product
  -Not required to comply with Part 430

If the establishment is producing post-lethality exposed products, you should ask the establishment management which alternative they have chosen for each of its post-lethality exposed RTE product. You should inform them that, as specified in §430.4(c)(7), "The establishment must make the verification results that demonstrate the effectiveness of the measures it employs …available upon request to FSIS inspection personnel."

You should verify that the establishment is meeting the requirements of the alternative that it has chosen. You will confirm that the establishment is using the selected alternative correctly through its HACCP plan (control) or through it's SSOP or other prerequisite program (prevention).

Use the appropriate 01(SSOP) or 03(HACCP) procedure, for example, 03F01/02 for heat treated, shelf-stable RTE products. If the establishment decides to produce different products using different alternatives, you should verify that they meet the requirements for **each** of the alternatives selected, for **each** of the post-lethality exposed RTE products.

Note: If an establishment is producing post-lethality exposed products and has failed to attempt to meet the requirements of **any** of the alternatives, you should contact the District Office through supervisory channels.

Alternative 1

9 CFR 430.4(b)(1) *Use of a post-lethality treatment (which may also be the antimicrobial agent) that reduces or eliminates microorganisms on the product AND an antimicrobial agent or process that suppresses or limits the growth of* L. monocytogenes.

Alternative 1 is the use of **BOTH** a post-lethality treatment (which may also be the antimicrobial agent or process) that is capable of reducing or eliminating microorganisms on the product **AND** an antimicrobial agent or process. In some cases, the antimicrobial agent added to the RTE SS product or the antimicrobial process applied to the RTE SS product has **BOTH** a lethality effect (i.e., actually reduces or eliminates *Lm*) **and** suppresses or limits the growth of *Lm* during the shelf-life of the product.

Use of a post-lethality treatment must be included in the establishment's HACCP plan because the use of a post-lethality treatment reflects a determination by the establishment that the pathogen is a hazard that is reasonably likely to occur and is controllable by a post-lethality treatment. Consequently, the plant must incorporate the post-lethality treatment in its HACCP plan as a CCP. As with any other CCP, the plant must validate the effectiveness of the post-lethality treatment in accordance with 417.4. In addition, the effectiveness of the anti-microbial agent or process, as used, must be documented in the HACCP plan, SSOP or other prerequisite program.

Alternative 1 inspection verification example: As part of the 03E01 procedure, you verify that the establishment is meeting the requirements of Part 430 and Alternative 1. You review the plant's hazard analysis for not heat treated dry salami and find that the fermentation, drying, and packaging steps have been identified as CCPs in the hazard analysis and have been incorporated into the HACCP plan. The hazard analysis identifies lowered acidity (pH) through the use of bacterial starter cultures and lowered water activity due to drying as measures to limit the growth of *L. monocytogenes (Lm)* in the finished product throughout the shelf-life of the product. A steam pasteurization process after the product has been vacuum packaged has been identified as the treatment to reduce or eliminate post-lethality contamination by *Lm.* There are critical limits at the respective steps in the plan for pH, water activity, and time and temperature exposure for the steam pasteurization process. You decide to request the supporting documentation for the decisions made in the hazard analysis. The plant provides scientific documents and the results of challenge studies conducted by a processing authority that show that the pH and water activity (achieved in the product) inhibits the growth of *Lm* during its shelf-life and that the surface steam pasteurization treatment is effective in reducing or eliminating the level of pathogens resulting from the contamination from post-lethality exposure. Based upon your review, you determine that the establishment is in compliance with §430.4(b)(1).

Noncompliance with Alternative 1
The following are examples of noncompliance with Alternative 1.

1. The establishment has a post-lethality treatment to reduce or eliminate *Lm* incorporated into the HACCP plan, but does not have the use of the antimicrobial agent or process to suppress or limit the growth of *Lm* incorporated into its HACCP plan, its Sanitation SOP, or a prerequisite program. (Cite 430.4(b)(1) and 417.5(a)1&2.)

2. The establishment is testing food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Lm* or of an indicator organism, but does not have a post-lethality treatment to reduce or eliminate *Lm* incorporated into the HACCP plan OR the use of the antimicrobial agent or process to suppress or limit the growth of *Lm* incorporated into its HACCP plan, its Sanitation SOP, or a prerequisite program. (Cite 430.4(b)(1) and 417.5(a)1&2.)

3. The establishment has included a post-lethality treatment to reduce or eliminate *Lm* in its HACCP plan, but has not validated the effectiveness of the treatment. (Cite 430.4(b)(1) and 417.4.)

You will document any noncompliance in accordance with our discussion of documentation and enforcement in a later section.

Alternative 2

9 CFR 430.4(b)(2) *Use of either a post-lethality treatment (which may be the antimicrobial agent) that reduces or eliminates microorganisms on the product OR an antimicrobial agent or process that suppresses or limits the growth of* L. monocytogenes.

Under Alternative 2, an establishment may select **either** Choice 1 or Choice 2 as follows.

Choice 1 - An establishment that produces post-lethality exposed product that selects this alternative and chooses to use a post-lethality treatment (which may be an antimicrobial agent or process) that **reduces or eliminates** microorganisms on the product. Again, the use of a post-lethality treatment must be included in the establishment's HACCP plan because the use of a post-lethality treatment reflects a determination that the pathogen is a hazard reasonably likely to occur, controllable by a post-lethality treatment. Consequently, the plant must incorporate the post-lethality treatment in its HACCP plan as a CCP. As with any other CCP, the plant must validate the effectiveness of the post-lethality treatment. In addition, the effectiveness of the anti-microbial agent or process, as used, must be documented in the HACCP plan.

OR

Choice 2 - An establishment that produces post-lethality exposed product and that selects this alternative chooses to use an antimicrobial agent or process that **suppresses or limits growth** of *L. monocytogenes*.

The application of an antimicrobial agent or the growth suppressing or limiting process must be included in the establishment's HACCP plan, SSOP or other prerequisite program. Because establishments that do not incorporate a post-lethality treatment are placing greater reliance upon plant sanitation, they must also provide for the testing of food contact surfaces in the post-lethality processing environment to ensure surfaces are sanitary and free of *Lm* or an indicator organism in accordance with 430.4(b)(2)(iii).

Note: Processes used to produce shelf-stable products are fermentation, salt curing, and drying. These processes can result in lethal treatment of pathogens and

suppression of growth during storage at ambient temperature. These processes can enable the establishment to choose Alternative 1 or 2 for their products depending on the validation and documentation provided. Sometimes, the establishment cannot provide validation or documentation to show growth suppression or bacterial reduction, and in this case the establishment may chose Alternative 3.

Alternative 2, Choice 2 inspection verification example: As part of the 03F01 procedure, you verify that the establishment is meeting the requirements of Part 430 and Alternative 2, Choice 2. You review the plant's hazard analysis for beef jerky products and find that the cooking and drying steps have been identified as CCPs in the hazard analysis and have been incorporated into the HACCP plan. In addition to these CCPs, *Lm* was considered a potential hazard at the packaging step but was not likely to occur because the establishment has *Listeria* control measures in its SSOP to prevent *Lm* in the post-lethality processing environment. You decide to request the supporting documentation for the decision made in the hazard analysis that *Lm* is not likely to occur in the post-lethality environment. The plant provides a scientific document that identifies that the dryness of the jerky product would inhibit *Lm* growth in the finished product throughout the shelf life of the product. The plant also provides the procedures (verification activities) and the associated records it uses to demonstrate that products are dried below the level which the scientific validation document establishes as preventing the growth of *Lm.* The records for the past several months show that the product is achieving the level of dryness needed to suppress the growth of *Lm*. You review the establishment's SSOP and records and find that the plant is testing food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Listeria* spp. The plant has identified the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food contact surface for *Listeria* spp., the size and location of the sample sites, and the testing frequency. It also provided a thought process as to why the testing frequency it selected is sufficient to ensure that effective control of *L. monocytogenes,* or an indicator organism, is maintained. Based upon your review, you determine that the establishment is in compliance with §430.4(b)(2).

Noncompliance with Alternative 2
The following are examples of noncompliance with Alternative 2.

1. The written sanitation procedures the establishment is using to meet the requirements of Choice 2 only address the testing of non-food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Lm* or of an indicator organism. (Cite 430.4(b)(2), 416, and 417.5(a)1&2.)

You will document any noncompliance in accordance with our discussion of documentation and enforcement in a later section.

Alternative 3

9 CFR 430.4(b)(3) *Use of sanitation measures only*

If the establishment does not use a post-lethality treatment and/or an antimicrobial agent or process, or, is unable to validate the effectiveness of their post-lethality treatment or antimicrobial process or agent, they may decide to control *Lm* in the post-lethality processing environment through the use of sanitation measures only. Such sanitation measures must include testing of food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Lm* or an indicator organism in accordance with 430.4(b)(3)(i).

Under Alternative 3, establishments that produce a deli or hot dog product must meet more prescriptive requirements than other post-lethality exposed RTE products produced under Alternative 3. In these situations the plants must initiate corrective actions with respect to sanitation after an initial positive test result for *Lm* or an indicator organism on a food contact surface. If the establishment obtains a second positive test result for *Lm* or indicator organism during follow-up testing, it must hold lots of product until the plant can show that they have corrected the problem by obtaining negative test results on those implicated food contact surfaces. Before lots of product that have tested positive for an indicator organism can be released into commerce, the establishment must sample and test the lots of product for *Lm* or an indicator organism or rework the product in a manner destructive to *Lm* in accordance with 430.4(b)(3)(ii). Product that has tested positive for *Lm* is considered adulterated, and it cannot be re-sampled in order to release the product.

Alternative 3 inspection verification example: As part of the 03F01 procedure, you verify that the establishment is meeting the requirements of Part 430 and Alternative 3. You review the plant's hazard analysis for heat treated shelf-stable product such as pepperoni, summer sausage, etc., packaged and sold un-refrigerated. You find that the fermentation, heating and drying steps have been identified as CCPs in the hazard analysis and have been incorporated into the HACCP plan to control hazards other than *Lm*. *Lm* was considered a potential hazard at the packaging step but the establishment concluded that it was a hazard not likely to occur because it has *Listeria* control measures in a prerequisite program to prevent *Lm* in the post-lethality processing environment. You request the supporting documentation for the decision that *Lm* is not likely to occur in the post-lethality environment. You review the establishment's prerequisite program and records and find that the plant is testing food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Listeria* spp. It also has identified the conditions under which it will implement hold-and-test procedures following a positive test of a food contact surface for *Listeria* spp., the size and location of the sample sites, and testing frequency. The establishment provided a thought process as to why the testing frequency it selected is sufficient to ensure that effective control of *L. monocytogenes,* or an indicator organism, is maintained. Based upon your review, you determine that the establishment is in compliance with §430.4(b)(3).

Noncompliance with Alternative 3
The following are examples of noncompliance with Alternative 3.

1. The establishment does not have sanitation measures incorporated into its HACCP, Sanitation SOP, or other prerequisite program. (Cite 430.4(b)(3), and 417.5(a)1&2.)

2. The written sanitation procedures the establishment is using to meet the requirements of this alternative only address the testing of non-food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Lm* or of an indicator organism. (Cite 430.4(b)(3), and 417.5(a)1&2.)

You will document any noncompliance in accordance with our discussion of documentation and enforcement in a later section.

9 CFR 430.4(c) *For all three alternatives in paragraph (b):*

(1) Establishments may use verification testing that includes tests for *L. monocytogenes* or an indicator organism, such as *Listeria* species, to verify the effectiveness of their sanitation procedures in the post-lethality processing environment.

(2) Sanitation measures for controlling *L. monocytogenes* and procedures for antimicrobial agents or processes that suppress or limit the growth of the pathogen may be incorporated either in the establishment's HACCP plan or in its Sanitation SOP or other prerequisite program. When these control procedures are incorporated into the Sanitation SOP or prerequisite program, and not as a CCP in the HACCP plan, the establishment must have documentation that supports the decision in its hazard analysis that *L. monocytogenes* is not a hazard that is reasonably likely to occur.

(3) The establishment must maintain sanitation in the post-lethality processing environment in accordance with part 416.

(4) If *L. monocytogenes* control measures are included in the HACCP plan, the establishment must validate and verify the effectiveness of measures for controlling *L. monocytogenes* included in its HACCP plan in accordance with Sec. 417.4.

(5) If *L. monocytogenes* control measures are included in the Sanitation SOP, the effectiveness of the measures must be evaluated in accordance with Sec. 416.14.

(6) If the measures for addressing *L. monocytogenes* are addressed in a prerequisite program other than the Sanitation SOP, the establishment must include the program and the results produced by the program in the documentation that the establishment is required to maintain under 9 CFR 417.5.

(7) The establishment must make the verification results that demonstrate the effectiveness of the measures it employs, whether under its HACCP plan or its Sanitation SOP or other prerequisite program, available upon request to FSIS inspection personnel.

9 CFR 430.4(d) *An establishment that produces post-lethality exposed RTE product shall provide FSIS, at least annually, or more often, as determined by the Administrator, with estimates of annual production volume and related information for the types of meat and poultry products processed under each of the alternatives in paragraph (b) of this section.*

Workshop, *Listeria monocytogenes* Verification

1) Establishments are required to comply with section 430.4 (Control of *Listeria monocytogenes*) if they produce

a. Ready-to-eat products processed and sold in impermeable packaging.
b. Not ready-to-eat products with secondary inhibitors.
c. Ready-to eat products.
d. Ready-to-eat products exposed to the environment after the lethality step.

2) Fill in the blanks with one of the following:
Alternative 1
Alternative 2, Choice 1
Alternative 2, Choice 2
Alternative 3

a. _____Use of only a post-lethality treatment (which may be the antimicrobial agent or process) that reduces or eliminates microorganisms on the product

b. _____Use of a post-lethality treatment (which may also be the antimicrobial agent or process) that reduces or eliminates microorganisms on the product AND an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes*

c. _____Sanitation measures only, in the HACCP plan, SSOP, or prerequisite program, including testing of food contact surfaces to verify the effectiveness of the sanitation procedures

d. _____Use of an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes*, along with a sanitation program addressing the testing of food contact surfaces to verify the effectiveness of the sanitation procedures

3. An establishment **MUST** implement hold and test procedures when a positive result for an indicator organism is found on a food-contact surface during follow-up testing (second consecutive food contact surface positive) if

a. the establishment is producing RTE products exposed to the environment after the lethality treatment using either Alternative 1, 2, or 3.

b. the establishment is producing non-deli and hot dog type RTE products exposed to the environment after the lethality treatment using Alternative 3.

c. the establishment is producing deli and hot dog type RTE products exposed to the environment after the lethality treatment using Alternative 3.

d. the establishment is producing deli and hot dog type RTE products exposed to the environment after the lethality treatment using Alternative 2, Choice 2

4. An establishment **MUST** identify the conditions under which it will implement hold and test procedures after a positive result for an indicator organism is found on a food-contact surface if:

a. the establishment is producing either non-deli and hot dog type or deli or hot dog type RTE products exposed to the environment after the lethality treatment using either Alternative 2 (Choice 2) or Alternative 3.

b. the establishment is producing deli and hot dog type RTE products exposed to the environment after the lethality treatment using either Alternatives 1, 2, or 3.

c. the establishment is producing deli and hot dog type RTE products exposed to the environment after the lethality treatment using Alternative 1 or Alternative 2, Choice 1.

d. the establishment is producing non-deli and hot dog type RTE products exposed to the environment after the lethality treatment using Alternative 2, Choice 1

FSIS Compliance Guidelines ATTACHMENT 1 - CONTROL REQUIREMENTS for *LISTERIA MONOCYTOGENES*

Requirements	→ Increasing Risk Levels and Verification Testing →				
	ALTERNATIVE 1	**ALTERNATIVE 2**		**ALTERNATIVE 3**	
	Post-lethality Treatment AND Antimicrobial agent or Process	Post-lethality Treatment OR Antimicrobial agent or Process		Sanitation and Testing Program	
		Post-lethality Treatment	Antimicrobial Agent or Process	Non-deli, Non-hot dog	Deli or hot-dog product
Validate effectiveness of post-lethality treatment	X	X			
Document effectiveness of antimicrobial agent or process	X		X		
Sanitation Program Requirements			X	X	X
Testing food contact surfaces (FCS)			X	X	X
State testing frequency			X	X	X
Identify size and location of sites to be sampled			X	X	X
Explain why testing frequency is sufficient			X	X	X
Identify conditions for Hold-and-Test, when FCS (+)			X	X	X
Additional Sanitation Program Requirements					X
Follow-up testing to verify corrective actions are effective after 1st FCS (+)					X
If follow-up testing yields 2nd FCS (+), hold products that may be contaminated until problem is corrected as shown by FCS (-) in follow-up testing.					X
Hold and test product lots for *L. monocytogenes* using sampling plan that provides statistical confidence. Release, rework or condemn products based on results. Document results and product disposition.					X

OTHER REQUIREMENTS

- Post-lethality treatments must be included in the HACCP plan.
- Antimicrobial agents must be included either in the HACCP plan, Sanitation SOP, or prerequisite program.
- Sanitation programs must be included either in HACCP plan, Sanitation SOP, or prerequisite program. If in the Sanitation SOPs or prerequisite program, there must be supporting documentation for the hazard analysis determination that this hazard is not reasonably likely to occur.
- Verification testing for sanitation in the post-lethality environment may be for *Listeria monocytogenes, Listeria* spp. *or Listeria*-like organisms.
- Product testing must be confirmed for *Listeria monocytogenes.*
- Establishment must maintain sanitation in the post-lethality environment per 9 CFR 416.
- If *L. monocytogenes* controls are in HACCP plan, establishment must validate and verify effectiveness per 9 CFR 417.4
- If *L. monocytogenes* controls are in Sanitation SOPs, their effectiveness must be evaluated per 9 CFR 416.14.
- If *L. monocytogenes* controls are in prerequisite programs, the program and results must be included in documentation required by 9 CFR 417.5
- Establishment must make verification results available to inspection program personnel.

FSIS Compliance Guidelines ATTACHMENT 2 - CHART OF RTE VS NRTE PRODUCTS

TYPE	CLASS	PROCESSING CATEGORY ISP CODE	REG REQUIRED SAFETY LABELING	WHAT THE HAZARD ANALYSIS/HACCP PLAN MAY ADDRESS
A product containing a meat/poultry product (in whole or in part) which has not received an adequate lethality treatment for pathogens (i.e. raw or partially cooked product).	Not-ready-to-eat	• Raw Product Ground – ISP 03B • Raw Product Not Ground – ISP 03C • Not Heat Treated Shelf-stable – ISP 03E • Heat Treated –shelf-stable – ISP 03F • Heat Treated but not Fully Cooked Not Shelf-stable - ISP 03H • Products with secondary inhibitors Not Shelf-stable – ISP 03I •	Product must be labeled with statements such as keep refrigerated, keep frozen, or refrigerate leftovers. Use of Safe Handling Instruction (SHI) labeling required.	• Use of SHI labeling (Some establishments may have a CCP for SHI labeling application). If it is not obvious that the product is raw and needs to be cooked: • Features on labeling are conspicuous so that intended user is fully aware that product must be cooked for safety. This is best conveyed through the product name (e.g., “Cook and Serve”) but may also be conveyed by the use of an asterisk on the product name that is associated with a statement on the principle display panel, or by a burst stating such things as “needs to be fully cooked,” “see cooking instructions,” or “cook before eating.” • Validation that: a. Cooking and preparation instructions on the product are sufficient to destroy pathogens. b. Instructions are realistic for the intended consumer.
A product containing a meat/poultry component that has received a lethality treatment for pathogens in combination with non-meat/poultry components that need to receive a lethality treatment by the intended user. This includes meals, dinners, and frozen entrees.	Not-ready-to-eat	• Heat Treated but not Fully Cooked Not Shelf-stable - ISP 03H	Product must be labeled with statements such as keep refrigerated or frozen. Use of SHI labeling is recommended.	• Validation that: a. The meat/poultry component received an adequate lethality treatment for pathogens. b. Cooking and preparation instructions on the product are sufficient to destroy pathogens. c. Instructions are realistic for the intended consumer. • Features on labeling are conspicuous so that intended user is fully aware that product must be cooked for safety. This is best conveyed through the product name (e.g., “Cook and Serve”) but may also be conveyed by the use of an asterisk on the product name that is associated with a statement on the principle display panel, or by a burst stating such things as “needs to be fully cooked,” “see cooking instructions,” or “cook before eating.” • If necessary, hazard analysis should address whether instructions on the label are needed related to cross-contamination (e.g., avoid contact of contents) and prevention of pathogenic growth (e.g., promptly refrigerate leftovers). NOTE: Inspection program personnel are to collect samples as RTE if the establishment does not follow the guidance above.
A product containing a meat/poultry component that has received a lethality treatment for pathogens that may or may not be in combination with a non-meat/ poultry component that does not need to receive a lethality treatment by the intended user.	Ready-to-eat	• Not Heat Treated Shelf-stable – ISP 03E • Heat Treated Shelf-stable – ISP 03F • Fully Cooked Not Shelf-stable – ISP 03G • Products with secondary inhibitors Not Shelf-stable – ISP 03I	If the product is not shelf-stable labeling such as keep refrigerated or frozen is required.	• See part 417 of the meat and poultry regulations.

Sampling RTE Shelf-stable Products

FSIS is continuously updating its sampling programs in order to keep pace with changes in policy. FSIS directives and notices for current sampling programs contain specific instructions for you to follow. It is important to read **recent** issuances, so that when you are requested to collect a sample you have the latest information.

Introduction

FSIS's microbiological testing program is designed to verify that the establishment's food safety system is effective. FSIS sampling is done to verify that FSIS performance standards and regulations are met. FSIS tests RTE products for pathogens because of the public health impact (there could be a breakdown in the lethality step, or post lethality contamination may occur). The pathogens of public health concern are *Listeria monocytogenes*, *Salmonella*, and, for certain products, *E. coli* O157:H7.

During the1980's, *Listeria monocytogenes*, which previously was known as a contaminant of dairy products, began to emerge as a problem in processed meat and poultry products. In 1998, an outbreak occurred which resulted in 101 illnesses, 15 adult deaths, and 6 stillbirths. *Listeria monocytogenes* can contaminate RTE products (including shelf-stable RTE products) that are exposed to the environment after they have undergone a lethality treatment. *L. monocytogenes* is a hazard that an establishment producing post-lethality exposed RTE products must control through its HACCP plan or prevent in the processing environment through a Sanitation SOP or other prerequisite program. RTE product is adulterated if it contains *L. monocytogenes*, or other pathogens, or if it comes into direct contact with a food contact surface which is contaminated with *L. monocytogenes*.

Definitions

Aseptic means "free from pathogenic organisms." An aseptic technique implies that you do not add any organisms (pathogenic or not) to the sample when it is collected. It does not imply that the sample is aseptic. The purpose of aseptically collecting a sample is to prevent contaminating the sample or the surrounding product/product contact area. That is why it is important to aseptically collect a sample even when the sample is intact. Wash and sanitize your hands before collecting an intact sample, but it is not necessary for you to sanitize the area and put on gloves. Good personal hygiene is essential anytime a sample is collected, whether it is intact or not.

Environmental samples are samples from surfaces that have

- indirect or potential contact with exposed RTE product in the RTE production area (mop handles, outer garments, etc., that may be handled by a person who may touch RTE product), or
- non-contact surfaces in a RTE production area (e.g., floors, drains, walls, overhead structures).

Food contact surface is specific to the RTE verification testing program. A food contact surface is the equipment or utensil surface with which exposed RTE product has

direct contact (for example, conveyor belt, tabletop, knife blade). A food contact surface does not include items that may have indirect or potential contact with exposed RTE product.

Food contact surface samples are a collection of samples (e.g., swabs) from food contact surfaces that represent the conditions under which the sampled lot was processed. The samples are collected during the production shift, not pre-operational, but without disrupting production, such as during breaks and at the end of a shift.

Intact means product in the final packaged form (immediate container) in which it will be shipped. The lab receives the sample in the same immediate container that the consumer will, so whatever is in the product the lab gets is what is in the consumer's product, too.

Recall is a plant's voluntary removal of distributed meat or poultry products from commerce when there is reason to believe that such products are adulterated or misbranded under the provisions of the Federal Meat Inspection Act (FMIA) or the Poultry Products Inspection Act (PPIA). Product that is adulterated and has left the establishment's control may be subject to a recall. The recall would involve at least the sampled lot, but it could be expanded depending upon a review by the Recall Management Division (RMD) of all factors in the situation. FSIS Directive 8080.1 gives additional details on recalls.

RTE production area is one where exposed RTE products are stored, further processed, or packaged. This is the area from which food contact surface samples and environmental samples are taken and analyzed for *L. monocytogenes* or indicator organisms.

Sample is a collection of product that represents a larger group (the sampled lot) that has passed the plant's pre-shipment HACCP review.

Sampled lot is the amount of product represented by the sample. For microbial issues, the actual (affected) product represented by the sample is usually interpreted as the product produced from clean-up to clean-up. Often, factors like the plant's coding system, the pathogen of concern, the processing and packaging, the equipment, the plant's sampling programs, the HACCP plan monitoring and verification activities, the SSOP records, etc., are considered when determining how much product is actually represented by the sample.

Short-weight or slack-filled containers meet the definition of an intact sample, but with less product (e.g., a liner from a bulk package which contains approximately 2-lb of product, folded down and sealed in the same manner that the bulk product is normally packed to prevent product contamination). A short-weight or slack-filled sample is one that has progressed through all the production steps that the product normally goes through (not changed in any way that would affect the processing parameters). A short-weight or slack-filled sample may appear to the lab as a non-intact sample and may be discarded if you do not indicate that it is short-weight or slack-filled in block 28.

Subsequent production is all product produced after the sampled lot. It is not usually part of the sampled lot, but it may or may not be affected product.

PBIS Procedure Code 05B02

Procedure 05B02 is used for the collection of samples for microbial analyses with a direct bearing on food safety and public health. (05B02 is also used for import samples.) Since a directed sample request is not a scheduled procedure, 05B02 is recorded as unscheduled, "performed," on the Procedure Schedule on the day that you collect the sample.

Sample Initiation

There are several ways that sampling is initiated. Most commonly, you will receive a directed sample request from OCIO-LITB (Office of the Chief Information Officer, Laboratory Information Technology Branch). When OCIO-LITB schedules a sample to be taken at an establishment, they will send a Requested Sample Programs Form, 10,210-3. Once the form is received, you are to **always** collect a RTE product sample, if requested product is available. (If a sample is not available, send forms and labels back to the laboratory using the United States postal service, **not** Federal Express.) FSIS Directive 10,210.1, Unified Sampling Form, lists the products and pathogens and toxins for which FSIS may collect and test samples. For example, FSIS may analyze a ready-to-eat meat and poultry product for *Salmonella* and *Listeria monocytogenes*. If the product is dry or semi-dry fermented sausage or fully cooked meat pattie, it will also be analyzed for *E. coli* O157:H7.

Inspector-generated samples are initiated by FSIS in-plant personnel, based on a suspicion about the product or process. You and your frontline supervisor will determine when inspector-generated sampling should occur. Before a sample is taken, you must obtain an FSIS Form 10,210-3 from OCIO-LITB. The frontline supervisor, District Office, or Washington headquarters may also initiate directed samples.

Special project samples are taken when FSIS is alerted to a food borne illness outbreak by a state or local government, or when there is a special project such as baseline studies.

Steps in Sampling

There are 5 general steps in actually sampling product.

1. Determine which product to sample
2. Notify plant management
3. Collect the sample
4. Pack and mail the sample and form
5. React to the results

Determine Product to Sample

FSIS has several sampling programs. You are to collect RTE samples under the following sampling project codes:

ALLRTE: Under the ALLRTE sampling project code, you (IPP) are to make every effort to sample all of the RTE products produced at an establishment by rotating through the products when you receive sample request forms. If a specific product is not pre-selected for sampling in Block 18 of the sample request form, 10,210-3, ***Randomly*** collect (select a day, shift and time) a RTE product (post-lethality exposed RTE product and non-post-lethality exposed RTE product) produced.

RTE001: You should follow the risk-based priority list in FSIS Directive 10,240.4, Rev.2 (see below) to determine which type of post-lethality exposed RTE product to select. This sampling project includes **only** the collection of **post-lethality exposed product.** Select the highest risk post-lethality exposed RTE product produced at the time of collection.

RTE001 Priority:

1. Deli-meats that are sliced in the federal establishment
2. Deli-meats shipped whole from the federal establishment (this does not include cook-in-bag products; only those exposed post-lethality)
3. Hot dog products
4. Deli salads, pâtés, and meat spreads
5. Fully cooked type products (other than cooked products in 1-4 above)
6. Fermented products
7. Dried products
8. Products labeled as “Keep Frozen”

If FSIS *Lm* sampling projects are scheduled at the same establishment during the same time period, all samples are to be collected as scheduled. For example, if you receive sample request forms for both the ALLRTE and the RTE001 sampling projects, you will collect samples for both projects. Do not collect samples for the ALLRTE and the RTE001 projects from the same lot. Also, whenever possible, collect samples from different weeks for each project. By doing so, FSIS will have a more comprehensive understanding of the establishment’s process. RLm sample collection does not take precedence over the other sampling projects.

Notify Plant Management

Plant management must be notified whenever a sample is going to be taken. This gives management the option of holding the product represented by the sample pending test results. You should notify management enough in advance to allow them to hold the product, but not soon enough to allow them to alter the process. You should discuss the notification timeframe with plant management prior to any sample requests being received in order to have an agreed upon protocol in place.

In the case of RTE products, you must give plant management a handout (Attachment 1) stating that you will take a sample and that the establishment may wish to voluntarily hold the product pending microbial analyses results.

You should verify that all product represented by the sample (that is, the sampled lot) is held by the establishment, should it elect to do so.

Collect and Mail the Sample

Collect and mail samples using FSIS standard procedures. Note that you must indicate in Block 28 when the sample is dry or semi-dry fermented sausage (Attachment 2). Also, shelf stable products should contain the freeze pack to ensure that the product does not get over-heated during shipping. The "coolboard" goes on top of the freeze pack to separate the freeze pack from the sample.

React to Results

Access LEARN to track sample receipt and results. LEARN (Laboratory Electronic Application for Results Notification) is a computer application that notifies FSIS personnel and establishment management of the receipt and status of samples sent to the FSIS analytical laboratories for testing. LEARN reports when a sample was received at the lab, if it was discarded and the reason for the discard (Attachment 3), and the results of the analysis when it is completed.

When a sample is submitted for analysis, you must check LEARN the following day to see that the sample was received and was not discarded. Go to the following address. http://dchqintra/learn/estindex1.cfm

When you go to the LEARN address, you have three options.

1. Enter the form number,
2. Enter a single establishment number to obtain all the results in the database for that establishment, or
3. Go to a customizable list of samples for all establishments in a circuit.

Click on "Submit" to see the collection date, the form number, and whether the sample was "Received" or "Not Analyzed".

The results are posted once the analyses are complete. The FSIS laboratory reports results as negative, presumptive positive and positive. OCIO-LITB e-mails sample results to plants that provide their email address, which you can indicate on the PBIS Plant Profile. **You should provide the sample results to establishment management even if the establishment receives e-mail notifications from OCIO-LITB.**

RLm Testing Program

Inspection personnel trained in the EIAO methodology for collecting samples will select samples under the routine Lm risk-based (RLm) sampling program. CSIs **will not** conduct sampling under the new RLm program.

The new RLm testing program consists of the following sampling projects:

1. **RLMCONT** – the routine risk-based testing of surfaces that have direct contact with RTE product in the RTE production area, e.g., conveyor belts, cooler storage racks, luggers, slicers, peelers, loaders, table tops;

2. **RLMENVR** – the routine risk-based testing of environmental (non-food contact) surfaces in the RTE production areas, e.g., floors, drains, walls, air-vents, overhead structures; and

3. **RLMPROD** – the routine risk-based testing of intact product samples collected concurrently with food and environmental contact surface swabs throughout the selected production shift.

Noncompliance under the RLm Sampling Program

When necessary, the CSI is to document an NR at the completion of the food safety assessment (FSA) conducted by an EIAO. The CSI bases the NR on the determinations of the EIAO's FSA including positive sample results from the RTE RLm Sampling Program. The CSI is to issue an NR under the appropriate 03 code using the verification trend indicator and referencing 9 CFR 417.4(a) and 301.2 or 381.1 for positive product or food contact surface results. If the determination of the EIAO's FSA is to document an NR related to the design or execution of environmental sampling, the CSI is to issue an NR under the 06D01 procedure code using the product-based trend indicator and referencing 9 CFR 416.4(b).

ALLRTE and RTE001 Sampling Project Positive Results

If any RTE product sample under the RTE001 or ALLRTE sampling projects tests positive for *Listeria monocytogenes*, product in the sampled lot is adulterated. If FSIS finds the product positive, and the establishment tested the product, you are to check establishment *Listeria monocytogenes* test results to determine whether the establishment also found the sampled product positive for *Listeria monocytogenes*.

If the establishment held the product or maintained control of the product (e.g. the establishment moved the product off site but did not complete pre-shipment review or transfer ownership of the product to another entity) pending its own test results, and FSIS and the establishment found the product positive for *Listeria monocytogenes*, you **are not** to issue an NR. You are to verify that the establishment performs the appropriate corrective actions.

Issue an NR using the appropriate 03 procedure code and the "verification" trend indicator referencing 9 CFR 417.4(a) and 301.2 or 381.1, when the establishment either **did not** find the product positive and **did not** hold the affected product, or **did not** take

the appropriate corrective actions. If any product in the sampled lot has entered commerce, contact the District Recall Officer (DRO). FSIS will request a recall.

Establishment Sampling Program Positive Results

If an establishment's product or food contact surface test result is positive for *L. monocytogenes*, you **should not** issue an NR unless the establishment failed to hold the affected product and did not implement corrective actions, which includes safely disposing of the sampled product lot.

An establishment may or may not conduct environmental sampling, other than on food contact surfaces, under its HACCP plan or Sanitation SOPs or other prerequisite program. If the establishment is conducting such sampling, and positive results are received, you are to verify that the establishment takes the appropriate action as outlined in the program under which the establishment did the sampling. If the establishment is conducting such sampling but is not addressing the sampling under HACCP or Sanitation SOPs or other prerequisite programs, and you find that such sampling is resulting in repetitive positive results, you are to notify the DO through supervisory channels.

Verification of Corrective Actions

A positive RTE product sample result (FSIS or the establishment) for a pathogen of public health concern is a food safety hazard regardless of what type of program the establishment is using to address the pathogen. The product represented by the sample is adulterated. If a post-lethality exposed RTE food contact surface sample (FSIS or establishment) tests positive for *L. monocytogenes*, the product passing over the surface is adulterated unless a validated post-lethality treatment was applied to it.

You are to verify that the establishment implements corrective actions in accordance with the appropriate regulation during the performance of the HACCP 01 or 02 procedure. If the EIAO recommended, and the District Office implemented an enforcement action, you are to perform the activities in the verification plan to verify the effectiveness of the establishment's corrective actions. In all cases, the plant must meet the corrective action requirements in the HACCP regulations, 9 CFR 417.3. The establishment must meet 9 CFR 417.3(a) when the pathogen is addressed in the HACCP plan.

If the pathogen is prevented through the Sanitation SOPs, then the establishment must implement the corrective action in 9 CFR 417.3(b) and also implement the corrective action requirements for SSOP, 9 CFR 416.15. If the pathogen is prevented through a prerequisite program that is used to support the decision that a hazard is not likely to occur at a particular point in a process, then the establishment must implement the corrective action in 9 CFR 417.3(b) and 417.4(a)(3) which states that when there is a change in the process that could impact the hazard analysis, a reassessment must be performed. In each situation, you will need to review all information available to determine whether the establishment has implemented all appropriate corrective actions.

In addition, you are to verify the establishment's disposition of the sampled product lot by verifying that the establishment has documentation to support that potential

contamination would be limited to individual production lines or individual product lots. If the establishment elects to destroy the product, you should verify that it has destroyed the sampled lot. If the establishment elects to rework the product, you should verify that it has reworked the sampled lot with a process that is destructive of *L. monocytogenes*. Verify that the hazard analysis has considered the use of the reworked product.

You are to verify all the factors for testing in establishments that have chosen to use Alternative 3. If the establishment produces deli products or hot dog products under Alternative 3, verify that the establishment conducts follow-up testing of the targeted site on the food contact surface and other sites after an initial positive result for *L. monocytogenes,* or indicator organism, to verify that the corrective action implemented with respect to sanitation was effective. Verify that the establishment holds lots of product that may have become contaminated by contact with the food contact surface that tests positive again (second consecutive) during follow-up testing, that it samples and tests the lots of product that may have been contaminated with *L. monocytogenes,* for *L. monocytogenes* or an indicator organism using a sampling method and frequency that provides statistical confidence that each lot is not adulterated with *L. monocytogenes* before releasing the lots of product into commerce, and that it documents the test results.

Off-Site Product Disposition

Adulterated product may be moved off-site for proper disposition, under appropriate controls. Product may be transferred to another official establishment for further processing to destroy the pathogen. Plants may opt to dispose of the product through rendering or disposal in a landfill.

When the establishment moves positive product off-site for disposition, verify the plant that produced the positive product maintains appropriate control of the product at all times, including while it is in **transit** to the off-site location where the product will either be reworked to destroy pathogens before entering commerce or be disposed of so it will not be used for human consumption.

When you perform the HACCP 02 procedure verify that the establishment:

- Maintained records identifying the official establishment, renderer, or landfill operation that received positive product;

- Maintained control of the product that was destined for a landfill operation or renderer while the product was in transit (e.g., through company seals);

NOTE: If an establishment ships adulterated product to renderer or landfill operations, you are to verify the establishment denatures the product before the product leaves the establishment (9 CFR 314).

- Maintained control of product that was destined for an official establishment while the product was in transit (e.g. through company seals) or ensured that such product moved under FSIS control (e.g. under USDA seal or accompanied by FSIS Form 7350-1);

- Maintained records showing that positive product received the proper disposition, including documentation showing proper disposal of the product from the official establishment, renderer, or landfill operation where the disposition occurred; and

- Completed the pre-shipment review for the positive product only after it has received the records described above for that particular product. You cannot complete your HACCP 02 procedure for this specific production until the plant completes the corrective action and documentation requirements (417.3(a) or 417.3(b) and 416.15), which includes receiving documentation from the official establishment or landfill operation or renderer that demonstrates proper disposition/disposal of the positive product and conducts pre-shipment review of the corrective actions.

NOTE: If the product is shipped to another official establishment for disposition, CSIs at that establishment are to periodically verify that the receiving establishment disposes of the product in an appropriate manner.

Issue an NR if you find noncompliance while verifying the plant's off-site product disposition corrective actions. Document the noncompliance under 9 CFR 417.3(a) if *L. monocytogenes* is addressed in the HACCP plan or 9 CFR 416.15 and 417.3(b) if *L. monocytogenes* is addressed in the Sanitation SOPs or 9 CFR 417.3(b) if *L. monocytogenes* is addressed in a prerequisite program. You should contact the DO through supervisory channels if the determination is made, or if questions arise about whether the establishment committed the prohibited act of selling or transporting adulterated articles that have not been inspected and passed. The DO will investigate further.

The DO will assign an EIAO to conduct a FSA in conjunction with collecting product, food contact, and environmental (non-food contact) samples (INPROD, INTCONT, INTENV, respectively) using the Intensified Verification Testing (IVT) methodology within 30 days of being notified of an FSIS RTE product sample that tested positive for Lm, E. coli O157:H7, or Salmonella. District Managers should contact OCIO-LITB through the IVT Sampling Scheduling Mailbox to request forms for the sampling. This sampling should not be initiated until the corrective and preventive measures have been put in place.

Workshop, Sampling RTE Product

1) You are assigned to a plant which produces a variety of ready-to-eat (RTE) products including those that are shelf-stable. You receive a directed sample request from OCIO-LITB for a RTE product (project code RTE001). Which of the following would you choose based on the priority listed in Directive 10,240.4, Rev. 2?

   a. Deli-meats that are cooked in an impervious bag and shipped from the establishment without being removed from the impervious bag.
   b. Deli-meats that are sliced in the federal establishment
   c. Deli salads
   d. Fermented products

2) FSIS sampling is done to

   a. verify that FSIS performance standards and regulations are met.
   b. validate HACCP plans and compare results to plant analyses.
   c. generate public support.
   d. monitor in-plant activities.

3) When a plant has a sanitation program that includes sampling RTE product as part of the HACCP plan, you do not have to collect RTE samples.

   a. True
   b. False

4) When a plant has a sanitation program that includes sampling RTE <u>product</u> as part of the HACCP plan, and they receive a positive for *L. monocytogenes*, what actions would we require them to do? (circle all that apply)

   a. Hold the affected product
   b. Implement corrective actions per §417.3(a)
   c. Make appropriate disposition of the sampled product
   d. Notify the IIC

5) When a plant has a sanitation program that includes sampling RTE product contact surfaces as part of the SSOP program, and they receive a positive for *L. monocytogenes*, what actions would we require them to do? (circle all that apply)

a. Hold the affected product
b. Implement corrective actions per §417.3 & 416.15
c. Make appropriate disposition of the sampled product
d. Notify the IIC

6) Under what circumstance might the DO (through OCIO-LITB) schedule intensified verification sampling?

What would be the purpose?

7) When should a RTE sample be sent to the lab for a *L. monocytogenes* directed sample?

a. the day before the "use by" date
b. just prior to packaging
c. the first day FedEx is available after the sample is collected
d. once the establishment has received their testing results

8) Plant management must be notified of pending sample collection

a. when you receive the analysis result (either from LEARN or the DO).
b. after pre-shipment review has been completed.
c. enough in advance to allow the plant to hold the product, but not soon enough to allow it to alter the process.
d. because of the Freedom of Information Act (FOIA).

9) An establishment produces fully cooked pepperoni, in the shelf-stable (03F) processing category. This product is produced using Alternative 2, Choice 1. The establishment performs a post-lethality treatment on the pepperoni immediately following packaging. As a verification activity for the post-lethality treatment, it samples the pepperoni for *Lm*, and holds product pending results. This morning, the establishment obtained a positive result for *Lm* from one of its samples. Based on the information presented so far, answer the following questions.

a. Which corrective action regulation would apply in this situation?

b. What would you verify in this case? List all that apply.

c. Would you issue an NR?

d. Would FSIS request a recall?

ATTACHMENT 1

Notice to Give Plant Management When Certain Regulatory Samples Are Taken

To Establishment Manager:

X The inspector will be taking a sample of your ready-to-eat meat, poultry, or egg product or raw ground beef product to be tested for microbial hazards. Sampling is one component of verifying your food safety system.

In addition, the Food Safety and Inspection Service (FSIS) conducts tests of FSIS-inspected product for possible threat agents. This sample may be analyzed for a threat agent. The timeframe for analyzing the sample for a possible threat agent will be the same as the current timeframe for microbiological sampling. FSIS will report the findings for all analyses on the sample in one response, i.e., the establishment will not receive sample results indicating a negative or positive for a pathogen and then later receive confirmation that the sample was negative or positive for the threat agent. No response from FSIS regarding the threat agent sample result equals a negative for the threat agent sampling.

X To protect the public health and to avoid the negative impact of a recall, FSIS strongly recommends that you hold all product represented by the sample until results are obtained.

X Most negative results are available within 2-6 days; confirmed positive results may take up to 8 days. Results will be provided to you by the inspector or the District Office.

X If a test result is positive for either the microbial contaminant or threat agent, and you have distributed the product, FSIS will request that you conduct a recall. If a recall is needed, FSIS expects you to initiate the recall in a timely fashion, usually the same day. (See FSIS Directive 8080.1 for further details.)

It is your responsibility to determine the amount of product represented by the sample. For more information, see FSIS Directives 10240.4, and 10,010.1, Revision 1 and accompanying Questions and Answers.

FSIS may determine that more product or less product than that produced in the establishment-defined lot is represented by the sample based on a review of the support rationale for how the production lot was defined. In making this determination, FSIS will consider such factors as the establishment's coding of product; the pathogen of concern; the processing and packaging; the equipment; the establishment's testing under its food safety system; the establishment's HACCP plan monitoring and verification activities performed in accordance with 417.2 and 417.4; Sanitation SOP records as required in 416.16; and whether some or all of the products controlled by the same or substantially similar HACCP plans have been affected.

ATTACHMENT 2

Sampling Resources

Currently, there are several directives associated with microbial sampling of RTE products that fall into the 03E, 03F, 03G, and 03I process categories. Each CSI should review the pertinent directives prior to obtaining a sample. The review should consist of checking to see if the directive is the current version. The FSIS website lists those directives that have been published most recently. The Outlook Folder (Public Folders ⇒All Public Folders ⇒ Agency Issuances ⇒Directives or Indexes and Checklists) has a listing of the current directives (and any revisions, etc.). The actual directives are posted under the Directives Folder. New listings may also be posted in LEARN on the "What's New" page.

Selected FSIS Sampling References for RTE (03E, 03F, 03G, and 03I)		
FSIS Directive Number	**Directive Title**	**Directive Date**
5000.1, Rev 3	Verifying an Establishment's Food Safety System	6/24/08
7355.1, Rev 2	Use of Sample Seals for Laboratory Samples and Other Applications	12/3/02
8080.1, Rev 4	Recall of Meat and Poultry Products	1/19/00
10,200.1	Accessing Laboratory Sample Information via LEARN	7/19/01
10,210.1, Amend 6	Unified Sampling Form	12/18/03
10,230.2, Amend 1	Procedures for Collecting and Submitting Domestic Samples for Microbiological Analyses	9/4/92
10,240.4, Rev. 2	Verification Procedures for Consumer Safety Inspectors for the *Listeria monocytogenes (Lm)* Regulation and *Lm* Sampling Programs	2/3/09
10,600.1	Sample Shipment Procedures	10/6/83

ATTACHMENT 3

Sample Discard Reasons

This table includes common discard reasons for samples. The codes are not given in this table since they are used for tracking purposes. You should review the sample and paperwork before submitting them to the lab to ensure these mistakes are not made.

COLLECTED SAMPLES/NOT ANALYZED
RTE-Sample Submitted in Error
No Sample Received with Form
Collected Outside Scheduled Time Frame
Temperature Too High
Tissue/Sample Spoiled/Rancid
Container Damaged
Commingled Tissues
No Identification on Tissues
Wrong Tissue/Sample for Requested Analysis
Insufficient Tissue or Sample
Delayed Shipment
Shipped on Friday w/o Saturday Delivery label
Sample Forwarded to Another Lab
Original Form Not Submitted w/Sample
Target Tissue Not Received
No Form Received with Sample
Original Form Altered by Sample Submitter
Plant Has It's Own Testing Program-Sample Submitted
Laboratory Problem*
No Freeze Packs/Coolants in Sample Box
Sample Container Leaking
Collection Date Not Day Prior to Sample Receipt
Cooked Product
Excessive Fat
Sent to Wrong Lab
Sample ID # on Bag does not match ID # on Form
Non-Intact Sample Package
Raw Product Submitted for RTE program
Security Seal Missing or Not Intact
Temperature Too Low
No Accredited Lab Tests Performed
Headquarters/ PDD/DO Discard
Sampling Instructions Not Followed

ATTACHMENT 4

Sample Request Form

Internal lab code here	U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE **REQUESTED SAMPLE PROGRAMS** ☐ FOOD CEMISTRY ☐ MICROBIOLOGY ☐ RESIDUE	Barcode here 1. SAMPLE FORM NO.

PART 1. SAMPLE COLLECTION AND MAILING INSTRUCTIONS

2. SAMPLE TYPE CODE	3. EST. NO.	4. COLLECT TISSUES/SAMPLES ON			5. REGION/ DISTRICT	6 STATE	7. CIRCUIT/IFO
		Day of:	Week of:	Wthin 30 days of:			

8. ESTABLISHMENT ADDRESS/SAMPLE COLLECTION ADDRESS (i.e., Est.,Retail Store)	9. NAME & ADDRESS OF RECEIVING LABOATORY

10. SLAUGHTER CLASS CODE	11. SPECIES TO COLLECT	12. TISSUE	13. ANALYSIS REQUESTED

14. PROJECT NO.	15. COUNTRY OF ORIGIN	16. COUNTRY COPY	17. FOREIGN EST. NO.

18. ADDITIONAL INSTRUCTIONS

PART II. COLLECT SAMPLE INFORMATION (To be compluted by sample collector)

19. DATE COLLECTED	20. DATE SENT TO LAB	21. PRODUCT TEMPERATURE	22. PRODUCT HELD ☐ YES ☐ NO
23. FSIS N9540-1 NO.	24. LOT NO.	25. IMPORTS ☐ NORMAL (06) ☐ INCREASED (07) ☐ SPECIAL (53) ☐ HOLD (24)	

26. PRODUCER/DEALER/OWNER-NAME/ADDRESS/STATE/ZIP CODE	27. ANIMAL ID (Tag No.)

28. REMARKS

29. COLLECTOR'S SIGNATURE	30. NAME OF COLLECTOR (Print)	31. BADGE NO.	32. TELEPHONE NO. AT EST.

33. IF THE REQUESTED SAMPLE(S) ARE NOT COLLECTED, CHECK OFF THE APPROPRIATE REASON & RETURN THIS FORM TO THE LAB INDICATED ABOVE

(72) ☐ *REQUESTED PRODUCT(S) NOT PRODUCED DURING THE SAMPLING TIME FRAME. (If checked, plant will be subject to sampling at a later date)*

(60) ☐ PLANT DOES NOT SLAUGHTER SPECIED/CLASS OR PRODUCE THE REQUESTED PRODUCTS *(If checked, plant will be removed from this sampling program)*

(57) ☐ NEEDED SUPPLIES OR APPROPRIATE SHIPPING CONTAINER NOT AVAILABLE

(53) ☐ *OTHER (Explain)*

PART III, LABORATORY RECEIPT INFORMATION

34. SAMPLE PACKAGING ☐ 3034 Intact Package ☐ 3035 Non-intact Package		35. SAMPLE RECEIPT DATE
36. PRODUCT CODE	37. NO. SAMPLES IN COMPOSITE	38. SAMPLE RECEIPT TEMPERTURE
39. SAMPLE RECEIPT CONDITION CODE	40. SEAL CONDITION CODE	41. DISCARD CONDITION CODE

FSIS FORM 10,210-3(3/97)

HACCP Regulatory System

FSIS has the overall authority and oversight to regulate meat/poultry products intended for distribution into commerce. The official establishment's responsibility is to produce safe wholesome meat/poultry products. When the Pathogen Reduction/HACCP System Final Rule was published in July 1996, and the regulation was first implemented in large establishments in January 1998, in small establishments in January 1999, and in very small establishments in January 2000, FSIS required all establishments that produce federally inspected meat and poultry products to design and operate HACCP systems. HACCP provides a framework for establishments to conduct science-based process controls that can be validated as effective in eliminating, preventing, or reducing to an acceptable level the food safety hazards that are reasonably likely to occur in an official establishment's particular production processes. Under the HACCP regulatory system, establishments must assume responsibility for producing products that are safe for consumers.

The 7 HACCP Principles

The National Advisory Committee on Microbiological Criteria for Food (NACMCF) working group created guidelines and redefined the seven basic principles of HACCP as an effective and rational means of assuring food safety from harvest to consumption. The HACCP guideline with the seven principles is not an enforceable document; however, it is helpful for inspection personnel to be familiar with the basis for the development of the HACCP plan which will be regulated under Title 9 Code of Federal Regulation (CFR) Part 417.

HACCP is a science based system designed to improve food safety. HACCP focuses on the "prevention" of food safety hazards. HACCP ensures that appropriate and effective measures are taken at each step in the process where a food safety hazard could be introduced or enhanced. HACCP focuses on 3 types of food safety hazards: biological, chemical, and physical.

The seven principles of HACCP, which encompass a systematic approach to the identification, prevention, and control of food safety hazards include:

1. Conduct a Hazard Analysis
2. Determine Critical Control Points
3. Establish Critical Limits
4. Establish Monitoring Procedures
5. Establish Corrective Actions
6. Establish Recordkeeping and Documentation Procedures
7. Establish Verification Procedures

Food Allergens

Food allergies are responses of the immune system to naturally occurring proteins in certain foods that most individuals can eat without any adverse effect. Frequently such reactions occur because the presence of the allergenic substances in the foods is not declared on the food label. Evidence indicates that some food allergens can cause serious reactions in sensitive individuals upon ingestion of very small amounts, therefore, the presence of an ingredient that contains an allergen must be declared on the product label. There is scientific consensus that the following foods can cause serious allergic reactions in some individuals and account for more than 90% of all food allergies.

Peanuts
Soybeans
Milk
Eggs
Fish
Crustacea
Tree nuts
Wheat gluten

Under the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA), under which FSIS operates, all ingredients used to formulate a meat, poultry, or egg product must be declared in the ingredients statement on product labeling. A product is ***misbranded*** under the Acts when it contains ingredients that are permitted, but are not declared on product labeling.

Manufacturers are responsible for ensuring that food is not adulterated or misbranded as a result of the presence of undeclared allergens. There may be situations where these substances are added intentionally to food, but not declared on the label. Other situations involve substances unintentionally introduced into a food product and consequently not declared on the label. When an allergen, not formulated in the product, is identified as likely to occur in the food due to the firms' practices (e.g., use of common equipment, production scheduling, rework practices), then you should determine if the establishment has identified and implemented controls to prevent potential allergen cross-contact, e.g., dedicated equipment, separation, production scheduling, sanitation, proper rework usage (like to like).

Relationship Between the HACCP Regulations and the Canning Regulations

417.2 (b) Hazard analysis
(3) HACCP plans for thermally processed/commercially sterile products do not have to address the food safety hazards associated with microbiological contamination if the product is produced in accordance with the requirements of part 318, subpart G, or 381, subpart X, of this chapter.

9 CFR 417.2(b)(3) states that HACCP plans for thermally processed/commercially sterile products do not have to address the food safety hazards associated with microbiological contamination if the product is produced in accordance with the requirements of 9 CFR 318, subpart G, or 9 CFR 381, subpart X (the canning regulations). "Canned product" is defined in 9 CFR 318/381.300(d) as a meat/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. When an establishment chooses to use the canning regulations instead of addressing the food safety hazards associated with microbiological contamination, the establishment needs to evidence this fact by documenting in its hazard analysis that food safety hazards associated with microbiological contamination are not reasonably likely to occur because it is following the applicable canning regulations.

In such cases, the canning regulations act as supporting documentation for the decision made in the hazard analysis that the food safety hazards associated with microbiological contamination are not likely to occur, as required in 9 CFR 417.5(a)(1). In those establishments that produce thermally processed/commercially sterile products and that do not address the food safety hazards in their HACCP plan, but address the hazards in the hazard analysis and determine that the hazards are not reasonably likely to occur, CSIs have the responsibility of verifying that the requirements of 9 CFR 318, subpart G, or 9 CFR 381, subpart X are met. These regulatory requirements must be met for inspection program personnel to determine that the decision made in the hazard analysis, and incorporated as part of the food safety system, is valid. Inspection program personnel verify the regulatory requirements of 9 CFR 318, subpart G, or 9 CFR 381, subpart X are met in the same way that they verify that the requirements of the Sanitation SOP regulations are met, when these regulations are used to support a decision in the hazard analysis.

When verifying the hazard analysis in a canning establishment, you should determine whether the establishment chose not to address food safety hazards associated with microbiological contamination in the canning process, based on the fact that they are producing the product in accordance with the canning regulations.

Note that the HACCP regulation §417.2(b)(3) only applies to food safety hazards associated with microbiological contamination. Chemical and physical hazards must still be addressed in the hazard analysis.

Verification of the Hazard Analysis

9 CFR 417.2(a)*—Hazard analysis. (1) Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment. A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product bring processed, in the absence of those controls. (2)A flow chart describing the steps of each process and product flow in the establishment shall be prepared, and the intended use or consumers of the finished product shall be identified. (3) Food safety hazards might be expected to arise from the following: (i) Natural toxins; (ii) Microbiological contamination; (iii) Chemical contamination; (iv) Pesticides; (v) Drug residues; (vi) Zoonotic diseases; (vii) Decomposition; (viii) Parasites; (ix) Unapproved use of direct or indirect food or color additives; and (x) Physical hazards.*

The hazard analysis is the key to an effective HACCP plan. If the hazard analysis is <u>not</u> conducted thoroughly so that the food safety hazards are completely identified, the HACCP plan will not be effective – regardless of how well it is implemented. The hazard analysis is used to create the list of food safety hazards reasonably likely to occur in the production process and identify preventive measures that can be applied to those hazards. This meets the first principle of HACCP and is used for the basis of the HACCP plan. The hazard analysis and HACCP plan are building blocks of the HACCP system. If the hazard analysis is flawed, the whole HACCP system will be flawed.

You should use the regulatory thought process and methodology when verifying the hazard analysis and HACCP plan. You should gather information by asking questions. Assess the information gathered and determine compliance. You will verify compliance by reviewing the flow chart, the hazard analysis, the HACCP plan, and HACCP records.

You must review hazard analysis records to determine if the analysis considered those properties that have a real chance of occurring in the food or in the processing of the food, and of causing the food to be unsafe. The hazards are those that would be identified by a reasonable consideration of the food, how it is processed, and where safety issues can arise. The fact that it is possible to imagine a hazard (e.g., a meteor may fall onto the plant) does not mean that the hazard is likely to occur or that the analysis must address that hazard. If you have concerns about whether the relevant hazards have been considered, you may discuss this with the establishment during the weekly meeting, with the PDD, or your District Office.

03A01 Procedure

You should verify that an establishment has performed a hazard analysis as part of basic compliance with the regulations (9 CFR 417.2(a)) during the performance of the **03A01 procedure**. You should conduct this procedure for any **new** establishment, or whenever an existing establishment adds a **new** HACCP plan. You can use the HACCP System—Basic Compliance checklist (FSIS Form 5000-1) to assist in assessing compliance with Part 417. Procedure 03A01 is also performed to verify the annual

reassessment and establishment training requirements, but only the one question related to the annual reassessment on the checklist is answered. More information for verifying these requirements is given in a later section.

Prerequisite Program - GMPs and SOPs

A prerequisite program is a procedure or set of procedures that is designed to provide basic environmental or operating conditions necessary for the production of safe, wholesome food. Some establishments may use prerequisite programs, such as Good Manufacturing Practices (GMPs) and/or Standard Operating Procedures (SOPs) to reduce the likelihood of certain hazards. The prerequisite program may be used by the establishment to support its decision that a hazard is not reasonably likely to occur. GMPs are minimum sanitary and processing requirements and SOPs are step-by-step directions for completing important procedures. GMPs are fairly broad and general and can be used to help guide the development of Standard Operating Procedures (SOPs), which are very specific. GMPs are not designed to control specific hazards, but are intended to provide guidelines to help establishments produce safe and wholesome products. SOPs, on the other hand, are very specific instructions for performing a procedure and may address a specific hazard. Sanitation SOPs (SSOPs) may be considered by establishments to reduce the likelihood of occurrence of some food safety hazards. For example, the SSOP may address washing and sanitizing of knife and hands between carcasses to reduce potential contamination with pathogens.

Based on the regulatory requirements of 9 CFR 417.2(a) and 417.5(a)(1), FSIS believes that the results of any testing and monitoring activities that are performed by the establishment that may have an impact on the establishment's hazard analysis, whether or not such testing or monitoring is incorporated into the actual HACCP plan, referenced in the HACCP plan or considered separate activities, are all subject to FSIS review and must be available to FSIS personnel upon request (refer to FSIS Directive 5000.2). You should be aware of all monitoring and testing conducted by the establishment and should ask establishment management to share the data that is generated by this monitoring and testing. When reviewing records, results, and supporting documentation associated with testing, monitoring, and verification activities that are from procedures or prerequisite programs outside the HACCP plans, you **should not** apply the same verification methodology as you would when verifying the regulatory requirements of HACCP plans. You should assess the overall effectiveness of the testing results and monitoring results to verify the overall effectiveness of the procedures or programs. You should verify that if there is information in the records that requires the establishment to reevaluate the effectiveness of the Sanitation SOPs or HACCP plan, the establishment has done so. If you have concerns about the design or results from testing, procedures or programs, you can contact the Policy Development Division (PDD) or an EIAO through supervisory channels. The EIAO may conduct a comprehensive food safety assessment in the establishment to verify that the design of the food safety systems in operation meet regulatory requirements.

If a hazard is judged reasonably likely to occur, the establishment must address the hazard with a CCP and **cannot** substitute a prerequisite program to control the hazard. Sometimes, however, an establishment determines that the hazard is not reasonably likely to occur, using the justification that a prerequisite program, properly implemented, is preventing the hazard from occurring. If the Consumer Safety Inspector determines that a prerequisite program is used as a justification for not addressing a hazard with a

CCP in the HACCP plan, the CSI should notify the District Office. These programs must be evaluated by a specially trained individual, such as an EIAO.

Verifying the Hazard Analysis

You should ask whether the establishment has considered and addressed the following questions when reviewing the hazard analysis.

1. Did the establishment conduct a hazard analysis or have one conducted for it?

2. Did the establishment's analysis start by identifying all hazards that may occur?

3. Does the hazard analysis identify preventive measures the establishment can apply to the food safety hazards?

4. Does the hazard analysis include a flow chart that describes (diagrams) the steps of each process and production flow in the establishment?

5. Does the hazard analysis identify the intended use or the consumers of the finished product?

6. Does the result of the establishment's hazard analysis reveal that one or more food safety hazards are reasonably likely to occur?

7. Does the establishment have a written HACCP plan for each of its products?

8. Has the establishment conducted validation activities to determine if a HACCP plan can function as intended?

   Note that Section 417.4(a)(1) provides more detail about the requirement for initial validation. "…The establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCPs, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan." Validation data for any HACCP plan must include some practical data or information reflecting an establishment's actual experience in implementing the HACCP plan. This is necessary because validation must demonstrate not only that the HACCP plan is theoretically sound, but also that the establishment can implement it and make it work on a day-to-day basis.

9. Do the establishment's records include multiple results that verify the monitoring of CCPs and conformance with critical limits?

10. Does the establishment have subsequent results that support the adequacy of corrective actions in achieving control at a CCP after a deviation from a critical limit has occurred?

You also verify that the establishment training requirement as prescribed in §417.7 is met when the establishment implements a **NEW** HACCP plan or hazard analysis during

the performance of procedure 03A01. At the next weekly meeting after the new plan is in place, you ask establishment management about the individual's training who developed the HACCP plan. Since documentation that the individual attended HACCP training is not required, you must use the gather, assess, and determine (GAD) thought process. Ask:

- Has the person who developed the HACCP plan successfully completed training that included instruction on the 7 principles of HACCP?
- Did the training include a segment on the development of a HACCP plan for a specific product?
- Did the training include a segment on the review of records?

Document the discussion from the weekly meeting with establishment management in Memorandum of Interview (MOI). Give a copy of the MOI to establishment management and keep a copy in the government file. If the establishment used an individual that does not have the training prescribed in §417.7 to develop its HACCP plan, there is noncompliance. This noncompliance is documented on an NR under the 03A01 procedure entering the "m" noncompliance result code on the procedure schedule.

When basic noncompliance is identified while conducting the 03A01procedure, you must know the appropriate regulatory actions to take. Whenever new federally inspected meat or poultry plants come under inspection or when a plant creates **a new HACCP plan that has not yet been in operation**, the following actions are appropriate if basic noncompliance is identified while performing procedure 03A01.

1. The basic compliance checklist is completed. This document is to be attached to the copy of the NR filed in the inspection office.
2. An NR is generated under procedure code 03A01 using the "m" noncompliance result code.
3. The establishment is not permitted to start the production of products under the noncompliant HACCP plan. In these situations, FSIS should not let the plant even start the production. The District Office should be notified of this action.
4. If the establishment has not yet received the grant of inspection, it is not under PBIS and no NR is issued. In this instance, the grant of inspection is withheld.

Workshop: Hazard Analysis

Refer to the module and to FSIS Directive 5000.1 to complete the following questions.

1. When should you perform 03A01?

2. If a hazard is determined by the establishment to be likely to occur, can the establishment use a prerequisite program to control the hazard?

3. Under what circumstance may a canning establishment choose not to address food safety hazards associated with microbiological contamination in its hazard analysis? What would you expect to see in the hazard analysis in this case?

Scenario

You review the following hazard analysis from a dry salami processing establishment.

Process Step	Food Safety Hazard	Likely to occur?	Basis	Preventive measures	CCP
Raw meat storage	B – Pathogens *Salmonella* *Listeria monocytogenes* *E. coli O157:H7* C – none P – none	No	Pathogens present in meat may grow if temperature not properly maintained.	Temperature control program Pathogens will be controlled at subsequent step through heating and drying	No

What would you do next?

Regulatory Process for 01 And 02 Procedures

In the remainder of this document, we will cover the regulatory process for HACCP procedures by following the blocks as depicted by the **diagram** on the next page. There are four main processes that we will cover.

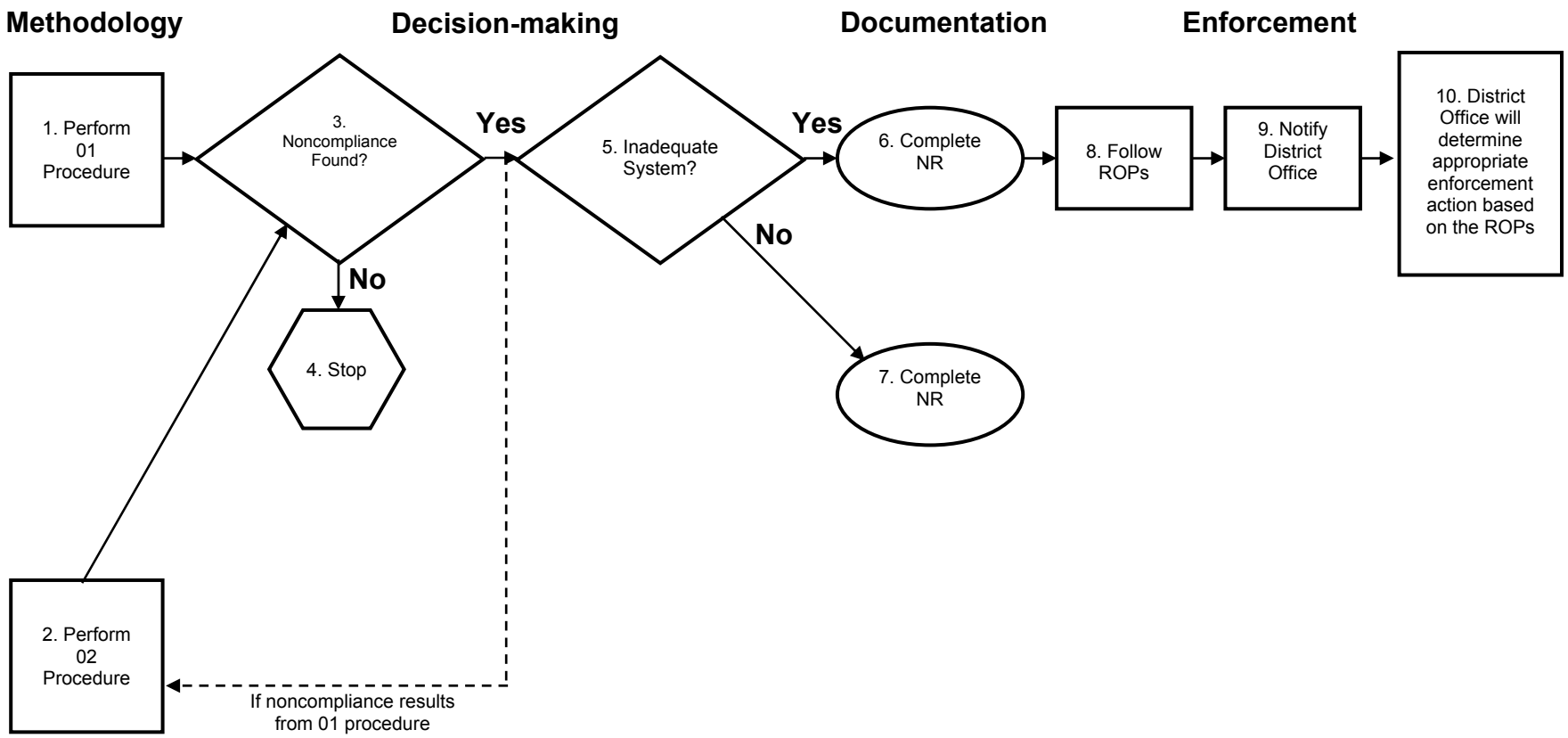
- **Methodology**
- **Decision-making**
- **Documentation**
- **Enforcement**

FSIS Responsibilities

FSIS responsibilities are outlined in **FSIS Directive 5000.1, Revision 1.** You are responsible for understanding and properly performing the procedures as described in this Directive. The information in the Directive follows the regulatory process. The Directive is the foundation for the remainder of this training.

Let's review what is covered in the Directive for HACCP verification. This includes verification methodology, which is the HACCP 01 and 02 procedures. Next is a discussion of how to perform verification of the establishment's hazard analysis. Then, the Directive covers how to perform verification of the monitoring, verification, recordkeeping, corrective action and reassessment requirements

Regulatory Process for 01 and 02 Procedures



Verification Methodology

HACCP 01 and 02 procedures are performed by FSIS personnel to verify that establishments are complying with Part 417. You will focus on the execution or implementation of the HACCP plan when performing your verification procedures.

The Five Regulatory Requirements

There are five regulatory requirements that the establishment must comply with during the day-to-day or ongoing operation of the HACCP system. The regulatory requirements are:

1. **Monitoring**
2. **Verification**
3. **Recordkeeping**
4. **Corrective Actions**
5. **Reassessment**

You will use the 01 and 02 procedures to verify that the establishment complies with these five regulatory requirements.

Remember that based on 9 CFR 417.2(b)(3), establishments may elect to use the canning regulations as the method of controlling for microbiological hazards in their food safety system. When this is the case, and the establishment identifies physical or chemical hazards in their hazard analysis, they will have a HACCP plan to address these hazards. Inspection personnel will verify the part of the establishment's food safety system addressed in its HACCP plan to control the physical and chemical hazards as described in this section of the training. Inspection personnel must also verify the part of the establishment's food safety system addressed by the canning regulations. We will cover the verification procedures related to the canning regulations in another section of this training. If the establishment elects to address microbiological hazards in its HACCP plan, inspection personnel will verify those controls as described in this section of the training.

01 and 02 HACCP Procedures

The 01 and 02 HACCP procedures are performed by inspection personnel to verify ongoing compliance with the regulatory requirements of 9 CFR Part 417 as the establishment executes its HACCP plan. The number of HACCP plans and the number of products produced within a processing category has no impact on the number of HACCP procedures that are scheduled for that process. The HACCP 01 and 02 procedures can be performed as scheduled or unscheduled procedures. Each of these procedures has two components:

- **recordkeeping component, and**
- **review and observation component.**

In most instances, you will use one of these components. There may be occasions when you use both. For example, you may choose to perform recordkeeping at one CCP and review and observation at another CCP. Or, you may observe something during recordkeeping that may prompt you to perform a review and observation of that CCP.

How to Perform the Two Components

►Recordkeeping

To perform the **recordkeeping** (Rk) component, you will review HACCP records to determine if the establishment recorded its tests or measurements at the required frequency, if all required data was recorded, if the data is accurate, if critical limits have been met, and if corrective action was taken when necessary. When you perform the recordkeeping component you are only reviewing records. Typically this review would take place where the records are maintained and may not be at the physical location of the CCP.

Example: *You are performing an 01 procedure and are verifying a monitoring procedure. You decide to perform the recordkeeping component. You examine the records associated with this monitoring procedure. You look at the frequency of the entries and the data recorded, and compare the recorded data to the critical limit at this step.*

►Review and Observation

To perform the **review and observation** (R&O) component, you may directly observe plant employees performing the procedures as stated in the HACCP plan (observation) or you may take measurements to see if the values you obtained match those recorded by the establishment (review).

Example: *You are performing an 01 procedure and are verifying a monitoring requirement, which in this case is a product temperature check. You decide to perform both parts of the review and observation component. You directly observe the plant employee carry out the product temperature check. Then, you take a product temperature measurement, and compare the result that you obtained to the one just recorded by the plant employee.*

01 Procedure

The 01 procedure is for verifying one or more of the HACCP regulatory requirements as the establishment executes its HACCP plan. The 01 procedure is designed to provide a "snapshot" of the HACCP system.

There are three requirements that are **randomly** verified during the 01 procedure: monitoring, verification, and recordkeeping. Corrective actions and reassessment are not randomly verified as part of the 01 procedure since they are performed as a result of some event that triggers them. For example, you would verify the corrective action requirements are met anytime there is a deviation from a critical limit, a deviation not covered by a specific corrective action, or an unforeseen hazard. Similarly, you would verify the reassessment requirement if the establishment significantly changes its process, or encounters an unforeseen hazard.

You must have a method to randomly select one (or more) of the three requirements to be verified during the performance of the procedure. For example, you may choose to draw pieces numbered one through three from a container. You can use your FSIS computer to select random numbers. See Appendix 1 for instructions.

*To perform the **01** procedure, you will do the following:*

1. **Randomly** select one (or more) of the three HACCP requirements to verify.

2. Select a HACCP plan and one (or more) of the CCPs from that plan to verify.

3. Determine which component (review and observation or recordkeeping) to perform.

4. Review those portions of the HACCP plan you are to verify and perform the verification for **that requirement** for **that CCP.**

01 Example: *Your PS for today lists 03F01. The establishment to which you are assigned has one HACCP plan in this processing category, for turkey jerky. You read the HACCP plan to be familiar with the CCPs. This HACCP plan has 3 CCPs. You decide to pick 1 regulatory requirement to verify. You have a die and a previously determined procedure that 1&2 represent monitoring, 3&4 represent verification, and 5&6 represent recordkeeping. You roll and get a 2 (monitoring), and make a note of this result. You decide to verify this requirement at CCP 3 of the HACCP plan. Next, you think about which component to perform, and decide to perform the review and observation component. You read the monitoring part of CCP 3 in the HACCP plan. You proceed to the processing floor to begin to perform the review and observation component to verify the monitoring regulatory requirements at CCP 3 for the turkey jerky.*

If the establishment had more than one HACCP plan in this processing category, you might pick one HACCP plan to verify regulatory compliance. You might also decide to verify regulatory compliance with a requirement, monitoring for this example, for more than one HACCP plan.

Note: If you determine noncompliance while performing the 01 procedure, you must then perform the 02 procedure.

02 Procedure

The 02 procedure is for verifying **all regulatory requirements** at all of the critical control points in the HACCP plan for a **specific production**. The 02 procedure cannot be completed until the establishment performs the pre-shipment review for that specific production. Because 02 procedure looks at a specific production, you are additionally determining whether the establishment prevented the distribution of adulterated product.

Note: You should follow-up on any 01 procedure that results in a noncompliance determination by performing an 02 procedure on that specific production.

Specific production is a term that is used to refer to whatever method the establishment uses to group product. FSIS does not determine the method used to define specific production, this is an establishment's responsibility. You will see a variety of different types of methods used. Establishment's might define all product from one formulation batch, one shift's production, or the product in one retort as a specific production. It is important for you to understand the method used by the establishment to which you are assigned. You can determine this by asking plant management.

There may be times when you are not able to finish reviewing the entire process on the day that the 02 procedure is begun. In this case you should mark the Procedure Schedule as "not performed" on the day that you start your review. When you have completed the review, you need to record on the Procedure Schedule that you completed the 02. If that particular 02 procedure is already scheduled on that day, then mark it according to your determination of compliance/noncompliance. If that particular 02 is not assigned on the day your review is completed, then document the 02 as unscheduled on the Procedure Schedule.

*To perform the **02** procedure, you will do the following:*

1. Verify that **all** of the HACCP requirements have been met for **all CCPs** in the HACCP plan for that **specific production**. Read each CCP that applies to specific production from the appropriate HACCP plan.

2. Verify that the **pre-shipment review** requirement for that specific production has been met.

***02 Example**: Your PS for today lists 03E02. This establishment has one HACCP plan in this processing category, salami sticks. You know from previous experience that this establishment defines specific production as each day's production lot. The establishment performs pre-shipment review each morning on the production lots which pass the final CCP, drying. This may take between 4-5 weeks. You proceed to the HACCP office and determine that one production lot passed the drying CCP today. You read the HACCP plan. You begin your verification that all of the HACCP requirements were met for all of the CCPs in the HACCP plan for this specific production, including the pre-shipment review. You will use the recordkeeping component in this case because production is complete.*

The following table summarizes the concepts we have just covered regarding the 01 and 02 HACCP procedures.

HACCP Procedures – Components Used and Requirements Verified

	COMPONENTS USED BY THE CSI	HACCP REGULATORY REQUIREMENTS VERIFIED
01	• Recordkeeping and/or • Review & Observation	**One or more** of the three regulatory requirements—randomly selected at **one or more CCPs.** Corrective Action and Reassessment can be verified using 01 but not randomly.
02	• Recordkeeping and/or • Review & Observation	**All** of the regulatory requirements for **all CCPs**, including the pre-shipment review for a specific production.

Note: We will discuss the performance of the 01 and 02 procedures in a canning establishment in more detail in a later section of this training.

Workshop: Verification Methodology

Refer to the module and to FSIS Directive 5000.1 to complete the following questions.

1. Which HACCP procedure is performed to verify all of the HACCP requirements for all CCPs in a HACCP plan for a specific production?

2. Which HACCP procedure is performed to verify one or more of the HACCP requirements for one or more CCP in a HACCP plan?

3. What are the two components of HACCP procedures (01 and 02)

4. Why can you **not** randomly verify the corrective action and reassessment requirements?

5. When you determine noncompliance during performance of a HACCP 01 procedure, what should be triggered?

Verifying Compliance with the Five Regulatory Requirements

This section covers how to verify regulatory compliance and make supportable decisions when performing the HACCP 01 and 02 procedures. The requirements are monitoring, verification, recordkeeping, corrective action, and reassessment. Below is a chart with the five HACCP requirements, regulatory references, and the procedures and components utilized in verifying compliance.

Requirement	Regulatory References	Pro-cedure	Com-ponent
Monitoring	417.2(c)(4) Monitoring Requirement	01 or 02	Rk R&O
Verification	417.2(c)(7) Verification Requirement 417.4(a)(2)(i)(ii)(iii)Verification Activities	01 or 02	Rk R&O
Recordkeeping	417.2(c)(6) Recordkeeping System	01 or 02	Rk
	417.5(a)(1)(2) Supporting Documentation For canning establishments also 318/381.300-311	01 (02[1])	Rk
	417.5(a)(3) HACCP Records	01 or 02	Rk
	417.5(b) Records Authenticity	01 or 02	Rk R&O
	417.5(d) Computerized Records	01 or 02	Rk
	417.5(e)(1)(2) Record Retention and Availability	01 or 02	Rk
	417.5(c) Pre-shipment Review	02	Rk R&O (on occasion)
Corrective Action	417.3(a) Deviation from a critical limit 417.3(b) Deviation not covered by a specified corrective action/unforeseen hazard	01[2] or 02	Rk R&O
Reassessment	417.3(b)(4) Deviation not covered by a specified corrective action/unforeseen hazard 417.4(a)(3) Annual Reassessment[3] or Changes in Plant Processes 417.4(b) Hazard Analysis Reassessment	01[2] or 02	Rk

[1] Product acceptability or disposition could be verified using the 02 procedure.
[2] Corrective actions and reassessment can be verified through 01 but not randomly.
[3] Annual Reassessment will be verified with the 03A01 procedure.

Regulatory References for Verifying the Five HACCP Requirements

Monitoring

417.2(c)4 - List the procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

Verification

417.2(c)7- List the verification procedures, and the frequency with which those procedures will be performed, that the establishment will use in accordance with Sec. 417.4 of this part.

417.4(a)2(i)(ii)(iii)- Ongoing verification activities -Ongoing verification activities include, but are not limited to: (i) The calibration of process-monitoring instruments; (ii) Direct observations of monitoring activities and corrective actions; and (iii) The review of records generated and maintained in accordance with Sec. 417.5(a)(3) of this part.

Recordkeeping

417.2(c)(6) Recordkeeping System -Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

417.5(a)(1)(2) Supporting Documentation -(a) The establishment shall maintain the following records documenting the establishment's HACCP plan:
(1) The written hazard analysis prescribed in Sec. 417.2(a) of this part, including all supporting documentation;
(2) The written HACCP plan, including decision-making documents associated with the selection and development of CCP's and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.

417.5(a)(3) HACCP Records - Records documenting the monitoring of CCP's and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot. Each of these records shall include the date the record was made.

417.5(b) Records Authenticity - Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the date and time recorded, and shall be signed or initialed by the establishment employee making the entry.

417.5(d) Computerized Records - Records maintained on computers. The use of records maintained on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

417.5(e)(1)(2) Record Retention and Availability -(1) Establishments shall retain all records required by paragraph (a)(3) of this section as follows: for slaughter activities for at least one year; for refrigerated product, for at least one year; for frozen, preserved, or shelf-stable products, for at least two years.
(2) Off-site storage of records required by paragraph (a)(3) of this section is permitted after six months, if such records can be retrieved and provided, on-site, within 24 hours of an FSIS employee's request.

417.5(c) Pre-shipment Review - Prior to shipping product, the establishment shall review the records associated with the production of that product, documented in accordance with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by someone trained in accordance with Sec. 417.7 of this part, or the responsible establishment official.

Corrective Actions

417.3(a) - The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure:
(1) The cause of the deviation is identified and eliminated;
(2) The CCP will be under control after the corrective action is taken;
(3) Measures to prevent recurrence are established; and
(4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.

417.3(b) - If a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment shall:
(1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met;
(2) Perform a review to determine the acceptability of the affected product for distribution;
(3) Take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce;
(4) Perform or obtain reassessment by an individual trained in accordance with Sec. 417.7 of this part, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.

Reassessment

417.3(b) Deviation not covered by a specified corrective action/unforeseen hazard - If a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment shall: Perform or obtain reassessment by an individual trained in accordance with Sec. 417.7 of this part, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.

417.4(a)(3) Reassessment of the HACCP plan. -Every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging; finished product distribution systems; or, the intended use or consumers of the finished product. The reassessment shall be performed by an individual trained in accordance with Sec. 417.7 of this part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of Sec. 417.2(c) of this part.

417.4(b) Reassessment of the hazard analysis -Any establishment that does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur shall reassess the adequacy of the hazard analysis whenever a change occurs that could reasonably affect whether a food safety hazard exists. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; packaging; finished product distribution systems; or, the intended use or consumers of the finished product.

Monitoring

The regulation that applies to monitoring is:

9 CFR 417.2(c)(4)*—List the procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits*

You will verify the monitoring requirement by performing the HACCP 01/02 procedures. You could use either the recordkeeping or review and observation component, or both.

The thought process you should use when verifying regulatory requirements includes:

- gathering information by asking questions;
- assessing the information; and
- determining regulatory compliance.

This thought process should be utilized when verifying all of the regulatory requirements.

Gather information by asking questions

Verify the regulatory requirements for monitoring by reviewing the HACCP plan, reviewing HACCP records, observing establishment employees performing monitoring activities, and taking measurements at CCPs. When verifying the monitoring requirements, seek answers to the following questions.

1. Does the HACCP plan list the monitoring procedures and frequencies that are used to monitor each of the critical control points to ensure compliance with the critical limits?

2. Are the monitoring procedures being performed as described in the HACCP plan?

3. Are the monitoring procedures being performed at the frequencies for the CCPs listed in the HACCP plan?

4. Are the critical limits met?

Assess the information

To answer these questions you should:

- Review the HACCP plan

- Review the HACCP monitoring records

- Observe the establishment employees perform monitoring activities

- Take measurements at critical control points

Now let’s review each of these activities in detail.

Reviewing the HACCP Plan

When reviewing the establishment's HACCP plan you will determine whether it includes the monitoring procedures and frequencies that are used to monitor each critical control point. It is very important for you to be familiar with the monitoring procedures and frequencies in the current HACCP plan. You should review the HACCP plan each time the monitoring requirement is verified since the establishment can modify the plan without notifying inspection.

***Monitoring Example 1**: You are performing the 03D01 procedure at a canning facility and have randomly selected to verify the monitoring requirement for the metal detection CCP for the Vienna sausage product. You review the establishment's HACCP plan and find that it specifies monitoring personnel will observe that the metal detector is functioning as designed by passing the seeded sample through the metal detector and observing that the metal detector properly detects and rejects the seeded sample. The plan states that this monitoring procedure is to be performed hourly and results recorded. Based upon your review of the plan, you decide the monitoring procedures and frequencies for this CCP are included in the HACCP plan.*

Reviewing HACCP Monitoring Records

You may decide to use the recordkeeping component to verify the monitoring requirement to determine if the establishment is performing the monitoring procedures at the frequency specified in the HACCP plan.

***Monitoring Example 2:** You are performing the 03F01 procedure at a dry sausage establishment and have randomly selected to verify the monitoring requirement for the fermentation CCP, using the recordkeeping component. The HACCP plan states that the pH of 3 pieces from each smokehouse will be measured at the completion of the fermentation cycle. Reviewing yesterday's record in the HACCP office, you find that monitoring personnel have recorded pH for 3 pieces from each smokehouse prior to initiating the cook cycle as per the HACCP plan for this CCP. You determine that the establishment's monitoring frequency for this CCP is in compliance. You have also verified that the critical limits were met.*

Observing Establishment Employees

You should observe an establishment employee performing HACCP monitoring activities to determine whether the procedures are being carried out as written in the HACCP plan.

***Monitoring Example 3:** You are performing the 03F01 procedure at a dry sausage establishment, you decide to perform the review and observation component as part of your verification of the monitoring requirements for the pH CCP. The HACCP plan states that the pH of 3 pieces from each smokehouse will be measured at the completion of the fermentation cycle. You observe the establishment monitoring personnel as they use the pH meter to determine pH for each of 3 pieces from one smokehouse and document the results on the monitoring records. From your observation, you determine that the*

establishment is in compliance with the monitoring procedure as it is described in the HACCP plan.

Taking Measurements at Critical Control Points

You may also take measurements at certain critical control points in the process.

Monitoring Example 4: *You are performing the 03F01 procedure at a dry sausage establishment and have randomly selected to verify the monitoring requirement for the cooking CCP. You proceed to the cooking unit area and observe that a batch is near the end of the cook cycle. You take a temperature of product when it is removed from the cooking unit. You then compare your temperature reading with the temperature that was recorded by the establishment monitoring personnel. You determine that the establishment is in compliance because your temperature reading is within the critical limit and compares with the reading as recorded by establishment monitoring personnel.*

Determine compliance

After you have gathered and assessed all available information pertaining to the monitoring requirement, you must determine regulatory compliance. If you find that the establishment has met all monitoring regulatory requirements, then there is no regulatory noncompliance. If you find that the establishment has not met all monitoring regulatory requirements, there is noncompliance. You will receive more information about making compliance determinations in a later section.

Noncompliance with the Monitoring Requirement

The following are examples of noncompliance with the monitoring requirement.

1. *The HACCP plan specifies that monitoring personnel will check the pH of 4 pieces of summer sausage from each smokehouse prior to initiating the cook cycle. The HACCP plan states that 2 pieces will be randomly selected from the front racks, and 2 pieces will be randomly selected from the rear racks. You observe that the smokehouse operator takes all 4 pieces only from the front racks.* ***The establishment is not conducting the monitoring procedures as specified in the HACCP plan.***

2. *The HACCP plan specifies that the surface temperature of 3 pieces of packaged, sliced product exiting the post lethality steam tunnel will be monitored hourly by establishment personnel and recorded. You review the record and find that the monitoring checks were recorded every 2 hours. Upon further inquiry, you determine that the monitoring checks were actually being performed every 2 hours.* ***The establishment is not performing the monitoring procedures at the frequencies specified in the HACCP plan.***

3. *The HACCP plan specifies that the temperature inside the post lethality steam tunnel will be maintained at a minimum of 180°F at the center of the tunnel. You observe the temperature gauge on the side of the equipment and find that it reads 177°F.* ***The critical limit for the CCP is not met.***

You will document any noncompliance in accordance with our discussion of documentation and enforcement in a later section.

Workshop: Monitoring

Refer to the module and to FSIS Directive 5000.1 to complete the following questions.

1. You are performing procedure 03D01 at a canning establishment which produces baby food in glass jars. The establishment has a HACCP plan which addresses one CCP, which is controlling the identified physical hazard of glass fragments. The establishment addresses microbiological hazards by compliance with the canning regulations. You review the HACCP plan.

HACCP plan: baby food					
CCP	**Critical Limits**	**Monitoring Procedures & Frequencies**	**HACCP Records**	**Verification Procedures & Frequencies**	**Corrective Actions**
Physical, glass fragments	Functional x-ray machine	Seeded sample run through x-ray equipment hourly.	x-ray log	Observe monitor perform the procedure once per shift Review record once per shift Check calibration of the x-ray equipment prior to the beginning of each shift and once during shift	417.3

You have decided to verify compliance by performing the review and observation component. You observe the monitor run the seeded sample through the x-ray equipment, which rejects the sample appropriately.
You review the x-ray log.

X-ray log			Date: 5-12-05
Time	Monitor	Results	Verification
			Checked calibration, operating within specifications 7:12 a.m. CC
7:30 am	HW	Correct operation	
8:04 am	HW	Correct operation	
8:32	HW	Correct operation	
9:00 am	HW	Correct operation	MP, direct observation. Results: performed monitoring according to procedure
9:22 am	HW	Correct operation	
10:02 am	HW	Correct operation	
10:37 am	HW	Correct operation	

What do you determine regarding compliance?

2. You are performing the 03E01 procedure and have selected to verify the monitoring regulatory requirement for the dry rubbed country cured ham at CCP2, drying. The HACCP plan lists a critical limit of "time in dry room at least 60 days, and no greater than 80% yield". You decide to use the review and observation component, and proceed to the drying room area. You check the records and see that lot xyz has been in the drying room for 60 days. You observe an employee take weights and perform a yield calculation. You review the results of the calculation and observe that the employee calculated an 81% yield for lot xyz.

What do you determine regarding compliance?

What actions do you take?

3. You are performing an 03F01 procedure and have selected to verify the monitoring requirement. You review the HACCP plan.

HACCP plan: Beef Sticks, Heat Treated, Shelf-stable			
CCP #	**Critical Limits**	**Monitoring Procedures & Frequencies**	**HACCP Records**
2. Lethality	≥158°F	Select 3 beef sticks at the specified cold spot, measure the internal temperature with a thermocouple thermometer and record the lowest temp.	Lethality log Corrective action log Calibration log

What do you determine regarding compliance?

Verification

Verification activities are tools the establishment uses to ensure that the HACCP plan is being followed correctly.

The regulations that apply to verification procedures and frequencies are:

9 CFR 417.2(c)(7)—*List the verification procedures, and the frequency with which those procedures will be performed, that the establishment will use in accordance with §417.4 of this part.*

9 CFR 417.4(a)(2)(i)(ii)(iii)—*Ongoing verification activities include, but are not limited to: The calibration of process-monitoring instruments; direct observations of monitoring activities and corrective actions; and the review of records generated and maintained in accordance with §417.5(a)(3) of this part.*

You will verify the verification requirement by performing the HACCP 01/02 procedures. You could use either the recordkeeping or review and observation component, or both.

The thought process you should use when verifying regulatory requirements includes:

- gathering information by asking questions;
- assessing the information; and
- determining regulatory compliance.

This thought process should be utilized when verifying all of the regulatory requirements.

Gather information by asking questions

Verify the regulatory requirements for verification by reviewing the HACCP plan, HACCP records, and observing establishment employees performing verification activities. When verifying the verification requirements, seek answers to the following questions.

1. Does the HACCP plan contain procedures and frequencies for the calibration of the process-monitoring instruments?

2. Does the HACCP plan contain procedures and frequencies for direct observations of monitoring activities and corrective actions?

3. Does the HACCP plan list procedures and frequencies for the review of records generated and maintained in accordance with 9 CFR 417.5(a)(3)?

4. Does the HACCP plan list product sampling as a verification activity?

5. Are process-monitoring instrument calibration activities conducted as per the HACCP plan?

6. Are direct observation verification activities conducted as per the HACCP plan?

7. Are records generated in accordance with 9 CFR 417.5(a)(3) [HACCP records] being reviewed by the establishment?

Assess the information

To answer these questions you should:

- Review the HACCP plan
- Review HACCP records
- Observe establishment employees performing verification activities

Now let's look at each of these activities in more detail.

Reviewing HACCP Plan

When reviewing the establishment's HACCP plan, you will determine whether it includes verification procedures such as direct observation procedures and frequencies, records review procedures and frequencies, and process monitoring instrument calibration procedures and frequencies. **All three verification activities do not have to occur at each CCP, but all three should be addressed in the HACCP plan.** You should review the HACCP plan each time the verification requirement is verified since the establishment can modify the plan without notifying inspection.

Verification Example 1: *You are performing the 03F01 procedure in a beef jerky operation and have randomly selected to verify the establishment verification requirements for the water activity (a_w) CCP. You review the establishment's HACCP plan and find that it specifies quality control personnel will review the water activity records and observe the monitoring procedures at this CCP once per shift. It also specifies that quality control personnel will verify the accuracy of the water activity measuring equipment once per shift by performing a calibration check procedure. Based upon your review of the HACCP plan, you determine that the establishment is in compliance with* ***this part*** *of §417.2(c)(7) and §417.4(a)(2)(i)(ii)(iii).*

It is important to point out here that some HACCP plans might not contain all three verification activities that are found in §417.4(a)(2)(i)(ii)(iii).

Verification Example 2: *You are performing the 03E01 procedure at a very small establishment which makes dry sausage, and have randomly selected to verify the establishment verification requirements for the water activity CCP. You review the establishment's HACCP plan and find that it does not provide for direct observation of monitoring procedures. You determine that the establishment only has one employee working in the production area and it would be impossible for direct observation of monitoring to take place. There is no noncompliance with §417.4(a)(2)(ii) in this instance.*

Reviewing HACCP Verification Records

You should review the verification records to determine if the establishment is performing the verification procedures at the frequency specified in the HACCP plan.

Verification Example 3: *You are performing the 03F01 procedure in a dry sausage operation and have randomly selected to verify the verification requirements for the addition of antimicrobial agent at the formulation CCP, using the recordkeeping component. You review the establishment's HACCP plan and find that* ***one*** *of the verification procedures specifies the HACCP Coordinator will observe production personnel perform the monitoring check once per shift. You review several recent formulation logs and observe that the HACCP Coordinator has recorded results for the verification procedure for each shift. You determine that this requirement is in compliance because this verification procedure is being performed at the frequency specified in the HACCP plan. You realize that this is just one of the verification activities.*

Observing Establishment Employees

You should observe an establishment employee performing the verification activities listed in the plan to determine if the procedures are being carried out as written in the HACCP plan.

Verification Example 4: *You are performing the 03E01 procedure in a pepperoni operation. Your review of the establishment's HACCP plan reveals that one of the verification procedures specified is that the HACCP Coordinator will check the accuracy of the raw product storage temperature monitoring equipment daily, and calibrate as necessary. You proceed to the HACCP office, and observe the thermometers being checked for accuracy, and results being recorded on the thermometer calibration log. You determine that this requirement is in compliance because* ***this*** *verification procedure is being carried out as written in the HACCP plan.*

Keep in mind that the establishment employee performing the direct observation ongoing verification procedure should directly observe the employee doing the monitoring activity. An establishment verifier that is performing the same activity as the monitor does not meet the regulatory requirement in §417.4(a)(2)(ii).

Verification Example 5: *As part of the 03F02 procedure, you decide to observe the direct observation verification procedure. You accompany the HACCP Coordinator to the packaging area, and watch while he observes the packaging personnel performing the monitoring check at the post lethality treatment CCP, and records the result. You determine that the direct observation verification procedure requirements are met.*

Product sampling is considered a verification activity if the establishment incorporates it as such into the HACCP plan. It may be used to verify a CCP or it may be used as an overall verification of the HACCP system and not be associated with any one CCP. For example, a dry sausage establishment may include a laboratory testing program for *E. coli* O157:H7 in its HACCP plan as a verification for a particular CCP. When that is the case, you must verify the testing program as part of the verification requirement (§417.4(a)(2)). Another establishment might include an end-product sampling and

laboratory testing program for *Salmonella* as an overall verification for a beef jerky HACCP plan. This verification is not associated with a single CCP, but it is considered to be an overall verification of all the CCPs from the HACCP plan. You should observe the establishment employee collecting samples and following all the procedures identified in the plan as part of the HACCP 01 and 02 procedures when verifying §417.4(a)(2).

Verification Example 6: *You are performing the 03F01 procedure in a beef jerky operation and have randomly selected to verify the establishment verification requirements for the finished product water activity CCP. You review the establishment's HACCP plan and find that as a verification of the* a_w*, one of the verification procedures specifies the establishment will conduct finished product testing for* Salmonella *daily. You observe the HACCP Coordinator take the samples from the finished product. You review several days' records in the laboratory testing log and find negative test results were recorded for each day. You determine that the establishment is in compliance because this verification procedure is being performed at the frequency and using the procedure stated.*

Determine compliance

After you have gathered and assessed all available information pertaining to the verification requirement, you must determine regulatory compliance. If you find that the establishment has met the verification regulatory requirements, then there is no regulatory noncompliance. If you find that the establishment has not met the verification regulatory requirements, there is noncompliance. You will receive more information about making compliance determinations in a later section.

Noncompliance with the Verification Requirement

The following are examples of noncompliance with the verification requirement.

1. *The HACCP plan, which has one CCP, at cooking, specifies that the verification procedure is that the QC supervisor will calibrate thermometers daily and that the QC supervisor will review the cooking logs daily. You observe that there is no direct observation verification procedure listed. You recall that the regulations require that all three verifications must be addressed in the HACCP plan.* ***The HACCP plan does not list direct observation verification procedures.***

2. *A beef jerky HACCP plan specifies that the verification procedure for the cooking/drying CCP is that QC will check the accuracy of the time, temperature and humidity monitoring equipment and have them calibrated if necessary; QC will observe the cook room operator performing the monitoring check daily; and that QC will review the cooking logs daily. You observe that there is no frequency listed for the calibration check of equipment.* ***The HACCP plan does not list the frequencies at which the calibration verification procedure will be performed.***

3. *The HACCP plan specifies that one of the verification procedures for the cooking CCP is that the QC supervisor will observe the plant employee performing the monitoring check. You observe that the QC supervisor performs a monitoring check and records it on the cooking log as a direct observation verification procedure. You observe that the QC supervisor did not perform a direct observation of the plant employee performing the monitoring check as described in the HACCP plan.* ***The establishment is not performing the direct observation verification procedures as specified in the HACCP plan.***

4. *The HACCP plan specifies that one of the verification procedures for the metal detection CCP is that the QC supervisor will review the metal detection logs daily. Your review of the records reveals that there is no documentation of this verification procedure for the last three days of production.* ***The establishment is not performing the records review verification procedures as specified in the HACCP plan.***

5. *The HACCP plan specifies that one of the verification procedures for the fermentation/cooking CCP is that the QC supervisor will verify the accuracy and calibrate all three production pH meters once per shift. You observe that the QC supervisor verifies the accuracy of only of one of the pH meters in use.* ***The establishment is not performing the process monitoring equipment verification procedures as specified in the HACCP plan.***

6. *The HACCP plan specifies that one of the verification procedures is that finished product will be sampled and tested for* Listeria monocytogenes *once per day. When you review the micro records, you observe that there are only results for one sample a week.* ***The establishment is not performing one of the verification procedures listed in the HACCP plan at the frequencies specified in the HACCP plan.***

You will document any noncompliance in accordance with our discussion of documentation and enforcement in a later section.

Workshop: Verification

Refer to the module and to FSIS Directive 5000.1 to complete the following questions.

1. You are performing the 03F01 procedure in a dry and semi-dry products operation and have randomly selected to verify the establishment verification requirements for the drying CCP. You proceed to the QC office and review the establishment's HACCP plan:

HACCP plan: beef jerky

CCP #	Critical Limits	Monitoring Procedures & Frequencies	HACCP Records	Verification Procedures & Frequencies	Corrective Actions
3 – Drying	Water activity not to exceed 0.80	QC personnel will measure and record water activity from three 4 oz samples (composite sample) randomly selected from each lot of product at end of drying cycle using a water activity meter	Drying log Corrective action log Water activity meter calibration log	HACCP Coordinator will review the Drying log and observe QC personnel performing monitoring once per shift QC personnel will check measuring devices for accuracy by following manufacturers instructions (copy posted by machine), and will verify to within .001 unit daily, results recorded in water activity meter calibration log Any water activity meter found to be inaccurate will be calibrated by returning to manufacturer.	Corrective actions shall meet all requirements of Part 417.3(a)

a. How would you determine whether process-monitoring calibration activities were being conducted as per the HACCP plan?

If you perform the review and observation component:

If you perform the recordkeeping component:

b. How would you determine whether direct observation verification activities were being conducted as per the HACCP plan?

If you perform the review and observation component:

If you perform the recordkeeping component:

c. How would you determine if records generated in accordance with 9 CFR 417.5(a)(3) were being reviewed by the establishment?

If you perform the review and observation component:

If you perform the recordkeeping component:

You request the water activity meter calibration logs and the drying (a_w) logs.

Water Activity Meter Calibration Log			**Check accuracy at 0.800 per lab procedure WAM**		
Meter ID #	Test Reading	Adjustment Required?	Date	Time	Initials
WAM1	0.800	No	1-2-05	6:05 am	*CC*
WAM2	0.800	No	1-2-05	6:10 am	*CC*

Drying Log	**Critical limit 0.80 or below**				**Date:** 1-2-05
Time	Lot	A_w	Initials	Comments	Verification
6:20 am	BJ810A	.750	*GH*		
7:30 am	BJ810B	.740	*GH*		*Direct observation, monitoring done according to HACCP plan. BA*

d. What do you conclude from the records?

You proceed to the production area and observe QC personnel collecting the samples and taking them to the lab. You observe the HACCP Coordinator watching the QC personnel perform monitoring and recording the monitoring check. You observe that the HACCP Coordinator reviews the drying log, and makes an entry on the record.

e. What is your determination regarding compliance based on what you have seen?

2. a. What are the 3 verification activities that the HACCP regulations specify?

b. Must all three occur at each CCP in the HACCP plan?

c. Would an establishment be in compliance if the same establishment employee performed all three of the verification activities at one CCP?

3. Describe in your own words the difference between FSIS inspection verification and plant verification activities.

4. You are assigned to a canning establishment and today's Procedure Schedule includes the 03D01. You have selected to verify the verification requirement at the metal detection CCP. You review the HACCP plan. The critical limit is "functional metal detector". The direct observation verification is that the QA manager observes the monitor perform a seeded sample check once per week. You proceed to the filling area and observe that the QA manager takes the seeded sample and runs it through the metal detector, getting the appropriate response, the equipment kicks out the seeded sample. She records this on the log as "direct observation verification performed, results per HACCP plan".

What do you conclude?

What actions do you take next?

Recordkeeping

You will verify some of the recordkeeping requirements when performing the HACCP 01 procedure. Other recordkeeping requirements are verified when performing the HACCP 02 procedure.

You will verify these requirements by reviewing the following:

- **HACCP plan**
- **HACCP records**
- **Hazard analysis**
- **Supporting documentation**
- **Decision-making documents**

In most instances, you will only use the recordkeeping component of the HACCP procedures when you are verifying the recordkeeping requirement. On occasion, you may use the review and observation component. For example, you may use the review and observation component to verify recordkeeping requirements by observing the establishment actually performing the pre-shipment review.

The thought process you should use when verifying regulatory requirements includes:

- gathering information by asking questions;
- assessing the information; and
- determining regulatory compliance.

This thought process should be utilized when verifying all of the regulatory requirements.

There are seven different regulations that pertain to HACCP recordkeeping. Whether you are performing an 01 or 02 procedure, you should verify as many of these requirements as are applicable and possible. Below is a table summarizing the recordkeeping regulatory requirements and procedures used to verify compliance.

HACCP Recordkeeping Requirements and the Procedures Used to Verify Compliance

Regulatory Recordkeeping Requirement	HACCP Procedure Performed
Recordkeeping system 417.2(c)(6)	01 or 02
Supporting Documentation 417.5(a)(1) and (2) For canning establishments, also 318.300-311/381.300-311	01
HACCP Records 417.5(a)(3)	01 or 02
Record Authenticity 417.5(b)	01 or 02
Computerized Records 417.5(d)	01 or 02
Record Retention and Availability 417.5(e)(1)(2)	01 or 02
Pre-shipment Review 417.5(c)	02

The **recordkeeping component** of the 01 and 02 procedures will be used the majority of the time for verifying the recordkeeping requirements. You may occasionally use **review and observation for verifying pre-shipment review and record authenticity.**

Product acceptability or disposition could be verified using the 02 procedure.

For canning establishments following §318/381.300 - .311, the 02 procedure will also include reviewing canning production records that apply to the specific production being verified.

Now let’s go into more detail about each requirement as they relate HACCP plans.

Recordkeeping System

The regulatory requirement for recordkeeping is:

9 CFR 417.2(c)(6)*—Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.*

You will verify the recordkeeping requirement by performing the HACCP 01/02 procedures.

Gather information by asking questions

In performing the procedures, you should be seeking answers to the following questions.

1. Does the HACCP plan set out a recordkeeping system that documents the monitoring of the CCP?

2. Do the records contain actual values and observations obtained during monitoring?

Assess the information

To verify that the establishment is in compliance with this regulation, you should review the following:

- HACCP plan
- HACCP monitoring records

►Reviewing the HACCP Plan for Recordkeeping Requirements

In reviewing the HACCP plan for compliance with §417.2(c)(6), you should verify that it lists the records that will be used to document the monitoring of critical control points.

►Reviewing HACCP Records for Recordkeeping Requirements

In reviewing the HACCP records for compliance with §417.2(c)(6), you should verify that it contains the actual values and observations that were obtained during the monitoring of critical control points.

Recordkeeping Example 1: *You are performing the 03F01 procedure at an establishment which produces various types of jerky. You have randomly selected to verify the recordkeeping requirement. You review the HACCP plan to verify that it lists the records used to document monitoring of critical control points and you find the following records listed for the lethality CCP: time, temperature and humidity at smoking log; calibration log; and corrective action log. You also review the time, temperature and humidity at smoking log and observe that monitoring personnel have recorded that the critical limit was met, the actual time, temperature and humidity; actual time of*

monitoring; and monitors initials. Based upon your review, you determine that the establishment is in compliance with ***this part*** *of the recordkeeping requirements of §417.2(c)(6) at this CCP.*

Determine compliance

After you have gathered and assessed all available information pertaining to the recordkeeping system requirement, and had verified the rest of the recordkeeping requirements that are applicable, you must determine regulatory compliance. If you find that the establishment has met the recordkeeping regulatory requirements, then there is no regulatory noncompliance. If you find that the establishment has not met the recordkeeping regulatory requirements, there is noncompliance. You will receive more information about making compliance determinations in a later section.

►Noncompliance with the Recordkeeping System Requirement

The following are examples of noncompliance with §417.2(c)(6).

1. *You are reviewing the HACCP monitoring log for the drying CCP in a large pepperoni establishment and find that monitoring personnel are placing a checkmark on the drying log instead of the actual water activity reading as specified in the HACCP plan.* ***The monitoring personnel are not recording actual values as required in §417.2(c)(6).***

2. *You are reviewing the HACCP plan for a very small establishment which makes dry sausage. You notice that there is a CCP for drying room temperature and humidity but the plan does not provide for any records for documenting the monitoring of humidity or temperatures.* ***The HACCP plan does not provide for a recordkeeping system that documents the monitoring of CCPs.***

You will document any noncompliance in accordance with our discussion of documentation and enforcement in a later section.

Supporting Documentation Requirements

The regulatory requirements for supporting documentation are:

9 CFR 417.5(a)—The establishment shall maintain the following records documenting the establishment's HACCP plan: (1) The written hazard analysis prescribed in §417.2(a) of this part, including all supporting documentation;
(2) The written HACCP plan, including decision-making documents associated with the selection and development of CCPs and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.

You will verify this requirement by performing the HACCP 01 procedure, using the recordkeeping component.

The thought process you should use when verifying regulatory requirements includes:

- gathering information by asking questions;
- assessing the information; and
- determining regulatory compliance.

This thought process should be utilized when verifying all of the regulatory requirements.

Note: As part of the requirement above, establishments will have documentation that address the requirement in §417.4(a). Section 417.4 specifies that "every establishment shall validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis." The CSI should determine compliance with the requirement of this regulation, by verifying that the establishment has the necessary documentation required in 9 CFR 417.5(a)(2). This verifies that the HACCP plan is theoretically sound.

You should use sound judgment in requesting supporting documents and should not just arbitrarily ask for them. You should ask for supporting documents if you have reason to believe that an establishment decision was not an appropriate one.

Prerequisite Programs. Based on the regulatory requirements of 9 CFR 417.2(a)(1) and 9 CFR 417.5(a)(1), FSIS believes that the results of testing and monitoring activities related to the production of product are subject to FSIS review and must be available to FSIS personnel upon request, including records from a prerequisite program. These instructions were clarified in FSIS Directive 5000.2, 3/31/04.

A ***prerequisite program*** is defined as a procedure or set of procedures that is designed to provide basic environmental or operating conditions necessary for the production of safe, wholesome food. It is called "prerequisite" because it is considered by scientific experts to be prerequisite to a HACCP plan.

You should be aware of all monitoring and of all food safety testing conducted by the establishment and should ask establishment management to make available for review the data that is generated by this monitoring and testing. You should review this data on at least a weekly basis.

When reviewing records, results, and supporting documentation associated with testing, monitoring, and verification activities that are from procedures or prerequisite programs outside the HACCP plans, CSIs should not apply the same criteria as they would when verifying the regulatory requirements of HACCP plans. For example, these records associated with monitoring and testing may include occasional instances of less than perfect control without resulting in threat to product safety. However, records generated from these programs must continue to support the decisions made in the establishment's hazard analysis.

You should determine whether the testing results suggest any food safety concerns that have not previously been recognized.

If you have concerns about the design of testing, monitoring, or verification activities outside of a HACCP plan, or concerns about results from such activities, procedures or prerequisite programs, you should contact the District Office. An EIAO may need to conduct a comprehensive food safety assessment in the establishment to verify that the design of the food safety systems in operation meet regulatory requirements.

If the establishment does not provide the CSI with records associated with a food safety concern when they are requested, the CSI should document this as noncompliance with the requirements specified in 9 CFR 417.5(a)(1).

Canning Operations. In a canning establishment which does not address food safety hazards associated with microbiological contamination in the hazard analysis, you should verify that the establishment is meeting all of the regulatory requirements of the canning regulations. This will include observing the canning process and reviewing associated records. If your review shows that the establishment is not complying with the canning regulations, then the establishment will not be able to support the decision made in the hazard analysis that they did not need to address microbiological contamination in the HACCP plan. We will discuss this in more detail later in this training.

CCP and Prerequisite Programs. If a hazard is judged reasonably likely to occur, the establishment must address the hazard with a CCP and cannot substitute a prerequisite program to control the hazard. Sometimes, however, an establishment determines that the hazard is not reasonably likely to occur, using the justification that a prerequisite program, properly implemented, is preventing the hazard from occurring. If you determine that a prerequisite program is used as a justification for not addressing a hazard with a CCP in the HACCP plan, you should notify the District Office. These programs must be evaluated by an employee trained in EIAO methodology.

Gather information by asking questions

In verifying these recordkeeping requirements, you should seek to answer the following questions.

1. Does the establishment have the supporting documentation for the decisions made in the hazard analysis?

2. Does the establishment have the decision-making documents associated with the selection of each CCP?

3. Do the documents explain why the establishment selected that location for the CCP?

4. Is there a control at the identified point in the process that will prevent, eliminate, or reduce to acceptable levels the identified hazards?

5. Does the establishment have scientific, technical, or regulatory support for the critical limit?

6. Does the support appear credible?

7. Does the establishment have documents supporting the monitoring procedures and frequencies listed in the HACCP plan?

8. Does the establishment have documents supporting the verification procedures and frequencies listed in the HACCP plan? Do the documents support what the establishment has done?

9. If the establishment has supporting documents for these decisions, does the documentation support the decisions?

Assess the information

When assessing the information gathered you will review the following:

- Hazard analysis with supporting documentation
- HACCP plan
- Decision-making documents associated with the selection and development of the CCPs and critical limits
- Supporting documentation for the verification procedures and frequencies
- Supporting documentation for the monitoring procedures and frequencies

Reviewing supporting documentation

Review the hazard analysis and supporting documentation to determine if the documents support the decisions made in the hazard analysis. Review the HACCP plan and decision-making documents to determine if documents are available for the selection and development of CCPs and critical limits, and documents support both the monitoring and verification procedures and the frequency of those procedures.

When you are verifying the recordkeeping requirement, you should be cognizant of the fact that there are many different kinds of supporting documents that an establishment might use to support the decisions it made in the hazard analysis and HACCP plan. The type of documentation necessary for support depends on the decisions made.

Some examples of supporting documentation used by establishments include:

- scientific journal articles or other published scientific literature,
- FSIS regulations, or regulatory performance standards,
- FSIS compliance guidelines,
- FSIS directives,
- industry standards or surveys,
- trade association guidelines,
- pathogen modeling programs,
- processing authority documents, instructions or research,
- written information from industry experts or consultants,
- university extension publications,
- in-plant studies, research or historical data,
- written materials from equipment manufacturers.

There must be at least one critical limit for each CCP. Each critical limit must have supporting documentation to demonstrate that it is adequate to actually control the specific food safety hazard. The establishment must have supporting documentation to show that the critical limits established in its process adequately kill the pathogens of concern.

The establishment has the flexibility to determine its own CCPs. If you have questions about a CCP, you should request the supporting documentation associated with the selection of that CCP. If you have questions regarding the validity of the data, you should seek technical guidance from the PDD by providing the relevant information along with an explanation of the situation, and what your specific questions are.

Keep in mind that even though the establishment may have documentation for its decisions, if that documentation does not support the decisions made in the hazard analysis and HACCP plan, that documentation would not meet the recordkeeping requirement.

Supporting Monitoring Frequencies. It is not a requirement that the establishment provide statistical data to support the monitoring frequencies. The documents supporting the monitoring frequency should demonstrate process control. The establishment may accomplish this by performing monitoring more frequently than stated in its HACCP plan. Over time, the establishment could show that actually monitoring less frequently satisfies process control and the more frequent monitoring records would serve as supporting documentation for the frequency.

Computer Modeling Programs. Some establishments may elect to use a microbial pathogen computer modeling program for supporting documentation. Since the models are only predictors, you would expect additional information to support any controls the establishment actually uses. Modeling programs must apply to the process and product produced.

Processing Authority. Sometimes the establishment uses scientific and technical data developed and analyzed by a processing authority or other scientific expert as the basis for decision-making for the selection and development of CCPs and critical limits. If this is the case, that data must be part of the establishment's supporting documentation. If the establishment's basis for CCPs, critical limits, or other aspects of the HACCP plan

are based on specific research, but do not use the exact control parameters used in the research, the establishment must have additional supporting documentation that justifies the modified control parameters.

Regulations - Lethality and Stabilization. Certain RTE products have a higher public health risk because they have historically been associated with food borne illnesses caused by specific pathogenic bacteria or their toxins (*Salmonella*, *E. coli* O157:H7, *Listeria monocytogenes*, *C. perfringens* or *C. botulinum*.). FSIS has published several regulations for lethality and stabilization of RTE meat and poultry products. §318.17, *Requirements for the production of cooked beef, roast beef, and cooked corned beef products*, requires a lethality of 6.5-log reduction of *Salmonella*. This regulation also has a stabilization standard which requires establishments to prevent the multiplication of spore-forming pathogens, usually by proper cooling, to ensure there is no multiplication of *C. botulinum* and no more than 1-log growth of *C. perfringens* in the product. FSIS regulation §318.23 *Heat-processing and stabilization requirements for uncured meat patties* lists specific temperature and time combinations for lethality, and the same stabilization standard as §318.17. FSIS regulation §381.150 *Requirements for the production of fully cooked poultry products and partially cooked poultry breakfast strips*, requires a lethality of 7.0-log reduction of *Salmonella*. This regulation also has a stabilization standard which requires establishments to prevent the multiplication of spore-forming pathogens, usually by proper cooling, to ensure there is no multiplication of *C. botulinum* and no more than 1-log growth of *C. perfringens* in the product.

FSIS has issued compliance guidelines that list specific temperature and time combinations that meet the FSIS performance standards for lethality and stabilization for RTE meat and poultry products. Processing establishments may use FSIS Directive 7111.1, 3/3/99, “Performance Standards for the Production of Certain Meat and Poultry Products” to support their processes. FSIS also published compliance guidelines for establishments to use to meet the performance standards described in §318.17 and §381.150. These guidelines are Appendix A for lethality and Appendix B for stabilization. Appendix A and Appendix B can be used also to support products not covered in the performance standard regulations.

FSIS Compliance Guidelines. FSIS has issued compliance guidelines for certain processes. The compliance guidelines are NOT regulatory, they are published to provide guidance to the industry, especially small and very small establishments. If the establishment uses an FSIS Compliance Guideline for setting its CCPs and critical limits, then the establishment should have a copy of that guideline in its records as supporting documentation. That is sufficient supporting documentation. If the basis for a critical limit is recent scientific publications describing similar processing systems, then copies of those publications are required as supporting documentation for the critical limit. Compliance guidelines are not regulations and you should not mandate that the establishment use them as supporting documentation for the critical limits. The establishment has flexibility to develop the CCPs and establish critical limits as it determines appropriate, provided the CCP and CL can be supported. It is your responsibility to verify that the establishment can support those decisions. FSIS guidelines can be used for support, but establishments are not required to support the critical limits with these documents; establishments may provide other supporting documentation that supports the safety of their processes.

If the establishment uses an FSIS compliance guideline, it is still required by §417.4(a) to validate the procedures and frequencies of its HACCP plan by repeatedly testing the adequacy of the CCP, critical limits, monitoring and recordkeeping procedures, and corrective actions. The establishment is not validating the compliance guidelines, but is validating that it can meet the criteria in the guidelines.

Control of *E. coli* O157:H7 in dry fermented sausages. In 1994, an outbreak of illnesses due to *E. coli* O157:H7 was associated with dry-cured salami. At that time, a group called the Blue Ribbon Task Force of the National Cattlemen's Beef Association, consisting of scientists from FSIS, ARS, academia and industry developed several options that would ensure a 5-log reduction *E. coli* O157:H7 in dry fermented sausages. These processes involve various combinations of fermentation temperature, pH at the end of fermentation, holding times and temperatures, and drying and cooking. Many establishments continue to follow these recommendations and you may see this report used as supporting documentation. These options include:

1. Utilize a heating step as described in §318.17 or §318.23.
2. Apply a validated heat treatment of equal lethality.
3. Hold and test finished products using ICMSF lot acceptance criteria.
4. Apply a validated minimum 5-log reduction or process that results in the level of *E. coli O157:H7* in the final product below 1 cfu/100 gram.
5. Sample raw ingredients to demonstrate there is less than 1 *E. coli* O157:H7 organism per 100g and apply a 2-log lethality treatment.

Control of *Listeria monocytogenes.* FSIS requirements for control of *Lm* are found in part 430.4 of the regulations. An establishment producing RTE product which is exposed post-lethality must meet one of the alternatives prescribed by the regulations. FSIS Directive 10,240.4 (2/3/09) describes verification procedures for this regulation. FSIS has also published compliance guidelines and Q&As for this regulation.

There are **three possible outcomes** for verification of the supporting documentation requirements.

1. Compliance
2. Noncompliance
3. Inability to determine compliance because more information is needed

When the CSI determines that there is not enough information available to determine whether the HACCP plan complies with 9 CFR §417.2, he or she should notify the establishment. This provides the establishment with an opportunity to support the decisions made, or to reassess the hazard analysis and the HACCP plan and make decisions that it can support. For example, if the establishment is monitoring its critical limit every hour, and the only supporting documents that are available are the monitoring records for the past year, the CSI should request additional information from the establishment to support the hourly frequency for conducting the monitoring activity. The monitoring records from the past year only demonstrate that the establishment can perform monitoring hourly. The records do not state **why** the establishment feels the hourly frequency would be adequate to ensure that the CCP is under control.

Note: Since CSIs have not been trained to assess the scientific and technical information that an establishment might have to support the HACCP system, they can contact the District Office or PDD through supervisory channels for assistance.

►Reviewing the Hazard Analysis with Supporting Documentation

You should review the hazard analysis along with the supporting documentation to verify that the establishment has the documentation to support the decisions made in the hazard analysis.

Recordkeeping Example 3*: While performing the 03E01 procedure for a pepperoni process to verify the recordkeeping requirements for supporting documentation, you review the records from product testing conducted outside the HACCP plan or Sanitation SOP. During this review, you find that the establishment received a positive* E. coli *O157:H7 result from pepperoni slices. You then review the establishment's corrective action records to verify the requirements of §417.3 were met. There was documentation on the corrective action record of a reassessment of the hazard analysis and HACCP plan. While reviewing the hazard analysis and HACCP plan, you request supporting documents for the decisions made in the hazard analysis and HACCP plan during the reassessment. The establishment provided supporting documentation when it was requested. You verify that the documents provided are adequate to support these decisions. You were able to determine that the supporting documentation supported the decisions made during the reassessment. You determine that there is compliance with these requirements.*

►Reviewing the HACCP Plan and Supporting Documentation

In reviewing the HACCP plan and supporting documentation for compliance with §417.5(a), you should verify that the establishment has the documents to support the selection of each CCP and why that location was selected. In addition, you should verify that there is a control at the identified point in the process that will prevent, eliminate, or reduce to acceptable levels the identified hazard. There should also be credible scientific, technical, or regulatory support for the critical limit at the CCP and there should be documents supporting the monitoring and verification procedures and their frequencies identified in the HACCP plan.

Recordkeeping Example 4 *You are reviewing the hazard analysis and HACCP plan in a beef jerky operation. You review the establishment's hazard analysis documentation, and the process flow diagram. You find that all of the steps in the actual plant operations are described in the flow diagram, and each step is addressed in the hazard analysis. You find the hazard analysis considers potential biological, chemical, and physical food safety hazards at each step. Where potential food safety hazards are identified, the establishment has made a determination about whether they are reasonably likely to occur or not, and recorded the basis for that decision. You observe that at the receiving step the establishment has identified that there is a food safety hazard, "presence of* E. coli *O157:H7" and determined that it was reasonably likely to occur. A later step in the process, Heating/drying, is identified as a CCP "destruction of pathogens including* E. coli *O157:H7" and lists critical limits for cooking time-temperature combination, relative humidity during heating, and final water activity. You decide to request the supporting documentation for these critical limits. The establishment provides a copy of*

"Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Plants", December 2004, along with Appendix A "Compliance Guidelines for Meeting Lethality Performance Standards for Certain Meat and Poultry Products". You review the guidelines and determine that the critical limits that the establishment has identified are supported by these guidelines. You determine that this requirement for the supporting documentation is in compliance in that the hazard analysis appears to have been conducted appropriately, and that the establishment has the documentation to support the hazard analysis and HACCP plan. Based upon your review, you determine that the establishment is in compliance with §417.5(a)(1)&(2).

Determine compliance

After you have gathered and assessed all available information pertaining to the supporting documentation requirement,, and had verified the rest of the recordkeeping requirements that are applicable, you must determine regulatory compliance. If you find that the establishment has met the recordkeeping regulatory requirements, then there is no regulatory noncompliance. If you find that the establishment has not met the recordkeeping regulatory requirements, there is noncompliance. You will receive more information about making compliance determinations in a later section.

►Noncompliance with the Supporting Documentation Requirement

The following are examples of noncompliance with this §417.5(a) *(1) or (2)*.

1. *You are reviewing the hazard analysis for a sliced pepperoni operation. You observe that the establishment has identified* Listeria monocytogenes *as reasonably likely to occur at the slicing and packaging steps. There are no preventive measures identified and there is no CCP established for control of this hazard. When you ask the establishment for support they tell you "everyone knows that Lm would not be able to survive on pepperoni slices" but they provide no documentation.* ***The establishment has no supporting documentation to support why it is not necessary to establish controls for food safety hazards identified in the hazard analysis.***

2. *You observe that the establishment is using a water activity meter to measure A_w at the end of the drying time. You ask the establishment how it calibrates the accuracy of the meter. Establishment management are not able to provide any information regarding calibration procedures for this equipment, nor does the establishment have support for not needing to calibrate.* ***The establishment has no documentation supporting the verification procedure and frequency.***

3. *An establishment producing beef jerky has one CCP, for lethality. You ask, but the establishment has no supporting documentation for this decision.* ***The establishment has no supporting documents associated with the decision-making process for the selection of the CCPs.***

4. *An establishment produces a variety of dry beef sausages using one HACCP plan. The plan has a CCP for lethality with critical limits of 3 minutes at 136°F . You ask for supporting documentation. The establishment replies, "this is the*

way we have always made it" and does not provide any documentation. ***The establishment has no scientific, technical, or regulatory support for the critical limit.***

5. *An establishment produces turkey jerky. The lethality CCP uses a critical limit of 145°F, with no associated time. You ask for support and they show you a pathogen modeling program printout showing a lethality curve for E. coli* O157:H7*.* **The establishment has documentation, but the documentation does not support the decisions made.**

You will document any noncompliance in accordance with our discussion of documentation and enforcement in a later section.

HACCP Records Requirement

The regulatory requirement for HACCP records is:

9 CFR 417.5(a)(3)*—The establishment shall maintain: Records documenting the monitoring of CCPs and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot. Each of these records shall include the date the record was made.*

You will verify compliance with this regulation by performing either the 01 or the 02 procedure. You would use the recordkeeping component to verify this regulation.

The thought process you should use when verifying regulatory requirements includes:

- gathering information by asking questions;
- assessing the information; and
- determining regulatory compliance.

This thought process should be utilized when verifying all of the regulatory requirements.

Gather information by asking questions

When reviewing HACCP records for compliance with §417.5(a)(3), you should seek answers to the following questions.

1. Do the records document the monitoring of CCPs and their critical limits?

2. Do the records include actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan?

3. Do the monitoring, verification, and corrective action records include product codes, product name or identity, or slaughter production lot, and the date each record was made?

4. Are the verification procedures and results of those procedures documented?

5. Is the time recorded when the verification activity was performed?

6. Does the record contain the date the record was made?

7. Are the process-monitoring calibration procedures and results being recorded?

Assess the information

You will review:

- HACCP records that document monitoring and verification procedures for CCPs and their critical limits.
- Documentation of corrective actions taken in response to a deviation from a critical limit, a deviation not covered by a critical limit, or an unforeseen hazard.

Recordkeeping Example 5: *You are reviewing the Fermentation Log at a Lebanon bologna establishment.*

Fermentation Log *Date 2-1-2005*

Product code	*Lot No.*	*Time*	*pH*	*Monitored by*	*Corrective Actions*	*Verification**
176a	*1*	*12:47pm*	*5.0*	*CL*	*--*	**KL(good)*
**=direct observation verification* *Good=The results are in accordance with HACCP plan (if not "good" then make note in CA and describe on back of this form).*						

Based upon your records review, you determine that the establishment is in compliance with this part of the recordkeeping requirements of §417.5(a)(3).

In addition, you will verify that monitoring, verification, and corrective action records include product codes, product name or identity, or production lot, and the date the record was made.

Recordkeeping Example 6: *You are performing the 03E02 at a proscuitto ham operation. You review the following record:*

Drying log for: *Proscuitto ham*			CL: *a_w .82 or less*			Date: *4-1-05*
Product code	Lot No.	Time	Water Activity	Monitor	Corrective Actions	Verified by*
1999b	*3*	*1:32pm*	*.82*	*SM*	*--*	*BH(DO)*
*DO=direct observation verification-results are in accordance with HACCP plan (if not make note in CA)						

Based on your review, you decide that the plant is in compliance with this part of the recordkeeping requirement.

You will also verify that process monitoring calibration procedures and results are recorded if that is part of the HACCP plan.

Recordkeeping Example 7: *You are performing the 03F01 procedure in a dry sausage operation and randomly select to verify the recordkeeping requirement as part of the recordkeeping verification, you look at the records to see if they comply with §417.5(a)(3). You review the HACCP records for this verification activity and find that the verification personnel have made the following entries:*

Thermometer Calibration Log						Date: *2-1-2003*	
Time	Area	Thermometer ID	Standard temperature reading	Personal Thermometer Reading	Adjustment Required	Initials	Comments
0800	*fermentation*	*2A*	*90*	*90*	*No*	*OT*	

Based upon your records review, you determine that the establishment is in compliance with this part of the recordkeeping requirement. You would then proceed to verify other recordkeeping requirements.

Determine compliance

After you have gathered and assessed all available information pertaining to the HACCP records requirement, you must determine regulatory compliance. If you find that the establishment has met the applicable recordkeeping regulatory requirements, then there is no regulatory noncompliance. If you find that the establishment has not met the recordkeeping regulatory requirements, there is noncompliance. You will receive more information about making compliance determinations in a later section.

►Noncompliance with the HACCP Records Requirement

The following are examples of noncompliance with §417.5(a)(3).

1.

Fermentation Log *Date 3-1-2005*

Product code	*Lot No.*	*Time*	*pH*	*Corrective Actions*	*Monitored by*	*Verified by **
176a	*1*	*12:47pm*	*ok*	*--*	*CL*	**KL*
179	*2*	*1:09pm*	*ok*	*--*	*CL*	
**=direct observation verification-results are in accordance with HACCP plan*						

The records do not have the monitoring actual values recorded.

2.

Fermentation Log *Date 4-4-2005*

Product code	*Lot No.*	*Time*	*pH*	*Corrective Actions*	*Monitored by*	*Verified by **
123a	*3*		*5.0*	*--*	*BL*	
125	*6*		*5.0*	*--*	*BL*	**KL*
**=direct observation verification-results are in accordance with HACCP plan*						

The records do not include the actual times that monitoring is performed.

3. *You are reviewing the monitoring records for the heat treatment CCP in a pepperoni establishment and you find that the temperature results are recorded simply as "meets" instead of the actual temperature as described in the HACCP plan.* ***The records do not include the actual values as required.***

4. *You are reviewing the HACCP records for the fermentation time/temperature CCP in a thuringer operation and notice that the fermentation log does not contain the lot number or product ID as is specified in the regulations.* ***The monitoring entries do not include the product identification or code.***

5. *From the above example, you notice that the fermentation log from the previous shift does not have the date on it.* ***The records do not include the date the record was completed.***

6. *You observe QC as they perform the daily calibration of the pH meter. You do not observe them write anything on the record. The next morning you review the records and observe that there are no results for pH meter calibration yesterday.* ***The verification procedures and results are not being recorded.***

7. *You are notified by the QC technician that they are dealing with a deviation from a critical limit at the cooking temperature. You observe that the establishment takes all required parts of §417.3(a). Later, you ask for the corrective action records and are told "we notified you verbally, we assumed that was enough and we didn't write anything down."* ***The corrective actions taken in response to a deviation from a critical limit are not recorded.***

8. *You are reviewing the records for the acetic acid dip CCP prior to heating in a turkey jerky operation and you find that the calibration for the pH meter had not been documented for the shift. The HACCP plan specifies that the calibration will be performed and recorded prior to every shift startup. You request more information and the establishment provides you with evidence that the calibration was performed.* ***The results of calibration of process monitoring instruments are not recorded.***

You will document any noncompliance in accordance with our discussion of documentation and enforcement in a later section.

Records Authenticity

The regulatory requirement for record authenticity is:

9 CFR 417.5(b)—*Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the date and time recorded, and shall be signed or initialed by the establishment employee making the entry.*

You will verify this requirement as part of the 01 or 02 procedure. You could use either the recordkeeping or review and observation component, or both.

The thought process you should use when verifying regulatory requirements includes:

- gathering information by asking questions;
- assessing the information; and
- determining regulatory compliance.

This thought process should be utilized when verifying all of the regulatory requirements.

Gather information by asking questions

In verifying that the establishment is in compliance with this requirement, you will seek answers to these questions.

1. Was each entry on the record made at the time the event occurred?

2. Does each entry include the time?

3. Was each entry on the record signed or initialed by the establishment employee making the entry?

4. Does each record include the date?

Note: The recordkeeping requirement in §417.5(a)(3) requires that the record include the date the record was made. In §417.5(b) every entry on a record is required to include the date recorded. These two separate sections of the regulation in essence mean the same thing in terms of compliance. The intent of this recordkeeping regulation is not to require that the establishment write the same date multiple times on a record with each entry, but to have a date on the record to represent the data entries.

Assess the information

You will review: HACCP records documenting monitoring, verification activities, and corrective action.

When reviewing the HACCP records for compliance with §417.5(b), you should verify that each record entry is made at the time the event occurred and includes the time as part of the entry. In addition, verify that each entry was signed and initialed by the establishment employee making the entry.

Recordkeeping Example 8: *You are performing procedure 03F01 at an establishment that produces snack sticks. You have randomly selected to verify the recordkeeping requirements for the formulation CCP (addition of antimicrobial agent – lactic acid). You review the establishment's HACCP plan and see that the monitoring procedure is that QC will check the pH of each batch of product prior to transportation to the stuffing room, and the associated record is the Formulation log. You look at today's Formulation log, which includes today's date at the top. You observe that for each batch there is an entry which includes the product ID, time, the actual value of the pH, and the monitor's initials. You observe the monitor perform a pH check, and immediately record the results. Based on your observations, you conclude that the establishment is in compliance with §417.5(b).*

Determine compliance

After you have gathered and assessed all available information pertaining to the HACCP record authenticity requirement, you must determine regulatory compliance. If you find that the establishment has met the applicable recordkeeping regulatory requirements, then there is no regulatory noncompliance. If you find that the establishment has not met the recordkeeping regulatory requirements, there is noncompliance. You will receive more information about making compliance determinations in a later section.

►Noncompliance with HACCP Record Authenticity

The following is an example of noncompliance with **§**417.5(b):

The Lethality CCP for the meat snack sticks HACCP plan reads "Temperature at thermometer gauge A and B are checked and recorded, and the number of tiers passing the checkpoint is counted for one minute and recorded, once per hour." You proceed to the smokehouse area at about 2:20 am. You observe this record:

Date: 6-19-05			Lethality log			Product: *teriyaki turk*ey	
Critical Limits	Temperature: *350*		Speed, no more than: *22/minute*				
Time	Monitor	Temp A	Temp B	Speed	Comments	Verification	Verifier
12:22 am	*ER*	*350*	*350*	*22*			
1:15 am		*350*	*350*	*22*			

The records do not include the signature or initials of the person performing the activity.

You observe the monitor perform a monitoring check. He checks both temperature gauges, then opens the door on the chain speed checkpoint and checks the wallclock and watches the chain moving for one minute. You observe that he goes about other duties for some time, without writing this down on the log. You return later in the shift, and observe that there is a notation for the 2:20 am check recorded.
Results are not being recorded when the events occur.

Computerized Records

The regulatory requirement for computerized records is:

9 CFR 417.5(d)—*Records maintained on computers. The use of records maintained on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.*

Electronic signatures are different from the digitized signature you might make when you sign for a credit card purchase. An electronic signature, or digital signature, uses computer technology to ensure the security of records or messages. The person making the record or message uses an electronic "code" to identify him/herself. The computer, using an electronic "key," decodes the record or message. This endorses the identity of the user.

This requirement will be verified by performing the 01 or 02 procedure.

The thought process you should use when verifying regulatory requirements includes:

- gathering information by asking questions;
- assessing the information; and
- determining regulatory compliance.

This thought process should be utilized when verifying all of the regulatory requirements.

Gather information by asking questions

When verifying this requirement you should seek the answer to this question:

1. Are appropriate controls provided to ensure integrity of electronic data and signatures?

Assess the information

To obtain answers to this question you would review the computerized recordkeeping system.

Recordkeeping Example 9: *An establishment enters all HACCP activity results into hand-held computer devices. Network access is for QA employees only. Each employee has a unique log-in name and password that is kept secure. Passwords are changed periodically. Once an entry is made, it is saved as read-only, and cannot be changed.*

Determine compliance

After you have gathered and assessed all available information pertaining to the computerized records requirement, you must determine regulatory compliance. If you find that the establishment has met the applicable recordkeeping regulatory requirements, then there is no regulatory noncompliance. If you find that the establishment has not met recordkeeping regulatory requirements, there is

noncompliance. You will receive more information about making compliance determinations in a later section.

►Noncompliance with the Computerized HACCP Records Requirement

The following is an example of noncompliance with §417.5(d).

> *The establishment uses a computer-based system to monitor and record the temperatures in all drying and fermentation rooms. You request information about controls to ensure the integrity of the records, which the establishment is not able to provide.* ***The establishment does not have controls in place to ensure the integrity of the electronic records.***

You will document any noncompliance in accordance with our discussion of documentation and enforcement in a later section.

Record Retention and Availability

The regulatory requirement for record retention and availability is:

9 CFR 417.5(e)(1)(2)*—Record retention. (1) Establishments shall retain all records required by paragraph (a)(3) of this section as follows: for slaughter activities for at least one year; for refrigerated products, for at least one year; for frozen, preserved, or shelf-stable products, for at least two years. (2) Off-site storage of records required by paragraph (a)(3) of this section is permitted after six months, if such records can be retrieved and provided, on-site, within 24 hours of an FSIS employee's request.*

You will verify this requirement as part of the 01 or 02 procedure.

The thought process you should use when verifying regulatory requirements includes:

- gathering information by asking questions;
- assessing the information; and
- determining regulatory compliance.

This thought process should be utilized when verifying all of the regulatory requirements.

Gather information by asking questions

You should seek answers to the following questions.

1. Are the records being maintained for the required amount of time, i.e., 2 years for shelf-stable products?

2. Are the records kept on-site for 6 months, and available upon request?

3. If the records are stored off-site after 6 months, can they be retrieved within 24 hours?

Assess the information

You should verify that the records are being maintained the required amount of time by reviewing:

- HACCP records.

You should not routinely request past records to verify that HACCP records are being maintained for the appropriate time. If you suspect that records are not being maintained for the required amount of time, you should contact the frontline supervisor for instructions. You might request records stored off-site one time to ensure they can be provided, but it would not be necessary for you to routinely request records that are stored off-site just to verify this requirement.

Note: If you determine that records are not available, you would communicate with establishment management in a professional manner that the HACCP regulations require records to be available to FSIS when the establishment is operating (§417.5(f)).

Determine compliance

After you have gathered and assessed all available information pertaining to the records retention and availability requirement, you must determine regulatory compliance. If you find that the establishment has met the applicable recordkeeping regulatory requirements, then there is no regulatory noncompliance. If you find that the establishment has not met recordkeeping regulatory requirements, there is noncompliance. You will receive more information about making compliance determinations in a later section.

►Noncompliance with Records Retention and Availability

The following are examples of noncompliance with §417.5(e)(1) and (2).

1. *In September, you ask the establishment to provide a sample of the pepperoni fermentation pH CCP monitoring log records from last January. They give you a folder that contains February through September records. You ask the establishment about January's records and they tell you the records cannot be located and have probably been discarded. The establishment cannot produce January's records.* ***The establishment is not maintaining records for the required length of time.***

2. *In January, you rotate into a new assignment and are reviewing the HACCP records for the sampling component of the lethality CCP in a large beef snack-sticks plant. You suspect the establishment is not maintaining records on site. You discuss this with your frontline supervisor and then you ask the establishment for the records from September. They tell you that they can give you the records for the past month but they will have to retrieve any other month's records from a record storage facility in another state.* ***The records are not being maintained on-site for 6 months.***

3. *You are new to an assignment at a canning plant (metal detection CCP) and are performing records maintenance verification as part of a 03D01. You wonder about whether the establishment is able to retrieve records stored offsite and discuss this with your supervisor. You decide to ask the establishment to provide a sample of records from 8 months in the past. They tell you that after 6 months they store them at corporate headquarters. You request they retrieve the records from corporate headquarters. You receive the records 3 days later.* ***The establishment cannot retrieve the records within 24 hours when stored off-site.***

You will document any noncompliance in accordance with our discussion of documentation and enforcement in a later section.

Pre-Shipment Review Requirement

The regulatory requirement for pre-shipment review is:

9 CFR 417.5(c)*--Prior to shipping product, the establishment shall review the records associated with the production of that product, documented in accordance with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by someone trained in accordance with §417.7 of this part, or the responsible establishment official.*

FSIS considers product to be **"produced and shipped"** when the establishment completes pre-shipment review. Verifying that the establishment has completed pre-shipment review enables you to know whether the company has taken full and final responsibility for applying its HACCP controls to the product that it has produced.

Verify an establishment's pre-shipment review of its records by performing the 02 procedure. Although you will normally verify this recordkeeping requirement using the recordkeeping component, you should occasionally perform a verification check by observing the establishment employee perform the pre-shipment review.

You should understand that pre-shipment review can be accomplished if the product is at a location other than the producing establishment, as long as the review of appropriate documents and compliance with 9 CFR 417.5(c) occurs before the product leaves the **control** of the producing establishment.

The thought process you should use when verifying regulatory requirements includes:

- gathering information by asking questions;
- assessing the information; and
- determining regulatory compliance.

This thought process should be utilized when verifying all of the regulatory requirements.

Gather information by asking questions

You should seek answers to the following questions.

1. Has the establishment reviewed the records associated with the production of the product, prior to shipment?

2. Has the pre-shipment review been signed and dated by an establishment employee?

Assess the information

You should review the pre-shipment review records.

Determine compliance

After you have gathered and assessed all available information pertaining to the pre-shipment review requirement, you must determine regulatory compliance. If you find that the establishment has met all applicable regulatory requirements, then there is no regulatory noncompliance. If you find that the establishment has not met all applicable regulatory requirements, there is noncompliance. You will receive more information about making compliance determinations in a later section.

►Noncompliance with Pre-Shipment Review Requirement

The following is an example of noncompliance with §417.5(c).

> *Your procedure schedule for today calls for performing the 02 procedure. You observe a specific production of the product being loaded onto trucks for distribution, and record the production codes. You proceed to the HACCP office and request the production records for that specific production. You observe that the pre-shipment records review form is not included, and upon further request the establishment is not able to provide the records. You verify that the product has left the control of the establishment.* ***The establishment shipped the product without conducting a pre-shipment review.***

You will document any recordkeeping noncompliance in accordance with our discussion of documentation and enforcement in a later section.

►Records Misrepresentation

Familiarity with an establishment's procedures and compliance history will help separate honest errors from deliberate record misrepresentation. When deliberate misrepresentation of records is suspected, do **not** discuss the situation with an establishment employee. Notify the IIC and document the findings in a memorandum to the files—**not on an NR**. The IIC should use a secure phone (off-premises if necessary) to call the District Office. FSIS does not consider the telephone in the government office and cellular phones to be secure. The District Manager will provide instructions for further action. If the IIC is not available, the inspector should use a secure phone to notify the District Office and follow the District Manager's instructions.

Workshop: Recordkeeping

Refer to the module and to FSIS Directive 5000.1 to complete the following questions.

1. When verifying the recordkeeping requirement, how many of the regulatory requirements should you verify?

2. **Case Study.** You select to verify the recordkeeping requirement as part of an 03F01 procedure at a summer sausage HACCP plan. This ready-to-eat process complies with regulation 430 by complying with Alternative 1. CCP 3-Antimicrobial Treatment is designed to monitor the use of the antimicrobial agent. The critical limit is "application of a solution of at least 3% to all surface areas of finished product before packaging". You review the monitoring records for the CCP and they are as follows.

Date	*Lot No.*	*Time*	*Solution Conc.(%)*	*Monitor*	*Verification*
2-1-2005	*1*	*1430*	*OK*	*LS*	

a. Is there noncompliance in this record? Please explain.

b. What would you do next?

3. You are assigned to a beef jerky establishment and are aware of the issuance of **updated** Compliance Guidelines for the Production of Meat and Poultry Jerky. In light of this new Agency issuance, you decide to review the hazard analysis and HACCP plan.

Process Step	Food Safety Hazard	Likely to occur?	Basis	Preventive measures	CCP
Cooking/ Lethality	B – Vegetative Pathogens (*Salmonella, E. coli* O157:H7) C – None P –None	Yes	Potential outgrowth of pathogens	Apply heat treatment in marination solution to eliminate vegetative cells	Yes
Drying	B – Growth of pathogenic sporeformers C – None P – None	Yes	Final product is shelf-stable and does not bear a "keep refrigerated" statement	Use of dehydrator to reduce the level of free water in finished product	Yes

HACCP plan: beef jerky					
CCP #	**Critical Limits**	**Monitoring Procedures & Frequencies**	**HACCP Records**	**Verification Procedures & Frequencies**	**Corrective Actions**
Cooking/ Lethality	≥158 °F	Measure the internal temperature of 3 pieces of jerky using a thermocouple thermometer from the marination solution per batch	Cooking Log	Observe monitor perform the procedure once per shift Review record once per shift Calibrate the thermocouple (needle thermometer) temperature sensing device once per shift	417.3
Drying	≤0.85 water activity	Select 3 pieces of jerky per drying cycle of the slowest drying location. Perform individual analyses for water activity using a water activity meter on each piece. Record the highest reading.	Water Activity Monitoring Log	Observe the monitor perform the procedure once per shift Review records once per shift Calibrate the Hygrometer (water activity meter) with 2 point procedure once per month.	417.3

What supporting documentation would you ask the establishment to provide?

Can the establishment use Appendix A for support of its lethality temperature? Please explain your answer.

If the establishment uses Appendix A for support of its lethality temperature, what concerns would you have?

What if the lethality and drying were taking place as one step, in a smokehouse? What other concerns might you have?

4. You are performing the 03E01 procedure at a country cured ham establishment, and have randomly selected to verify the establishment recordkeeping requirement. The CCP1- receiving, calls for review of certificates that must accompany each shipment. You observe the records for today's incoming product, and see that the establishment has recorded a checkmark "✓" for each shipment in the "certificate received" column of the incoming product log.

What do you determine regarding compliance?

5. How soon after the monitoring and verification activities do the results have to be recorded on the establishment records? What is the regulatory reference for this?

6. The establishment must always perform the pre-shipment review prior to the specific production leaving the official premises. True or False?

7. Evaluate the record below.

Water Activity Calibration Log Calibrate with saturated salt solution and distilled water							
Date and Time	Dept.	Meter ID	Salt Reading	Water Reading	Adjustment Required? (Yes or No)	Initials	Comments
8/15/2005 PM	Ripening rooms	1		1.00	No	WTR	

a. Is this record in compliance?

b. What are the regulatory references you would enter on the NR?

8. You are assigned to a dry and semi-dry products establishment. After each production lot passes through all steps in the operation it is transported to a nearby warehouse. The warehouse is operated by the establishment, although it is NOT part of the official premises. Each morning the pre-shipment review for all lots transported to the warehouse the previous day is conducted, the log is signed and dated, and those production lots are then clear to be shipped.

a. Does this fulfill the regulatory requirements for pre-shipment review? Why or why not?

Corrective Actions

Before we elaborate on the corrective action requirements, let's review the difference between a *deviation from a critical limit, HACCP noncompliance* and a canning *process deviation*.

A ***deviation from a critical limit*** is the failure to meet the applicable value determined by the establishment for a CCP. If a deviation from a critical limit occurs, an establishment is required to take corrective actions in accordance with 9 CFR 417.3.

A ***HACCP noncompliance*** is the failure to meet any of the regulatory requirements of 9 CFR part 417: monitoring, verification, recordkeeping, reassessment, and corrective action. If a HACCP noncompliance occurs, an establishment is expected to take immediate and further planned actions to correct the noncompliance. In addition, if the establishment uses the canning regulations in lieu of addressing microbiological contamination in a HACCP plan, failing to meet any thermal processing regulatory requirements (§318/381.300-318/381.311) is also noncompliance with §417.5(a)(1).

A ***process deviation*** is another term that is commonly used in canning establishments. The term ***deviation in processing,*** or process deviation, is used whenever the actual process is less than the process schedule or when any critical factor does not comply with the requirements for that factor as specified in the process schedule. If a process deviation occurs, the establishment is expected to follow the canning regulations, 318.308/381.308.

A. Corrective Actions in Response to a Deviation from a Critical Limit

The regulation that applies to corrective actions taken in response to a deviation from a critical limit is:

9 CFR Part 417.3(a)*—The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure: (1) The cause of the deviation is identified and eliminated; (2) The CCP will be under control after the corrective action is taken; (3) Measures to prevent recurrence are established; and (4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.*

This requirement cannot be randomly verified because corrective action occurs when something triggers it (a deviation from a critical limit). **Anytime** there is a deviation from a critical limit you will **always** verify that the corrective actions taken by the establishment meet the requirements of this regulation. This will be done as part of the 01 or 02 procedure. The recordkeeping component or the review and observation component can be used to verify these requirements.

The thought process you should use when verifying corrective action regulatory requirements includes:

- gathering information by asking questions;
- assessing the information; and
- determining regulatory compliance.

This thought process should be utilized when verifying all of the regulatory requirements.

Gather information by asking questions

To verify compliance with the corrective action regulatory requirements, you will seek answers to the following questions:

1. Did the establishment identify and eliminate the cause of the deviation?
2. Did the corrective actions ensure that the CCP is brought under control?
3. Were measures implemented to prevent recurrence of the deviation?
4. Did the actions ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce?

Assess the information

When seeking answers to these questions, you should:

- Observe the establishment executing the corrective actions.
- Review the corrective action records associated with the deviation from the critical limit.
- Compare the establishment's recorded corrective actions to the regulatory requirements listed in 9 CFR 417.3(a) to determine whether the corrective actions taken in response to the deviation from the critical limit meets all of these requirements.

Now let's have a look at each of these in more detail.

►Observing the Establishment Execute Corrective Actions

In observing the establishment executing corrective actions, you should verify that the appropriate affected product has been identified.

Corrective Action Example 1, part 1: *Upon arrival at a fermented dry sausage establishment at 0800, you are notified by the plant management that there has been a deviation from the minimum pH that must be achieved during fermentation for a lot of pepperoni. You thank the plant manager for voluntarily notifying you about this situation. You realize that you must verify that the corrective action requirements are met, and that you could do this by performing the review and observation component. You review the establishment's HACCP plan and find that the monitoring procedure is that the QA technician or designee will measure the pH of 3 individual samples from each lot at the completion of the fermentation cycle. Before product enters the heat cycle, the QA technician or designee will verify that a pH of 5.2 or less has been achieved at a*

fermentation chamber temperature of 105°F in 14 hours or less. The pH results are recorded on the fermentation control log. You proceed to the QA lab and review the fermentation control log, and find the deviation noted at the 0600 monitoring check. The results are pH readings of 5.12, 5.28 and 5.26, after the 14 hours had elapsed. You review the corrective action log. It states that a processing authority at a university has been contacted and is in the process of reviewing the deviation, and that the product was moved to the cooler and placed on QA hold. It also indicates that the temperature of the starter culture freezer was 42°F instead of below freezing, which affected the viability of the starter culture. You observe the QA hold tags on the lot of pepperoni and verify that the lot number and the amount of product matches the monitoring record. You determine that the plant has segregated the appropriate affected product.

You would observe the execution of corrective actions to verify that the cause of the deviation has been identified and eliminated.

Corrective Action Example 1, part 2: *Continuing with the above example, you go to the room where the starter cultures are kept and observe maintenance employees working on the freezer. The maintenance supervisor reports that the cooling coils are worn out, and are being replaced. The plant manager is there and informs you that a new SOP for handling starter cultures, including the daily monitoring of the freezer temperature and a quarterly examination of the cooling parts, will be established. Based on these observations, you determine that the establishment has identified and eliminated the cause of the deviation.*

You would observe the execution of corrective actions to verify that the CCP is under control upon completion.

Corrective Action Example 1, part 3: *Continuing with the above example, later in the morning you return to the room where the starter cultures are kept and see that the work is done on the freezer and it is up and running. You notice several starter culture containers in the trash. The maintenance supervisor notifies you that they will monitor the freezer temperature 3 times a day for the next two days, and record the results on the record developed for the new SOP. Based on these observations, you determine that the establishment has the CCP under control. You will need to verify that the establishment does monitor the freezer temperatures as the maintenance supervisor stated and that what he said is documented as part of the corrective actions.*

You would observe the execution of corrective actions to verify that the establishment prevents product that is injurious to health or otherwise adulterated, as a result of this deviation, from entering commerce.

Corrective Action Example 1, part 4: *Continuing with the above example, you return to the production area and see that an employee is loading racks of pepperoni sticks into the oven. You go to the QA office and question the QA technician about the plant's release of the lot of pepperoni. The QA technician tells you that the processing authority determined that the fermentation process was acceptable even though the critical limit was not met, because the rate of pH drop to 5.3 or below was within the "degree-hour" limit to prevent growth and enterotoxin production by* S. aureus*. You observe the corrective action log and find an attached e-mail from the processing authority with the degree-hours calculation and the website for American Meat Institute's Good Manufacturing Practices for fermented Dry and Semi-dry Sausage Products. The plant*

has attached information from that website that supports the determination made by the processing authority. Based on these observations, you determine that the establishment has prevented product that would be injurious to health or otherwise adulterated as a result of this deviation, from entering commerce.

You would observe the execution of corrective actions to verify that preventive measures are established.

Corrective Action Example 1, part 5: *Continuing with the above example, it is now one week since the deviation. You review the establishment's SOP and find that it has instructions for the proper handling of starter cultures, including a procedure for monitoring the freezer temperature and maintaining the freezer in good repair. You review the SOP records and observe that maintenance personnel observed the freezer temperature 3 times for the first two days and once a day since then, as proposed. Based on these observations, you determine that the establishment has established preventive measures.*

►Reviewing the Corrective Action Records

In reviewing the corrective action records, you should compare the establishment's recorded corrective actions with the requirements of §417.3(a).

Corrective Action Example 1, part 6: *Continuing with the above example, you review the establishment's corrective action log for this deviation. You compare the recorded corrective actions with what you have observed and with the requirements of §417.3(a), and find that all requirements were met. The establishment identified and eliminated the cause of the deviation, the CCP was under control after the corrective action was taken, measures to prevent recurrence were established, and no product that is injurious to health, or otherwise adulterated as a result of the deviation, entered commerce. You determine that this requirement is met, and you record 03E01 as an unscheduled procedure, and mark it as (a) performed.*

Determine compliance

After you have gathered and assessed all available information pertaining to the corrective action requirement, you must determine regulatory compliance. If you find that the establishment has met the corrective action regulatory requirements, then there is no regulatory noncompliance. If you find that the establishment has not met the corrective action regulatory requirements, there is noncompliance. You will receive more information about making compliance determinations in a later section.

►Noncompliance with the Corrective Action Requirements

The following are examples of noncompliance with §417.3(a).

1. *You are reviewing monitoring records for the fermentation step in a semi-dry sausage establishment and you find a pH of 5.3 or less was not achieved in the maximum hours, i.e., the degree-hour critical limit was not met, for a lot of summer sausage. A pH of 5.38 was achieved for the summer sausage. You*

proceed to verify that corrective actions were taken as required in §417.3(a) by reviewing the entries on the corrective action log, which reads as follows:

"The supplier of our meat starter cultures sent us cultures with the same organism but the culture was developed and prepared by a different manufacturer. We disposed of the remaining shipment of the cultures from that manufacturer and contacted the supplier and informed them of their error. When the next shipment of starter cultures from our supplier arrives, the manufacturer's name on the container of the starter cultures will be verified before it is received. The lot of summer sausage was moved to the cooler and placed on QA hold. Fifteen 25g samples from the outer 1/8 inch of the sausage were selected from the lot and sent to an accredited lab for staphylococci testing. The results of the samples did not indicate high levels of staphylococci thus thermonuclease (enterotoxin) testing was not necessary (see the attached lab results). The lot was released and cooked. pH measurements from the finished lot of summer sausage were 5.18 and 5.20".

You find no documentation and observe no evidence that the establishment ***established measures to prevent the deviation from the critical limit from recurring.***

2. *You are reviewing monitoring records for the cooking (lethality) step in a jerky establishment and find the critical limit of 90% or higher relative humidity was not maintained during the 2 hour cook cycle. Relative humidity is monitored every 30 minutes by comparing the wet bulb temperature reading to the dry bulb temperature reading. The wet bulb reading was not within 4.5°F of the dry bulb reading for the third and fourth monitoring checks. You proceed to verify that corrective actions by reviewing the corrective action log, which reads as follows:*

"The oven operator failed to replenish the water in the wet-bulb thermometer well. The well was re-filled. The operator was counseled regarding the importance of filling the water well to the required level before the next cook cycle is started. The HACCP plan is being modified to include a procedure for verifying that the wet-bulb water wick well contains the appropriate amount of water prior to startup and once during the shift. The relative humidity will be monitored every 15 minutes on the average for the next four cook cycles".

You review the HACCP plan and find that the verification column has been modified to include the new verification procedure. You find no documentation and observe no evidence that ***the establishment took measures to ensure that no product injurious to health or otherwise adulterated entered commerce.***

3. *You are reviewing the metal detection log in a snack stick establishment and find a deviation recorded at the 10:04 am monitoring check. The documentation on the log states that the machine failed to detect the metal in the seeded sample. The machine was operating properly at the last monitoring check that occurred at 7:58 a.m. You verify corrective actions by reviewing the corrective action log, which reads as follows:*

"Production was stopped. All product produced after the 7:58 a.m. check was identified, segregated and run through a functional metal detector. No metal was detected, and the packaging supervisor released the segregated product. Maintenance personnel removed the nonfunctioning metal detector and replaced it with another functioning metal detector. The packaging supervisor checked the replacement unit with a seeded sample and it responded appropriately. Production resumed at 1:10 p.m. The packaging supervisor will perform monitoring checks at an increased frequency of every half hour for the rest of the day".

You find no documentation and observe no evidence that ***the establishment identified and eliminated the cause of the deviation or established measures to prevent the deviation from the critical limit from recurring.***

4. *You are reviewing the product temperature log for the raw product storage CCP in a large fermented, non heat-treated, dry sausage establishment and find that one of the internal product temperatures recorded for the afternoon monitoring check in cooler 2 was 42°F, which exceeded the critical limit of 40°F. The recorded internal product temperatures for the morning monitoring check were lower than the critical limit. You proceed to verify that corrective actions were taken as required in §417.3(a) by reviewing the entries on the corrective action log, which read as follows:*

The internal temperatures of beef chucks in 3 combo bins along the north wall was 41°F, 42°F and 42°F. These combo bins were segregated and placed on QC hold in cooler 1. Combo bins with beef chucks with internal temperatures 40°F or below were moved to coolers 1 and 3. Maintenance personnel determined that the motor for one of the circulating fans in the refrigeration unit against the north wall had had a short. The motor was replaced. The time interval between the last acceptable monitoring check and the internal temperatures were plugged into a pathogen modeling program. Resulting growth curve indicated that the pathogens of concern would still be in the lag phase, thus no significant increase in the number of pathogens would occur. We found two scientific articles that support that it would take several hours at 42°F to get logarithmic increase in microorganisms and have included them in our supporting documentation file. An SOP has been established for the quarterly maintenance of the refrigeration units and the daily monitoring of a thermometer attached to the wall under each refrigeration units in the coolers. The 3 combo bins were released into production.

You find no documentation and observe no evidence that ***the establishment took appropriate measures to ensure the CCP was under control after the actions were taken.***

You will document any noncompliance in accordance with our discussion of documentation and enforcement in a later section.

B. Corrective Actions in Response to a Deviation Not Covered by a Specific Corrective Action, or an Unforeseen Hazard

The regulation that applies when a deviation not covered by a specific corrective action or an unforeseen hazard occurs is:

9 CFR 417.3(b)*—If a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment shall: (1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met; (2) Perform a review to determine the acceptability of the affected product for distribution; (3) Take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce; (4) Perform or obtain reassessment by an individual trained in accordance with §417.7 of this part, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.*

This requirement cannot be randomly verified because corrective action occurs when something triggers it (i.e., an unforeseen hazard or a deviation not covered by a corrective action). If an unforeseen hazard or a deviation not covered by a critical limit occurs, **always** verify that the regulatory requirements are met by comparing the corrective actions taken by the establishment with the regulatory requirements in 9 CFR 417.3(b).

These requirements should be verified as part of the HACCP 01 or HACCP 02 procedures.

The thought process you should use when verifying regulatory requirements includes:

- gathering information by asking questions;
- assessing the information; and
- determining regulatory compliance.

This thought process should be utilized when verifying all of the regulatory requirements.

Gather information by asking questions

You should answer the following questions to determine whether the corrective action requirements have been met:

1. Did the establishment segregate and hold **all** affected product?

2. Did the establishment perform a review to determine the acceptability of the affected product for distribution?

3. Did the establishment take necessary action with respect to the affected product to ensure that no product that is injurious to health, or otherwise adulterated as a result of the deviation, enters commerce?

4. Was a reassessment conducted to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan?

Assess the information

When seeking answers to these questions, you should:

- Review the corrective action records associated with the deviation or unforeseen hazard and observe the establishment executing the corrective actions.
- Compare the establishment's recorded corrective actions to the regulatory requirements listed in 9 CFR 417.3(b)(1), (2), (3) and (4) to determine whether the corrective actions taken in response to the deviation from the critical limit meets all of these requirements.
- Observe the establishment segregating and holding the affected product to verify that the establishment segregated and held **all** affected product.
- Observe the establishment evaluating the affected product to verify that only acceptable product is released.
- Review the corrective action records, determine if a reassessment was performed and, if so, verify that the establishment has supporting documentation for decisions made during the reassessment.

Now let's look at each of these in more detail.

►Reviewing the Corrective Action Records

In reviewing the corrective action records, you should compare the establishment's recorded corrective actions with the requirements of §417.3(b).

Corrective Action Example 2, part 1: *You are performing the 03E02 procedure in a fermented dry sausage establishment in response to a positive* Listeria monocytogenes *result, which the establishment received in a sliced pepperoni sample it sent for laboratory analysis as a quarterly verification of the HACCP system. The establishment has a CCP in the HACCP plan, at receiving, for confirming that suppliers certify that they apply a validated antimicrobial intervention and conduct* E. coli *O157:H7 testing. The establishment has controls for raw material storage temperature in a prerequisite program. It also has CCPs for fermentation and drying (the products don't receive a heat treatment). At the slicing and packaging steps, the plant concluded that Lm was not a hazard likely to occur because of the interventions that occur in previous steps. The plant has supporting documentation on file that the final product pH and water activity reduces the numbers of* E. coli *O157:H7,* Salmonella *and Lm and inhibits their growth and the growth of sporeforming bacteria in the products. Therefore, the antimicrobial process is both a post-lethality treatment and growth inhibitor for Lm; and the plant has selected Alternative 1. You review the corrective action log dated 4-1-2005 and find the following entry for this incident:*

"All affected product (pack codes 032605A and 032605B) was identified, segregated, and placed on QA hold in the finished product warehouse the day we submitted the sample to the laboratory. Since we don't have a lethality step (cooking) in our process sufficient to destroy Lm, the affected product lots will be moved off-site on the morning of 4-3-05, under appropriate company control including the use of company seals, to our sister establishment, 38A, for proper disposition. Establishment 38A has both a cooking step and validated steam pasteurization post lethality treatment in the HACCP plan that would render our product free of Lm. The HACCP plan will be reassessed by 4-3-2005".

Based upon your review of the records, you determine that the recorded actions meet the requirements of §417.3(b). ***You notify the DO via e-mail that the establishment intends to move product that tested positive for Lm off-site for proper disposition and provide the name and number of the establishment that will receive the product.***

►Observing the Establishment Execute Corrective Actions

You would observe the establishment executing corrective actions to verify that all affected product is segregated and held.

Corrective Action Example 2, part 2: *Continuing from the previous example, you verify that the establishment has segregated and held the affected product by going to the finished product warehouse to observe the product. In the warehouse, you find 15 pallets of boxed product segregated and on hold with QA control tags. You have the packaging supervisor open a few boxes and find immediate containers with the correct lot codes on them. You examine production records and determine that the two lots of sliced pepperoni were the only products produced on that day. Based upon your observations, you determine that the establishment has adequately held and segregated affected product.*

You would observe the procedures the establishment implements to maintain control of adulterated product while in transit to the official establishment for proper disposition.

Corrective Action Example 2, part 3: *Continuing from the previous example, it is now the morning of 4-3-05 and you observe a forklift loading the affected product onto a truck trailer in the shipping bay. You go into the shipping office and ask the shipping supervisor how the establishment intends to maintain control of the product while in transit to ensure that it is received by establishment 38A. The supervisor shows you a record that has establishment 38A identified as the receiving plant and the numbers of the seals that are to be affixed to the trailer, the total number of pallets of product, total number of boxes, etc. He tells you that a copy of this record will be attached to the first pallet inside the door of the trailer and establishment 38A will fax a record confirming receipt of the product that will be attached to the shipping record. Based upon your observations, the establishment took necessary measures to ensure that it maintained control of the adulterated product during transit.*

►Determine if a reassessment was performed

Verify that the establishment performed the reassessment and has supporting documentation for decisions made during the reassessment.

Corrective Action Example 2, part 4: *Continuing from the previous example, it is now 4-4-05 and you determine if the plant reassessed the HACCP plan by the date documented on the corrective action log. You review the corrective action log dated 4-1-2005 and find the following entry*

"…The HACCP plan will be reassessed by 4-3-2005. The HACCP plan was reassessed on 4-2-05 and modifications were made. SSOP was also modified".

Because the plant must reassess the HACCP plan as a result of the unforeseen hazard, you request the record documenting the decisions the plant made during the reassessment and observe the following:

"After evaluating the supporting data for the log reduction of Lm achieved by the fermentation and drying processes, we concluded that the positive Lm result was most likely due to Lm contamination during slicing and packaging. The positive Lm result suggests that the post-lethality treatment may have been challenged by the sanitation conditions in the environment. Since this is our first positive result for Lm, we still believe that Lm is not likely to occur in our process, but we are incorporating new sanitation measures to prevent Lm in the processing environment, and food contact surface testing for Listeria *spp. to evaluate the effectiveness of such measures, into our SSOP. As a precaution, we are modifying the HACCP plan to include a new intermediate heat treatment CCP after the fermentation step prior to the drying step. The critical limit is an internal product temperature of 128°F or above for 1 hour or more".*

You decide to investigate further and ask for supporting documentation from plant management for the critical limit at the new CCP and review the changes in the SSOP.

You are shown two scientific studies that applied this intermediate heat treatment to pepperoni which resulted in a 2-log lethality treatment for vegetative pathogens. The SSOP was modified to include the proposed changes. You determine that the establishment has met its requirement to perform reassessment when an unforeseen hazard arises, and to determine whether the unforeseen hazard should be incorporated into the HACCP plan.

Verify that the establishment maintains records that show that the Lm positive product received the proper disposition.

Corrective Action Example 2, part 5: *Continuing from the previous example, it now two weeks from when the plant shipped the pepperoni that tested positive for Lm to establishment 38A for cooking. You ask the plant to provide documentation that the adulterated product was given a lethality treatment sufficient to destroy Lm. Copies of establishment 38A's HACCP records that show that the product received a heat process sufficient to destroy Lm, supporting documentation for the heat cycle parameters (time and temperature), and an original letter certifying that the product received the heat treatment are attached to the corrective action log. While reviewing the records, you notice that the plant has signed and dated the pre-shipment review. You determine that*

the establishment is in compliance with §417.3(b) and all other regulatory requirements for that specific production,, you record 03E02 as an unscheduled procedure, and mark it as "A" for performed.

Determine compliance

After you have gathered and assessed all available information pertaining to the corrective action requirement, you must determine regulatory compliance. If you find that the establishment has met the corrective action regulatory requirements, then there is no regulatory noncompliance. If you find that the establishment has not met the corrective action regulatory requirements, there is noncompliance. You will receive more information about making compliance determinations in a later section.

►Noncompliance with the Corrective Action Requirements

The following are examples of noncompliance with §417.3(b).

1. *Continuing from our above example in which a RTE product sample submitted by the establishment tested positive for Lm, if you found evidence that product in addition to the two lots of pepperoni was produced on the same day and the establishment had not documented that contamination would be limited to an individual production line or individual products, you could conclude* ***that all of the affected product was not held.***

2. *If the establishment* ***did not perform a HACCP plan reassessment*** *after receiving the positive sample result for Lm in a RTE product (the pepperoni), it would not be in compliance with §417.3(b).*

3. *If the plant did not maintain appropriate control of the adulterated pepperoni while in transit (e.g., through company seals) to the official establishment (38A) for proper disposition,* ***the establishment did not take necessary action to ensure that no product injurious to health enters commerce.***

4. *If the establishment did not receive documentation that provided evidence that the adulterated pepperoni had received a lethality treatment sufficient to destroy Lm from the official establishment (38A) where final disposition of the product occurred,* ***the establishment did not take necessary action to ensure that no product injurious to health enters commerce.***

You will document any noncompliance in accordance with our discussion of documentation and enforcement in a later section.

Workshop: Corrective Actions

1. You are reviewing the steam pasteurization tunnel monitoring record for the packaging CCP and observe that one of the temperature readings recorded for the MIG is 187°F. The **critical limits** identified in the HACCP plan for this CCP are 190°F or higher steam tunnel temperature AND a belt speed of ≤ 2 feet per minute.

   a. **At this point in your review**, is this a deviation from a critical limit and/or a HACCP noncompliance?

   b. Continuing with the above, if the establishment's records indicate that ALL corrective actions met the requirements of §417.3(a), is there a HACCP noncompliance?

2. The HACCP plan specifies for the fermentation CCP that the pH of the product will be monitored by placing a pH electrode in a meat/distilled water slurry from two individual samples taken from pieces of product located in each cold spot of the chamber at the end of the maximum hours for fermentation prior to initiating the heat cycle. Each pH measurement will be recorded on the fermentation log. The establishment has heat distribution data for the fermentation chamber on file that indicates there are two cold spots. You review the fermentation log from yesterday and observe that for both fermentation cycles there are only two pH results recorded. All recorded results are within critical limits.

   a. Based only on the information given, is this a deviation from a critical limit, an unforeseen hazard, or a HACCP noncompliance?

   b. Would you expect to see all corrective actions in §417.3(a) taken for this situation? Please explain.

3. Establishment 38 is small operation that only produces a non-fermented sliced dry salami product for export to Japan. The HACCP plan includes a lethality treatment (cook step) CCP to inactivate pathogenic microorganisms and a drying CCP to inhibit growth of pathogens after the cook step. At the slicing step, the plant considered *Listeria monocytogenes* (*Lm*) as a potential biological hazard, but determined that it was not reasonably likely to occur because it has sanitation measures, including a written testing protocol for food contact surfaces, in the SSOP to prevent *Lm* in the post lethality processing environment. The water activity of the finished salami is lower than .92, but because the plant has no documentation to support that the lowered water activity kills *Lm,* the plant has chosen Alternative 2, Choice 2 for controlling *Lm* in its post lethality exposed RTE product. On 3-23-05, you collected and submitted an intact sample of sliced salami to the laboratory under the RTE001 sampling project. When you took the sample, the plant told you that it would place

the lot of product on hold. On the morning of 3-29-05, you check LEARN and find that the sample tested positive for *Listeria monocytogenes.*

a. Which regulations would apply in this situation?

b. At this point, is there a HACCP noncompliance? If so, what procedure code would be recorded on the NR?

c. What would you do next?

After you verify that the plant has the affected product on hold. You return to your other duties. Later in the morning, you begin the 03F02 procedure by going to the QA office and asking for documentation of the actions taken.

HACCP CORRECTIVE ACTION REPORT XYZ Corporation
Date: *3-29-05*
Product and amount affected: *500 lbs packaged sliced salami (pack code 032305)*
Actions:

All affected product (pack code 032305) was identified, segregated, and placed on QA hold on the afternoon of 3-23-05 because the USDA inspector selected and submitted a sample to the USDA lab for pathogen testing. Today, the USDA inspector informed us that the product tested positive for Listeria monocytogenes*. The affected product will remain on hold. We contacted our trade association who referred us to a processing authority to assist us with this problem. We are in the process of contacting the processing authority. The HACCP plan will be reassessed on or by 3-31-05.* AB 8:50 am

_____ _____
Plant Management, date QA Manager, date

Example: For Training Use Only

d. At this point, is there a HACCP noncompliance? If so, what procedure code would be recorded on the NR?

e. What would you do next?

You had to go to other establishments on your patrol assignment yesterday before finishing the corrective action verification. You know that you have to verify that the corrective actions the establishment implemented as a result of the positive pathogen result met the requirements in §417.3(b) and §416.15, so when you return the next day you review the corrective action log again.

HACCP CORRECTIVE ACTION REPORT XYZ Corporation
Date: *3-29-05*
Product and amount affected: *500 lbs packaged sliced salami (pack code 032305)*
Actions:

All affected product (pack code 032305) was identified, segregated, and placed on QA hold on the afternoon of 3-23-05 because the USDA inspector selected and submitted a sample to the USDA lab for pathogen testing. Today the USDA inspector informed us that the product tested positive for Listeria monocytogenes*. The affected product will remain on hold. We have contacted our trade association who has referred us to a processing authority to assist us with this problem. We are in the process of contacting the processing authority. The HACCP plan will be reassessed by 3-31-05.* AB 8:50 a.m.

All packaged product will be opened and reworked into new product batches over the next 10 days and will be given a heat process sufficient to kill this organism. Based on the processing information we gave the processing authority, she determined that there would be no additional hazards associated with reprocessing the product contaminated with this pathogen using the original lethality treatment already in our HACCP plan. See the attached letter from the processing authority. CD 1:50 p.m.

We initiated corrective actions outlined in our SSOP including intensified cleaning and sanitizing of the food contact surfaces in the post lethality processing environment at the end of production today. Intensified sampling of the food contact surfaces for Listeria *ssp. as outlined in the SSOP will start tomorrow.* CD 4:50 p.m.

We have reassessed the HACCP plan and have concluded that no changes to the plan are necessary. This is the first Listeria monocytogenes *positive we have had. We have evaluated the effectiveness of the SSOP and believe that making changes to our sanitation and microbial testing procedures in the SSOP will prevent anymore positives. See the revised SSOP, dated 3-29-05.* AB 10:40 p.m.

Adel Brezil 3-29-05 *Craig Darrow 3-29-05*
Plant Management, date QA Manager, date

f. Do the establishment's recorded corrective actions meet all of the corrective action regulatory requirements?

g. What else would you do in this situation?

4. You are performing a routine labeling verification (04B04) as part of an Other Consumer Protection procedure. You have decided to observe formulation of the canned chicken noodle soup. You notice that a new brand of noodles is being used in the formulation. You compare the ingredients on the bags of noodles to the establishment's formulation and the label being placed on these cans. You discover that there is an additional ingredient listed on the label of these noodles, sodium caseinate, which is not represented on the product labeling. You recall that the list of ingredients that are known allergens includes: cereals containing gluten (wheat), crustacean, eggs, fish, milk, peanuts, soybeans, and tree nuts. You realize that the sodium caseinate is a milk product, and therefore, this product contains a known allergen that is not declared in the ingredients statement. Because you reviewed the hazard analysis recently, you are aware that the establishment did not consider allergens as potential food safety hazards likely to occur in its process.

You ask the HACCP coordinator about this discrepancy. He tells you that the processing authority has "approved the use of the new noodles" and shows you a letter from the process authority. You read the processing authority documentation. It states that the critical factors for formulation were evaluated and the new noodles would not affect the current process schedule (i.e., time and temperature for retorting). You ask about the labeling and allergen issues and the HACCP coordinator has no further information.

a. Which regulations would apply in this situation?

b. At this point, is there a noncompliance?

c. What would you do next?

Reassessment

Reassessment (Annual and Changes in Plant Processes) and Establishment Training Requirements

The regulations that apply to reassessment of the HACCP plan and establishment training are:

9 CFR 417.4(a)(3)*—Reassessment of the HACCP plan. Every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging; finished product distribution systems; or, the intended use or consumers of the finished product. The reassessment shall be performed by an individual trained in accordance with §417.7 of this part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of §417.2(c) of this part.*

9 CFR 417.7(a)*—Only an individual who has met the requirements of paragraph (b) of this section, but who need not be an employee of the establishment shall be permitted to perform the following functions:*

(1) Development of the HACCP plan, in accordance with section 417.2(b) of this part, which could include adapting a generic model that is appropriate for the specific product, and

(2) Reassessment and modification of the HACCP plan, in accordance with section 417.3 of this part.

(b) The individual performing the functions listed in paragraph (a) of this section shall have successfully completed course of instruction in the application of the seven HACCP principles to meat and poultry product processing including a segment on the development of a HACCP plan for a specific product and on record review.

9 CFR 417.2(d)*—Signing and dating the HACCP plan. (1) The HACCP plan shall be signed and dated by the responsible establishment individual. The signature shall signify that the establishment accepts and will implement the HACCP plan. (2) The HACCP plan shall be dated and signed:*

(i) Upon initial acceptance;
(ii) Upon any modification; and
(iii) At least annually, upon reassessment, as required under section 417.4(a)(3) of this part

As set out in 9 CFR 417.4(a)(3), every establishment is required to reassess the adequacy of its HACCP plan at least annually and whenever any changes occur that could affect its hazard analysis or alter its HACCP plan.

Under 417.7(b), the individual who performs the annual reassessment, as well as any person who develops a HACCP plan for an establishment under 417.2(b) or who modifies a HACCP plan, must have completed a course of instruction in the application of the seven principles of HACCP to meat or poultry product processing, including a

segment on the development of a HACCP plan for a specific product and on record review.

Verification of the Annual Reassessment and Training Requirement

The establishment can reassess its HACCP plan, or plans, any time during the calendar year to meet the annual reassessment requirement. This requirement does not require the establishment to reassess every 12 months. To demonstrate that the annual reassessment has been performed, the establishment is required to sign and date the HACCP plan. The establishment **is not** required to have documentation that the individual that performed the reassessment and any modification to the HACCP plan successfully completed a HACCP training course.

Once a year, as close as possible to the anniversary of the date that FSIS implemented HACCP (January 25-26th), inspection program personnel are to verify that the establishment has:

1. performed its annual reassessment, at some point during the prior year, by reviewing its HACCP plans to verify that they have at least been dated and signed sometime during the previous calendar year, as required by 9 CFR 417.2(d)(2)(iii); and

2. complied with the training requirement for each of its HACCP plans at reassessment, including the annual reassessment, and when it made any modifications in its HACCP plans during the preceding year. Inspection program personnel are to perform this task using Performance Based Inspection System (PBIS) procedure 03A01. Because the verification of the training requirement will coincide with the verification of the annual reassessment, a separate ISP 03A01 is not recorded just for the training component of this verification activity.

When you perform procedure 03A01 verify **both** the annual reassessment and establishment training requirements. Use the HACCP system— basic compliance checklist (FSIS Form 5000-1), but only the parts which pertain to the annual reassessment (top of form and last block on form).

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE

HACCP SYSTEMS BASIC COMPLIANCE CHECKLIST

ESTABLISHMENT NAME		ESTABLISHMENT NO.	PROCESS
PRODUCTS COVERED BY PROCESS			
IMPLEMENTATION DATE	NEW PRODUCT	REASSESSMENT DATE *(Yearly: Check for dated signature only)*	
Use this checklist to document findings of noncompliance with the requirements set out in FSIS Directive 5000.1.			

ACCEPTANCE AND REASSESSMENT (417.2 (d)) The responsible establishment official did not sign and date the HACCP plan (1) upon initial acceptance, or	
(2) at least annually thereafter upon required plan reassessment.	
MODIFICATION The HACCP plan was modified, and the responsible establishment official did not sign and date the plan (417.2 (d) (2) (ii)).	

You are to record only one 03A01 procedure on the PBIS Procedure Schedule for each PBIS HACCP processing category (for example, 03B, 03C, 03D, 03E, 03F) that covers product the establishment produces, regardless of how many HACCP plans the establishment has under that HACCP processing category, or how many HACCP Systems – Basic Compliance checklists (FSIS Form 5000-1) inspection program personnel complete.

For example, if the plant has two fully cooked-not shelf stable HACCP plans (03G), three not heat treated-shelf stable HACCP plans (03E), and three heat treated-shelf stable HACCP plans (03F), you would record three unscheduled 03A01 procedures in the PBIS procedure results screen. This number represents each of the three HACCP processing categories that cover products the establishment produces, even though the establishment has eight HACCP plans. If the establishment has **ONE HACCP plan** that FSIS verifies **using two HACCP elements** or processing categories (such as 03B and 03E), then inspection program personnel are to record **two** unscheduled 03A01 procedures in the PBIS procedure results screen.

Verifying Training Requirements for New and Modified HACCP Plans

The establishment must reassess the adequacy of the HACCP plan whenever a change occurs that could affect the hazard analysis or alter the HACCP plan, but it is not required to document such reassessments, unless the reassessment reveals that modification of the plan is necessary. If reassessment reveals that the HACCP plan no longer meets regulatory requirements, the HACCP plan must be modified immediately, and signed and dated.

If you determine during the performance of your duties that an establishment has implemented a **NEW** HACCP plan or hazard analysis, then you are to ask establishment management at the next weekly meeting after the plan is in place whether the individual who prepared the plan met the training requirement in §417.7. Refer to the “Verification of the Hazard Analysis” section on pages 44-47.

Whenever an establishment does not use an individual having the training required by §417.7 to develop, modify, or reassess its HACCP plan, you are to document the noncompliance.

The thought process you should use when verifying regulatory requirements includes:

- gathering information by asking questions;
- assessing the information; and
- determining regulatory compliance.

This thought process should be utilized when verifying all of the regulatory requirements.

Gather information by asking questions

When verifying compliance with §417.4(a)(3), §417.7 and §417.2(d), you should consider the following questions:

1. Did the establishment perform the annual reassessment of its plan or plans at some point during the previous calendar year?

2. Did the establishment consider any significant developments that have occurred in the plant or that have occurred with respect to the types of products produced by the plant, in its analysis?

3. Has any change occurred that could affect the hazard analysis or HACCP plan?

4. Did the establishment reassess?

5. If the reassessment revealed that the HACCP plan no longer met regulatory requirements, was the HACCP plan modified immediately?

6. Did the establishment sign and date the HACCP plan or plans during the previous calendar year and upon any modification to the plan?

7. Has the individual who reassessed the HACCP plan, or who modified the plan, completed training or a course in the seven principles of HACCP including a segment on the development of a HACCP plan for a specific product and on record review?

Assess the information

To verify compliance with §417.4(a)(3) and §417.2(d), you should review:

- Reassessment records, if available.

- HACCP plan.

Verify that the annual reassessment has been performed by an individual having the training required by §417.7 and that the establishment has considered any changes or developments that could affect the hazard analysis or alter the HACCP plan.

Reassessment Example 1: *On 1-25-2008, the anniversary date that FSIS implemented HACCP, you decide to perform an unscheduled 03A01 procedure in a jerky operation to verify the annual reassessment and training requirements. You review the HACCP plan and verify that the annual reassessment was last performed and signed off on 1-1-2007. You learned in your HACCP training that the establishment reassessment requirement is based upon the calendar year and not upon a 12-month period. Plant management identified the person who signed the plan as someone who completed a HACCP training course meeting the requirements in §417.7. Therefore, you determine that the establishment is in compliance with the annual requirement since reassessment was performed in 2007and the person that reassessed the plan was HACCP trained.*

When the establishment is in compliance, enter "a" (for performed) on the procedure schedule for the unscheduled 03A01 procedure and file the completed checklist (FSIS form 5000-1) in the government file.

If changes have occurred that could affect the hazard analysis or HACCP plan, you should verify that a reassessment was performed by an individual meeting the training requirements in §417.7. If the reassessment revealed that the HACCP plan no longer met regulatory requirements, you should verify that the HACCP plan was modified immediately.

Reassessment Example 2: *You are performing the 03F01 procedure in an establishment that makes several kinds of salami. The establishment notifies you that it is planning to begin producing a different type of salami, dry Italian salami. This product will contain non-fat dry milk, and will be dried under controlled conditions that will result in growth of a white mold on the surface. Establishment management shows you a dry room that is being specially adjusted for this product line. You review the flow chart, and note the addition of the mold starter culture and the use of the dedicated dry room. You review the hazard analysis and HACCP plan and see that a reassessment was conducted recently. You observe that the establishment has considered the potential hazards due to the non-fat dry milk and the white mold. The establishment provides several sources of supporting documentation for the safety of the white mold, and shows you a new procedure in its SSOP to address cross contamination issues due to the use of the non-fat dry milk and mold. Management verbally confirms that the person who performed the reassessment has met the training requirements. Based on your review, you determine that the establishment is in compliance with the reassessment requirement as a result of process changes.*

Determine compliance

After you have gathered and assessed all available information pertaining to the reassessment requirement, you must determine regulatory compliance. If you find that the establishment has met the reassessment regulatory requirements, then there is no regulatory noncompliance. If you find that the establishment has not met the reassessment regulatory requirements, there is noncompliance. You will receive more information about making compliance determinations in a later section.

►Noncompliance with the Reassessment Requirements in 417.4(a)(3)

The following are examples of noncompliance with §417.4(a)(3).

> **Noncompliance Example 1:** *On 1-28-2007, you are performing the 03A01 procedure and are reviewing the HACCP plan to verify it meets the annual reassessment requirement. The HACCP plan is signed and dated 12-22-2005. You question the HACCP coordinator and determine that the last reassessment was in December of 2005.* ***The annual reassessment requirement was not met.***

When the establishment has not signed and dated each of its HACCP plans during the calendar year or signed and dated it upon modification, enter a check mark on the checklist. If the establishment does not meet the annual reassessment requirement or comply with the training requirement under 417.7 for each of its HACCP plans, enter the "m" noncompliance result code on the procedure schedule (PS) and complete the NR citing both 417.4(a)(3) and 417.2(d)(iii) for failing to meet the annual reassessment requirement, or 417.2(d)(ii) for failing to sign and date upon modification, or 417.7 for failing to meet the training requirement. Attach the completed checklist to the copy of the NR and maintain the copy in the government file.

> **Noncompliance Example 2:** *On 3-1-2008, a jerky producer reassesses its HACCP plan in light of new information regarding the importance of humidity in elimination of pathogens, contained in the FSIS jerky compliance guidelines. The establishment documents the need for humidity at the cooking CCP, which previously only had time and temperature, and their decision to add a critical limit for humidity. You review the hazard analysis and HACCP plan on 4-1-08, and observe that the establishment has not changed the CCP to address the identified need for a humidity critical limit at cooking.* ***Reassessment revealed that the HACCP plan no longer met the requirements of 417.2(c) and the plan was not immediately modified.***

Additional information for documenting noncompliance will be provided during discussion of documentation and enforcement in a later section.

Reassessment of the Hazard Analysis

9 CFR 417.4(b)--Reassessment of the hazard analysis. Any establishment that does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur shall reassess the adequacy of the hazard analysis whenever a change occurs that could reasonably affect whether a food safety hazard exists. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; packaging; finished product distribution systems; or, the intended use or consumers of the finished product.

You will have to rely on your knowledge of the operation and the changes that occur within that operation. You would verify this requirement using the 01 procedure.

The thought process you should use when verifying regulatory requirements includes:

- gathering information by asking questions;
- assessing the information; and
- determining regulatory compliance.

This thought process should be utilized when verifying all of the regulatory requirements.

Gather information by asking questions

When verifying compliance with §417.4(b), you must answer the following questions.

1. Does the establishment have a process without a HACCP plan because the hazard analysis has revealed there is no food safety hazard likely to occur?

2. Have any changes occurred in the process that could reasonably affect whether a food safety hazard exists?

3. If changes have occurred in the process, has a reassessment been conducted as a result of these changes?

4. Has the individual who reassessed the hazard analysis met the training requirement prescribed in §417.7?

Assess the information

You would review the hazard analysis.

FSIS knows of no process that inherently has no hazards. If you encounter an establishment with no HACCP plan, you should notify the District Office. You should verify food safety to ensure the process is not producing adulterated product.

Determine compliance

After you have gathered and assessed all available information pertaining to the reassessment requirement, you must determine regulatory compliance. If you find that the establishment has met the reassessment regulatory requirements, then there is no regulatory noncompliance. If you find that the establishment has not met the reassessment regulatory requirements, there is noncompliance. You will receive more information about making compliance determinations in a later section.

►Noncompliance with the Reassessment Requirements in §417.4(b)

A canning establishment which produces product in metal cans has no HACCP plan because the hazard analysis revealed no chemical or physical hazards likely to occur, and the establishment addresses food safety hazards associated with microbiological contamination by compliance with the canning regulation. You observe that the establishment has added a new production line, to produce baby food in glass jars. ***The establishment has a process with no HACCP plan, changes occurred that could affect whether a food safety hazard exists, and the establishment did not conduct a reassessment of the hazard analysis.***

►Noncompliance with the HACCP Plan Requirements in §417.2(b).

In March of 08 you review the hazard analysis and flow chart at a popped pork skin operation. You observe that a reassessment was done in January 08, due to a change in type of raw materials received. The reassessment revealed a microbiological hazard reasonably likely to occur, and the establishment determined that a CCP is now needed to control pathogens. You request the HACCP plan and are told that there is a contractor working on it, but the plan has not yet been completed. ***Changes occurred that could affect whether a food safety hazard exists, reassessment was conducted, the reassessment revealed that a food safety hazard exists, and no HACCP plan was developed. Note: Since the reassessment was conducted, this is noncompliance with 417.2(b)(1).***

You will document any noncompliance in accordance with our discussion of documentation and enforcement in a later section.

Workshop: Reassessment

Refer to the module and to FSIS Directive 5000.1 to complete the following questions.

1. How often are establishments required to reassess their hazard analyses and HACCP plans?

2. An establishment reassesses its hazard analysis and HACCP plan in June of 05 due to major equipment changes. It determines that there are no changes in hazards identified as reasonably likely to occur, and it makes no changes to the HACCP plan. This is documented in the cover sheet of the hazard analysis. Can this establishment consider this the annual reassessment for this plan for 05?

3. You are performing the 03F01 procedure at a pepperoni operation. You observe employees adding the starter culture at the mixer. You are familiar with this plant, and they have always used a frozen can of liquid starter culture. Today, they are mixing dry pellets from a bag into a container of water, and then pour it into the mixer. You ask the employees about this, and they explain that yesterday the establishment started using this new type of starter culture. After verifying that other consumer protection requirements have been met, you go to the HACCP office and review the HACCP plan, hazard analysis and reassessment records. You find no documentation that this change to the product formula has triggered a reassessment.

a. What conclusions do you make?

b. What would you do next?

c. Is there a HACCP noncompliance?

d. What regulations apply to this situation?

Summary-Verifying the Five Regulatory Requirements

The following tables (**Table 1** and **Table 2**) provide a quick reference for the questions that you would seek answers to when verifying each of the requirements.

Table 1—Monitoring, Verification, and Recordkeeping Requirements

Monitoring	Verification	Recordkeeping
9CFR 417.2(c)(4) 1. Does the HACCP plan list the monitoring procedures and frequencies that are used to monitor each of the CCPs to ensure compliance with the critical limits? 2. Are the monitoring procedures being performed as described in the HACCP plan? 3. Are the monitoring procedures being performed at the frequencies for the CCPs listed in the HACCP plan? 4. Was the critical limit met?	**9CFR 417.2(c)(7) 417.4(a)(2)(i)(ii)(iii)** 1. Does the HACCP plan contain procedures and frequencies for the calibration of the process-monitoring instruments? 2. Does the HACCP plan contain procedures and frequencies for direct observations of monitoring activities & corrective actions? 3. Does the HACCP plan list procedures and frequencies for the review of records generated and maintained in accordance with 9 CFR 417.5(a)(3)? 4. Does the HACCP plan list product sampling as a verification activity? 5. Are process-monitoring instrument calibration activities conducted as per the HACCP plan? 6. Are direct observation verification activities conducted as per the HACCP plan? 7. Are records generated in accordance with 9 CFR 417.5(a)(3) being reviewed by the establishment?	**Recordkeeping Requirement – 9CFR 417.2(c)(6)** 1. Does the HACCP plan set out a recordkeeping system that documents the monitoring of the CCP? 2. Do the records contain actual values & observations obtained during monitoring? **Supporting Documentation Requirement – 9CFR 417.5(a)** 1. Does the establishment have the supporting documentation for the decisions made in the hazard analysis? 2. Does the establishment have the decision-making documents associated with the selection of each CCP? 3. Do documents explain why the establishment selected the location of the CCP? 4. Is there a control at the identified point in the process that will prevent, eliminate, or reduce to acceptable levels the identified hazards? 5. Does the establishment have scientific, technical, or regulatory support for the critical limit? 6. Does the support appear creditable? 7. Does the establishment have documents supporting the monitoring procedures and frequencies listed in the HACCP plan? 8. Does the establishment have documents supporting the verification procedures and frequencies listed in the HACCP plan? Do the documents support what the establishment has done? 9. If the establishment has supporting documents for these decisions, does the documentation support the decisions? **HACCP Records Requirement – 417.5(a)(3)** 1. Do the records document the monitoring of CCPs and critical limits? 2. Do the records include actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan? 3. Do the monitoring, verification, and corrective action records include product codes, product name or identity, or slaughter production lot, and the date each record was made? 4. Are verification procedures and results documented? 5. Is the time recorded when the verification activity was performed? 6. Does the record contain the date the record was made? 7. Are process-monitoring calibration procedures & results recorded? **Records Authenticity Requirement – 417.5(b)** 1. Was each entry on the record made at the time the event occurred? 2. Does each entry include the time? 3. Was each entry on the record signed or initialed by the establishment employee making the entry? **Computerized Records Requirement – 417.5(d)** Are appropriate controls provided to ensure integrity of electronic data and signatures? **Record Retention and Availability Requirement – 417.5(e)(1)(2)** 1. Are the records being maintained for the required amount of time, i.e., one year for slaughter and refrigerated products and two years for frozen, preserved, or shelf-stable products? 2. Are the records kept on-site for 6 months? 3. If the records are stored off-site, can they be retrieved in 24 hours? **Pre-shipment Review Requirement – 417.5(c)** 1. Has the establishment reviewed the records associated with the production of the product, prior to shipment? 2. Has the pre-shipment review been signed & dated by an establishment employee?

Table 2-Corrective Action and Reassessment Requirements

Corrective Actions	Reassessment
Corrective actions in response to a deviation from a critical limit – 9CFR 417.3(a) 1. Did the establishment identify and eliminate the cause of the deviation? 2. Did the corrective actions ensure that the CCP is brought under control? 3. Were measures implemented to prevent recurrence of the deviation? 4. Did the actions ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce? **Corrective Actions in Response to a Deviation Not Covered by a Specific Corrective Action or an Unforeseen Hazard – 9CFR 417.3(b)** 1. Did the establishment segregate and hold all affected product? 2. Did the establishment perform a review to determine the acceptability of the affected product for distribution? 3. Did the establishment take necessary action with respect to the affected product to ensure that no product that is injurious to health, or otherwise adulterated as a result of the deviation, enters commerce? 4. Was a reassessment conducted to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan?	**Annual reassessment requirement or changes in plant processes - 9CFR 417.4(a)(3)** 1. Did the establishment perform the annual reassessment of its plan or plans at some point during the previous calendar year? 2. Did the establishment consider any significant developments that have occurred in the plant or that have occurred with respect to the types of products produced by the plant, in its analysis? 3. Has any change occurred that could affect the hazard analysis or HACCP plan? 4. Did the establishment reassess? 5. If the reassessment revealed that the HACCP plan no longer met regulatory requirements, was the HACCP plan modified immediately? 6. Did the establishment sign and date the HACCP plan or plans during the previous calendar year and upon any modification to the plan? 7. Has the individual who reassessed the HACCP plan, or who modified the plan, completed training or a course in the seven principles of HACCP including a segment on the development of a HACCP plan for a specific product and on record review? **Reassessment of the Hazard Analysis – 9CFR 417.4(b)** 1. Does the establishment have a process without a HACCP plan because the hazard analysis has revealed there is no food safety hazard likely to occur? 2. Have any changes occurred in the process that could reasonably affect whether a food safety hazard exists? 3. If changes have occurred in the process, has a reassessment been conducted as a result of these changes. 4. Has the individual who reassessed the hazard analysis met the training requirement prescribed in §417.7?

Note: Corrective Action and Reassessment requirements are verified at **each occurrence**. For example, if you are performing the 01 or 02 procedure and you notice that the establishment had a deviation from a critical limit, you would verify that the corrective action requirements had been met.

Now let's summarize and review the methodology for verifying compliance with the five requirements by performing the 01 and 02 procedures.

Performing the 01 Procedure

Remember that the 01 procedure is for verifying compliance with a random sample of the regulatory requirements. To perform the 01 procedure, you will do the following:

1. **Randomly** select one (or more) of the three HACCP requirements to verify.
2. Select a HACCP plan and one (or more) of the CCPs from that plan to verify.
3. Determine which component (review and observation or recordkeeping) to perform.
4. Review those portions of the HACCP plan you are to verify and perform the verification for **that requirement** for **that CCP.**

Corrective Actions and Reassessment will be verified as part of the 01 procedure at each occurrence but cannot be randomly selected.

Performing the 02 Procedure

The 02 procedure is performed by verifying **all requirements at all CCPs for a specific production** including the pre-shipment review. The 02 procedure verifies implementation of the HACCP plan as it is applied to a specific production. You may use either, or both, components in performing the 02 procedure. To perform the 02 procedure, you will do the following:

1. Verify that **all** of the HACCP requirements have been met for **all CCPs** in the HACCP plan for that **specific production**. Read each CCP that applies to specific production from the appropriate HACCP plan.
2. Verify that the **pre-shipment review** requirement for that specific production has been met.

Corrective Actions and Reassessment will be verified as part of the 02 procedure at each occurrence for the same specific production.

Note: You will **always** perform the 02 procedure when noncompliance is found as a result of performing the 01 procedure.

Verification Activities in Canning Operations

When an establishment chooses to use the canning regulations instead of addressing the food safety hazards associated with microbiological contamination

The regulation 9 CFR 417.2(b)(3) states that HACCP plans for thermally processed/commercially sterile products do not have to address the food safety hazards associated with microbiological contamination, if the product is produced in accordance with the requirements of 9 CFR 318, subpart G, or 9 CFR 381, subpart X (the canning regulations). When an establishment chooses to use the canning regulations instead of addressing the food safety hazards associated with microbiological contamination in a HACCP plan, the establishment needs to document in its hazard analysis that food safety hazards associated with microbiological contamination are not reasonably likely to occur because it is following the applicable canning regulations.

In such cases, the canning regulations act as supporting documentation for the decision made in the hazard analysis that the food safety hazards associated with microbiological contamination are not likely to occur, as required in 417.5(a)(1). An example would be the use of a prerequisite program, which the establishment uses to prevent a hazard from occurring in a process. In those establishments that produce thermally processed/commercially sterile products and that do not address the food safety hazards associated with microbiological contamination in their HACCP plans, but address the hazards in the hazard analyses and determine that the hazards are not reasonably likely to occur, you have the responsibility of verifying that the requirements of the canning regulations, §318/381, are met. These regulatory requirements must be met in order for you to find that the decision made in the hazard analysis is valid. If the establishment is not meeting the requirements of these regulations, it is not meeting the requirements of 9 CFR 417.5(a)(1). If the establishment is not meeting the requirements of 9 CFR 417.5, it may not be meeting the requirements of 9 CFR 417.2, and the HACCP system may be found to be inadequate as described in 9 CFR 417.6(a). You should verify the canning regulatory requirements are met in the same way that you verify that the Sanitation SOP regulations are met, when these regulations are used to support a decision in the hazard analysis.

The Agency generally utilizes Enforcement Investigation and Analysis Officers (EIAOs) to verify that prerequisite programs are successful in preventing identified food safety hazards from being likely to occur. However, sanitation standard operating procedures (Sanitation SOPs) under 9 CFR 416, the canning procedures under 9 CFR 318.300 and 381.300, and the *Listeria monocytogenes* control procedures under 9 CFR 430, are prerequisite programs for which, unlike other prerequisite programs, there are explicit regulatory requirements. For the prerequisite programs for which there are explicit regulatory requirements, FSIS uses in-plant inspection program personnel to verify program compliance.

PERFORMING AN 03D01 PROCEDURE

Since there are numerous requirements in the canning regulations, you will need to verify some of these requirements each time a HACCP 01 procedure is performed.

When procedure 03D01 is performed, you:

- Randomly select one or more of the three HACCP requirements (monitoring, verification and recordkeeping) for verification.

- Select one (or more) of the sections of the canning regulations (e.g., 318.301, 381.301; 318.302, 381.302, etc.) for verification that the establishment is meeting the requirements of the regulation.

  You will need to use your knowledge and judgment to ensure that all sections of the canning regulations are verified at some frequency.

- Determine which component (review and observation or recordkeeping or a combination of the components) to perform in verifying each HACCP regulatory requirement and the canning regulatory section you selected.

  The majority of the time when the HACCP recordkeeping requirement is verified you will use the recordkeeping component of the 03D01 procedure. In verifying some of the canning regulatory requirements, however, you will need to use the review and observation component. For example, when verifying that the establishment is meeting the requirements of §318.305(a) or §381.305(a), you would have to go into the establishment and verify that each retort is equipped with at least one indicating temperature device that measures the actual temperature within the retort, and that the indicating device, not the temperature/time recording device, is used as the reference instrument for indicating the process temperature. This cannot be determined by reviewing records. It requires direct observation of the process.

- Verify the HACCP regulatory requirements (monitoring, verification, and recordkeeping) and also verify that the establishment is meeting the requirements of the sections of the canning regulations you selected to ensure the supporting documentation is implemented. Verifying that the canning regulations are met is part of verifying the HACCP recordkeeping requirement (§417.5(a)(1)--supporting documentation). This means that you verify the <u>recordkeeping regulatory requirement</u> as part of <u>every</u> 03D01 procedure performed.

Note: If you have verified that the persons supervising the operators of the thermal processing systems and container closure technicians have completed the appropriate training, and that there is a recall procedure on file, 9 CFR 318/381.310 and 318/381.311 would not have to be verified again unless there are supervisory changes or reason to believe that a recall procedure is no longer on file.

The thought process you should use when verifying regulatory requirements includes:

- gathering information by asking questions;
- assessing the information; and
- determining regulatory compliance.

This thought process should be utilized when verifying all of the regulatory requirements.

***01 Example**: Your PS for today lists 03D01. The establishment to which you are assigned has one HACCP plan in this processing category, for a variety of soups. You review the hazard analysis and HACCP plan. The establishment has elected to follow the canning regulations and not to address food safety hazards associated with microbiological contamination in its HACCP plan. The HACCP plan has one CCP, for foreign material contamination (metal). You realize that you will verify the recordkeeping regulatory requirement, because this is a canning assignment, therefore verification of recordkeeping requirements is mandatory. You decide to select one HACCP regulatory requirement to verify. Using a pre-determined method of random selection, you chose monitoring, and make a note of this result. Next you think about which component to perform, and decide to perform the review and observation component. You read the monitoring information in the HACCP plan at the only CCP. You proceed to the processing area to begin to perform the review and observation component to verify the monitoring regulatory requirements at CCP 1. You will also verify the recordkeeping regulatory requirement by reviewing the canning operation, and reviewing the canning records for one or more sections of the canning requirements.*

Verification activities for the regulatory requirements of the canning regulations

9 CFR 318.301/381.301 – Containers and Closures:

This section of the canning regulations requires that establishments ensure that empty containers and container materials are clean and free of structural defects and damage that may affect product or container integrity. Additionally, this section also specifies visual and physical examinations of closure or container defects are to be made, and that necessary corrective actions are to be performed when defects are found. You should verify that:

a. the establishment has a statistical sampling plan for evaluating incoming containers and rejection actions, if needed,

b. the establishment is following its statistical sampling plan,

c. the establishment is ensuring that empty containers, roll stock for container forming, and lidding materials are clean and free from structural defects prior to filling,

d. the establishment's empty container handling practices (e.g., conveying, unscrambling, denesting, manual handling) are adequate to prevent soiling and damage,

e. the containers are free of damage after filling,

f. the establishment is conducting container closure examinations,

g. the containers and closures (after closure) are protected from damage which could cause defects likely to affect the hermetic condition of the container,

h. corrective actions are taken in response to detection of improper container closure or damage,

i. the containers are marked with a permanent, legible, identifying code mark per regulatory requirements, and

j. the maximum time lapse between container closure and the initiation of the thermal process is 2 hours or less, unless otherwise approved.

Canning Regulations Example 1: *You are performing the 03D01procedure at a canning facility, and have selected to verify §381.301(d)(1)(i). You decide to use the review and observation component for the post-retorting visual examination of the flexible pouches. You review the plant's written program for this examination. You determine the closure technician is to assess the container integrity of 10 containers at least every 2 hours of continuous production. All containers with defective seals are to be discarded. You proceed to where the closure technician is working. You look at the record and see hourly entries and that the first entry of the day showed there were some containers with seam defects. You see an entry indicating that all containers were held for further seam review and that the sealing machine had been adjusted. You see documentation that the closure tech continued to hold containers until the sealing machine was functioning properly. The entry also noted that all held product was held with a QC tag. You observe the closure tech select 10 containers. She carefully examines the seams and documents that no defects were found. You select 3 filled and sealed containers from the line and examine all seams, you observe no defects. This result is the same as what the QC tech had found. You go to the holding area and see a pallet with a QC hold tag as described on the record. You determine there is compliance with §381.301(d)(1)(i).*

9 CFR 318.302/381.302 – Thermal Processing:

This section of the canning regulations requires that all product be produced by the establishment is produced according to a process schedule developed by a process authority. You should verify that:

a. the establishment verifies that it has process schedules/documents from the processing authority on file for each product produced,

b. the establishment ensures that no unauthorized changes are made to the process schedule in use (e.g., formulation, preparation, process equipment), and

c. the establishment ensures that the products are prepared according to the formulation and procedures specified in documents that the processing authority has developed.

Canning Regulations Example 2: *You are performing the 03D01procedure at a small canning operation, and have selected to verify §381.302(b)(2) using the review and observation component. You are verifying that the plant is not using any unauthorized product formulation changes. You go to the QC office and request the approved process schedules on file that are being used today. You note in the file that there are 2 different types of starch that may be used in the turkey chili formulation they are running currently. The process is different for each of the two types of starch they may use. You see that for the first starch, they need to use process schedule 023. You go to the formulation room and see they are adding bags of the first type of starch to make the turkey chili. You look at the formulation log and see they have used this type of starch in the product all day. You go to the retort area and see process schedule 023 posted. You ask the retort operator which process schedule he is using and he says he is only running the one posted on the wall today. You read the posted schedule and see that it matches the one you saw in the QC office. From this, you determine the operation is in compliance for §381.302(b)(2).*

9 CFR 318.303/381.303 – Critical Factors and the Application of the Process Schedule:

This section of the canning regulations requires that establishments ensure that the critical factors identified in the process schedule are measured, controlled, and recorded as specified in the process schedule. Factors that are often critical to process schedule adequacy may include: maximum fill or drained weight; arrangement of pieces in the container; container orientation; product formulation; particle size; maximum thickness for flexible or semirigid containers during thermal processing; maximum pH; percent salt; ingoing nitrite level; maximum water activity, product consistency or viscosity; container filling sequence; minimum head space; retort conveyor or reel speed; steam/air ratio; and heating medium flow rate. You should verify that:

a. the critical factors specified in the process schedule are measured, controlled and recorded by the establishment to ensure that these factors remain within the limits used to establish the process schedule,

b. all measurements are within limits used to establish the process schedule,

c. the establishment ensures that the types of ingredients (hydrated vs. not hydrated, acidified vs. not acidified, blanched vs. not blanched, slow set vs. rapid set starch, etc.), as specified in the process schedule, are prepared or utilized in the product formulation, and

d. the establishment ensures that the product is prepared according to the formulation specified in the process schedule, including but not limited to the specified amount and characteristics (e.g., pH, cure, water activity, viscosity, etc.) of each ingredient.

Canning Regulations Example 3: *You are performing the 03D01 procedure to verify the canning regulations at a canned chili establishment. You have selected to verify the requirement for §318.303. You review the process schedule on file to determine the critical factors specified for the product, and find that product formulation and use of*

hydrated beans are critical factors. You then proceed to observe the formulation procedures used by the establishment. You determine that hydrated beans were used and that all ingredients were incorporated in the amounts specified in the process schedule. You conclude that the establishment was in compliance with §318.303.

9 CFR 318.304/381.304 – Operations in the Thermal Processing Area:
This section of the canning regulations requires that establishments ensure that the process schedule (or operating process schedule) for daily products, including minimum initial temperatures and operating procedures for the thermal processing equipment, is posted near the thermal processing equipment, or available to the thermal processing system operator and inspection program personnel. Additionally, this section also states that establishments shall have product traffic control to prevent product from bypassing the thermal process, that the initial temperature of the contents of the coldest container to be processed shall be determined and recorded, that timing devices shall be adequate to time applicable thermal processing operation functions or events, and that measurement of pH shall be conducted using potentiometric electronic instruments (pH meters) unless other methods are approved. You should verify that:

a. the process schedules (or operating schedules) for daily production, including minimum initial temperatures and operating procedures for thermal processing equipment, are posted in a conspicuous place near the processing equipment,

b. the establishment has a system in place for product traffic control to prevent product from bypassing the thermal processing operation,

c. the establishment personnel are measuring the coldest container to be processed, and recorded at the time the processing cycle begins, to ensure that the temperature of the contents of every container to be processed is not lower than the minimum initial temperature specified in the process schedule,

d. the establishment is following its written procedures on file for determining the initial temperature,

e. measures are in place to prevent water from lowering the initial temperature below the prescribed minimum (if the establishment is placing containers in holding tanks or using water in the retort),

f. there are adequate product traffic control procedures (e.g., heat sensitive indicators in each retort load) to prevent unprocessed product from bypassing the system,

g. the establishment has accurate devices to time applicable thermal processing operation functions or events, such as process schedule time, come-up time, and retort venting, to assure that all such functions or events are achieved, and

h. the establishment uses potentiometric methods that employ electronic instruments for making pH determinations when a maximum pH value is specified as a critical factor in a process schedule.

Canning Regulations Example 4: *You are performing the 03D01 procedure at a canned spiced ham establishment. You have selected to verify the requirements for §318.304(a). You review the process schedule on file. You then proceed to the retort area to determine if the process schedule is posted or available to the retort operator. You observe that the process schedule is posted and matches the process schedule on file. You conclude that the establishment was in compliance with §318.304(a).*

9 CFR 318.305/381.305 – Equipment and Procedures for Heat Processing Systems:

This section of the canning regulations requires that the equipment and procedures used for heat processing systems be adequate to deliver a thermal process to product that renders it commercially sterile. This regulation identifies specific criteria or parameters for the various instruments, controls, and components of the various types of thermal processing systems, including retort design. The establishment must have the various items addressed in this section of the canning regulations, including but not limited to: temperature indicating devices; temperature/time recording devices; pressure recording devices; steam controllers; air valves and supplies; water inlets and valves; steam inlets and spreaders; bleeders and condensate removal systems (including vents and mufflers); crate supports; stacking equipment; retort/reel speed timing; conveyor speed; heat distribution systems; drain valves; and circulation systems for the various types of retort systems. Additionally, these regulations also address equipment maintenance, container cooling and cooling water, and post-process handling of containers. You should verify that:

a. each retort system is installed, operated, and maintained as required,

b. each retort system is equipped with at least one indicating temperature device that measures the actual temperature within the retort,

c. the indicating temperature device, not the temperature/time recording device, is used as the reference instrument for indicating the process temperature,

d. the mercury-in-glass thermometers meet the requirements specified,

e. each thermal processing system is equipped with at least one temperature/time recording device to provide a permanent record of temperatures within the thermal processing system, and each retort is equipped with an automatic steam controller to maintain the retort temperature,

f. all air lines connected to retorts designed for pressure processing in steam are equipped with a globe valve or other equivalent-type valve or piping arrangement that will prevent leakage of air into the retort during the process cycle,

g. all retort water lines that are intended to be closed during a process cycle are equipped with a globe or other equivalent-type valve or piping arrangement that will prevent leakage of water into the retort during the process cycle,

h. the steam inlet to each retort is large enough to provide steam for proper operation of the retort, and enter at a point to facilitate air removal during venting,

i. steam spreaders, bleeders, stacking equipment, and divider plates are installed and used as per the regulatory requirements,

j. vents are located in the portion of the retort opposite the steam inlet and designed, installed, and operated in such a way that air is removed from the retort before timing of the thermal process is started,

k. vents are not connected to closed drain systems without an atmospheric break in the line,

l. all instruments and controls are checked any time their functioning or accuracy is suspect,

m. maintenance records and the annual thermal process system audit records indicate that the thermal process systems are functioning properly,

n. recycled or reused container cooling waters are handled in systems that are designed, operated, and maintained so that there is no buildup of microorganisms, organic matter, and other materials in the systems and in the waters, and

o. containers are handled in a manner that will prevent damage to the hermetic seal area.

Canning Regulations Example 5: *You are performing the 03D01 procedure in a canning establishment, and have selected to verify §318.305(b)(1)(viii) using the review and observation component. You notice that the bleeders on the horizontal still steam retorts are equipped with mufflers. You ask the retort room supervisor if the establishment has documentation on file that the mufflers do not impede the removal of air from the retorts. The retort room supervisor provides heat distribution data from a processing authority that the mufflers will not impede air removal from the retorts. You determine that the establishment is in compliance with §318.305(b)(1)(viii).*

Canning Regulations Example 6: *You are performing the 03D01 procedure at a canning facility, and have selected to verify §318.305(h), container cooling and cooling water. You chose to use the review and observation component. You request the written program from plant management for cleaning, replenishing with potable water, and measuring the residual chlorine.*

After review of the procedure, you determine that the plant's written program specifies that the residual chlorine will be measured at the discharge point of the canal with a

colorimetric test kit every hour by a QC technician. The value specified is 2 ppm or above. You proceed to that location and observe the QC technician measure and record 2 ppm measurement at 0910. You determine the establishment is in compliance with §318.305(h).

9 CFR 318.306/381.306 – Processing and Production Records:

This section of the canning regulations requires that establishments obtain and record all information necessary to demonstrate that the product is prepared, processed and handled in a manner that is in compliance with the regulations for commercially-sterile, hermetically-sealed shelf stable product. The records required by this part of the canning regulations include, but are not limited to: date of production; product name and style; container code; container size and type; process schedule, including the minimum initial temperature; measurements made to satisfy the requirements for the control of critical factors; and recorded information and data associated with the particular type of thermal processing system used to process the product. You should verify that:

a. establishment personnel record the date of production, product name and style, container code, container size and type, and the process schedule, including the minimum initial temperature,

b. additional records are completed for the specific types of retorts in the establishment, and

c. establishment personnel review and maintain production records.

Canning Regulations Example 7: *You are performing the 03D01 procedure in a canning establishment that uses batch still retorts to verify §318.306(a). You decide to use the recordkeeping component.*

You proceed to the QC office and ask to see yesterday's production records. You review the records and see that they include the product name, container code, size and type and process schedule. Since the plant processes in steam with batch still retorts, you also verify that the records include: retort number; approximate # of containers per load; product IT; steam-on time/temp vent closed; start of process timing; time steam-off; and actual process time. The records also indicate that the temperature device/recorder was read at least once during process timing and the temperature was recorded. You determine that the plant is in compliance with §318.306(a).

9 CFR 318.307/381.307 – Record Review and Maintenance:

This section of the canning regulations requires that establishments prepare processing and production records associated with the production of commercially- sterile, hermetically-sealed shelf stable product appropriately, review the records in a timely manner, and maintain them for a minimum of three years (one year at the establishment and an additional two years at the establishment or other location). Additionally, these regulations also specify that records must be maintained by the establishment that identify the initial distribution of the finished product, and that all records be made available to inspection program personnel for review. You should verify that:

a. entries on the records are made at the time the event occurs,

b. establishment personnel (no later than 1 working day after the actual process) review all processing and production records to ensure completeness and to determine if all product adhered to the process schedule, and

c. all records, including the temperature/time recorder charts and critical factor control records, are signed or initialed and dated by the person conducting the review.

Canning Regulations Example 8: *You are performing the 03D01 procedure in a canning establishment that uses batch still retorts. You select to verify compliance with a part of §318.307(a) which states "each entry on a record must be made at the time the specific event occurs, and the recording individual shall sign or initial each record form." You decide to use the review and observation component.*

You proceed to the processing floor where the still retorts are located. You observe the retort operator venting retort # 1. You observe the posted process schedule and retort log and see that the date, IT, product code, and time steam-on has been recorded and that the retort operator has initialed the process record. You observe the vent operator close the vent and record the time that the vent was closed and the temperature of the retort. Based on your observation, you determine that the plant is in compliance with this part of §318.307(a).

On the following day, you proceed to the QC office and you ask to see the records from the previous day's production to verify if the plant reviewed the process records for the previous day's production. Using the recordkeeping component, you see that the responsible plant official signed the record indicating that he has reviewed all process records for retort #1. Based upon your records review, you determine that the plant is in compliance with this part of §318.307(a).

9 CFR 318.308/381.308 – Deviations in Processing:

This section of the canning regulations requires that whenever the actual process is less than the process schedule, or any critical factor does not comply with the requirements for that factor as specified in the process schedule, such events are considered deviations in processing, and that deviations are to be handled in a manner to prevent the distribution of under processed product. These regulations specify the requirements for handling deviations identified either in-process or through records review. You should verify that:

a. establishment personnel detect all deviations,

b. establishment personnel handle process deviations in accordance with these regulations, whether identified in-process or through records review,

c. the establishment only reprocesses or repacks product with a process schedule authorized by the processing authority,

d. deviations in a continuous retort, including, but not limited to, emergency stops (jams or breakdowns) or temperature drops, are handled according to regulatory requirements, and

e. the establishment's process deviation file contains full records regarding the handling of each deviation, including at a minimum, the appropriate processing and production records, a full description of the corrective actions taken, the evaluation procedures and results, and the disposition of the affected product.

9 CFR 318.309/381.309 – Finished Product Inspection:

This section of the canning regulations is designed to ensure that only safe and stable product is shipped in commerce. This regulation specifies the finished product inspection procedures that the establishment must follow, including the handling of abnormal containers, to ensure that only normal-appearing, hermetically-sealed containers of product that are commercially sterile and shelf stable are distributed in commerce. You should verify that:

a. the establishment has finished product inspection procedures that are in compliance with these regulations,

b. the establishment has documented procedures in place for finished product inspection,

c. the establishment has an incubator, when incubation is used, with an accurate recorder, accurate thermometer, a means for air circulation within the incubator, and a means to prevent unauthorized entry into the incubator,

d. the establishment's container incubation program, when applicable, complies with required time, temperature, range, sampling program, identification of product requiring incubation, checks, and records,

e. the establishment (when it uses a reduced incubation rate) has controls that include incoming container and closure examinations, packer's end double seam examinations, handling of filled and sealed containers, retort traffic control container cooling practices, recordkeeping and records review, and procedures for ensuring the container soundness of finished lots,

f. the establishment (when it uses a reduced incubation time) has adjusted the amount of product incubated (a percentage of the total lot rather than a single container for still retorts or 1 per 1000 containers for continuous retorts) and has narrowed the temperature range for incubation (e.g., from ±5°F to ±2°F),

g. the establishment (when it ships product without incubation) has a letter from its process authority stating that its HACCP plan, QC program(s), and/or process schedule(s) adequately provide for product safety and stability,

h. establishment personnel are performing incubation checks,

i. incubator records are maintained as required, and

j. abnormal containers are handled according to regulatory requirements.

Canning Regulations Example 10: *While performing the 03D01 procedure for canned chili to verify compliance with §318.309(d). You review the establishment's written program for handling finished product inspection. Based upon your review, you determine that the establishment is shipping product without incubation because it has a letter from a process authority indicating that the establishment has programs in place to ensure container integrity and stability. Therefore, you conclude that the establishment is in compliance with §318.309(d).*

9 CFR 318.310/381.310 – Personnel and Training:

This section of the canning regulations requires that all operators of the thermal processing systems within the establishment and all container closure technicians are under the direct supervision of a person who has successfully completed a school of instruction that is generally recognized as adequate for properly training supervisors of canning operations. You should verify that:

> all operators of thermal processing systems and container closure technicians are under the direct supervision of a person who has successfully completed a school of instruction that is generally recognized as adequate for properly training supervisors of canning operations

9 CFR 318.311/381.311 – Recall Procedures:

The purpose of this part of the canning regulations is for the establishment to ensure that it has prepared and maintains a current recall procedure for all canned product they produce that are covered by the canning regulations. You should verify that:

> the establishment has prepared and maintains current procedures for the recall of all canned product covered by the canning regulations

Noncompliance with the Canning Regulations

The following are examples of 03D01 noncompliance with the canning regulations.

Noncompliance Example 1: While performing the review and observation component of 03D01, you observe the temperature indicating device (MIG) on several vertical still steam retorts. The MIG on one retort has divisions that are readable to 2°F. **The MIG must be readable to 1°F so the establishment is not in compliance with §318.305(a)(1)(i).**

Noncompliance Example 2: The plant is using a process schedule from the neighboring establishment for its Vienna sausages with broth. "*Process schedules used*

by an establishment shall be developed or determined by a processing authority." This is noncompliance with §318.302(b)(1) because **the process schedule is not from a processing authority.**

Noncompliance Example 3: The plant is using frozen meatballs in its spaghetti and meat balls in a can. The formulation, as written and given to the process authority, specified fresh meatballs.*"Any change in product formulation, ingredients, or treatments that are not already incorporated in a process schedule and that may adversely affect either the product heat penetration profile or sterilization value requirements shall be evaluated by the establishment's processing authority. If it is determined that any such change adversely affects the adequacy of the process schedule, the processing authority shall amend the process schedule accordingly."* You determine there is noncompliance with §318.302(b)(2) because **there is no process schedule for frozen meatballs in the formulation.**

Noncompliance Example 4: You rotate into a canning assignment and ask to see the process schedule for chicken noodle soup. The plant says all its process schedules are kept at the headquarters plant in another state. "*…process schedules shall be maintained on file by the establishment..."* You determine there is noncompliance with §381.302(c)(2) because **the process schedule is not on file at the establishment.**

Noncompliance Example 5: One of the canned products was formulated with uncured pork. The processing schedule was established for cured pork. "*Any change in product formulation, ingredients, or treatments that are not already incorporated in a process schedule and that may adversely affect either the product heat penetration profile or sterilization value requirements shall be evaluated by the establishment's processing authority. If it is determined that any such change adversely affects the adequacy of the process schedule, the processing authority shall amend the process schedule accordingly."* You determine there is noncompliance with §318.302(b)(1) because **the product could be underprocessed. There is no processing schedule for uncured pork.**

Noncompliance Example 6: While performing the 03D01 procedure for canned chili to verify the requirement for supporting documentation, you review the requirement for §318.303. You reviewed the process schedule on file to determine the critical factors specified for the product, and found that product formulation, meat chunk size of ≤ ¼ inch, and use of hydrated beans are critical factors. You then proceeded to observe the formulation procedures used by the establishment and determined that hydrated beans were used and that all ingredients were incorporated in the amounts specified in the process schedule. However, you observe that the meat chunk size is about ½ inch. **The meat chunk size exceeds that critical limit specified in the process schedule.**

Noncompliance Example 7: While performing the 03D01 procedure for canned chili to verify the requirement for supporting documentation, you review the records associated with compliance with §318.309(d). You review the establishment's written program for handling finished product inspection. Based upon your review, you determine that the establishment complies with §318.309(d) by incubating one container from each load of the vertical still retorts for at least 10 days at 95±5 F. When conducting the review and observation component, you observe that all sample containers are removed from the incubator at 10 days of incubation and temperature of the incubator is 89 F. **You conclude that the establishment is not in compliance with §318.309(d).**

Noncompliance Example 8: You are conducting the 03D01 procedure in a canning establishment that uses batch agitating retorts and decide to verify compliance with §318.306(a)(2). That regulation requires recording the reel or retort speed and the functioning of the condensate bleeder. You proceed to the processing area where the retorts are located and observe the retort operation. You examine the retort log and determine that although the reel speed of the retort has been recorded, the function of the condensate bleeder has not. **You conclude that there is non-compliance with §318.306(a)(2).**

Noncompliance Example 9: You are conducting the 03D01 procedure in a canning establishment that uses batch agitating retorts and decide to verify compliance with §318.307(c) using the Rk component. You go to the QC office and ask to see the container closure records. You review the container closure records. They include the results of container closure examination. However, the record does not include the signature or initials of the container closure technician, as required. **You determine that the plant is not in compliance with §318.307(c).**

Noncompliance Example 10: Today, February 1, 2005, you are conducting the 03D01 procedure in a canning establishment that uses batch agitating retorts and decide to verify compliance with §318.307(e). You proceed to the QC office and ask to see the processing records for the batch agitator retort for June 1, 2004. The QC technician informs you that they only keep records on-site for 6 months, all other records are stored off-site at their corporate office. **You determine that the plant is not in compliance with §318.307(e).**

Noncompliance Example 11: While performing the 03D01 procedure for canned chili to verify the supporting documentation, you review the requirement for §318.304. You review the process schedule on file. You then go to the retort area to determine if the process schedule is posted or available to the retort operator. You observe that the process schedule is posted and matches the process on file. However, you observe that the container IT is below that specified in the process schedule for the process. **You determine that the plant is not in compliance with §318.304(c).**

Noncompliance Example 12: While performing the 03D01 procedure, you verify the canning regulatory requirement §318.305(b)(1)(vii)*(b)*. You are familiar with this establishment, and you know that divider plates are not normally used in the steam batch still retorts for small production orders. The majority of product was retorted with the hydrostatic systems. Today you observe stacking of layers in the crate using divider plates in the vertical still retort when verifying this procedure. You request documentation that the venting procedure allows air to be removed from the vertical still retort before timing of the thermal process is started. Plant management could not provide documentation in the form of heat distribution data with the use of divider plates. **You determine noncompliance with §318.305(b)(1)(vii)*(b)* exists.**

Noncompliance Example 13: While performing the 03D01 procedure, you request the maintenance procedures for the periodic cleaning and sanitizing of the container cooling water recycling system. You also request the water quality standards (microbiological, chemical, or physical) record for the monitoring procedure. The QC manager provides a cleaning and sanitizing procedure. The procedure specifies water quality standards for recycled water, but does not include the sampling frequency, sample site location, and

corrective action when the water quality standards are not met. **You determine that noncompliance with §318.305(h)(3)(iii)&(iv) exists.**

PERFORMING AN 03D02 PROCEDURE

When procedure 03D02 is performed, you should verify that the establishment is meeting the requirements specified in the canning regulations for the specific lot of production in question. The review and observation component, the recordkeeping component, or a combination of these components of the 03D02 procedure can be used. The canning regulations have requirements that must be met for specific production to be determined commercially stable.

The thought process you should use when verifying regulatory requirements includes:

- gathering information by asking questions;
- assessing the information; and
- determining regulatory compliance.

This thought process should be utilized when verifying all of the regulatory requirements.

02 Example*: Your PS for today day lists procedure 03D02. You decide to verify compliance for the beef vegetable soup, which was the first production lot produced this morning. You will verify that all of the HACCP requirements have been met for the one CCP in the HACCP plan for that specific production. You proceed to the HACCP office to review records for monitoring, verification and recordkeeping regulatory requirements, including corrective actions and reassessment if they apply to this specific production. You will also verify that the canning regulations were met for that specific production by reviewing all canning production records that apply to this specific production, that are required by §318.301-311 for the type of process used in this establishment. It is not necessary or practical to verify that* ***all*** *of the canning regulations are met for a specific production of product.*

You should verify that:

a. this production received the appropriate process schedule for the containers and product,

b. the initial temperature was measured and recorded,

c. all critical factors associated with this production were met,

d. there was no unauthorized formulation change,

e. the product was prepared in accordance with the formulation in the processing authority's documents,

f. the required processing and production information was recorded,

g. all process deviations have been handled appropriately,

h. only normal containers were selected for incubation, and, that only normal-appearing containers were shipped from the establishment, as determined by an appropriate sampling plan, and

i. the regulatory requirements of §417.5(a)(3) were met if the establishment has HACCP plans addressing chemical or physical hazards .

You also verify that the establishment has reviewed all processing and production records to ensure completeness and to determine whether all product received the process schedule no later than one working day after the actual process. All records including the temperature/time recorder charts and critical factor control records are required to be signed or initialed and dated by the person conducting the review. The records required may vary slightly depending on the type of retorting system and the establishment's lotting system. The requirements of 9 CFR 318.307 and 9 CFR 381.307 are very similar to the requirements of 9 CFR 417.5(c). Therefore it is not necessary for the establishments that are following the canning regulations to conduct pre-shipment review as per 9 CFR 417.5. If the establishment does not conduct the records review in the manner described in 9 CFR 318.307 or 9 CFR 381.307, it would recordkeeping noncompliance.

Canning Regulations Example 10: *Your PS for today lists procedure 03D02. This establishment has a HACCP plan that includes one CCP for metal detection at the filling step. The establishment is addressing microbiological hazards by complying with the canning regulations. You know from past experience that the establishment defines specific production as one day's production. You proceed to the Q.C. office to begin your verification that all of the HACCP requirements are met at the CCP and that the plant is in compliance with the canning regulations for this specific production. Since you are conducting the 02 on yesterday's specific production you will use the recordkeeping component.*

You review the monitoring records for the CCP and any verification records. You also review the following records to verify that the plant has complied with the canning regulations in §318.307:

You will verify:
- specific production received the appropriate process schedule
- initial temperature was measured and recorded
- all critical factors associated with specific production were met
- no unauthorized formulation changes were made
- required processing and production information is recorded
- all process deviations are handled appropriately
- product was prepared in accordance with formulation in the processing authority's documentation
- the establishment's alternate procedures (when not incubating product) for ensuring only safe and stable products are shipped have been completed.
- the regulatory requirements of §417.5(a)(3) were met for the metal detection CCP

As a result of your verification, you determine that all of the applicable HACCP and canning regulatory requirements were met for this specific production. You mark your PS as "performed".

Corrective Actions

If a process deviation occurs, the establishment must take corrective actions as described in §318.308 and §381.308. Because these regulations are very prescriptive concerning the establishment's response to process deviations, the establishment would not have to also meet the requirements of 9 CFR 417.3. If the process deviation is identified prior to the completion of the intended processing schedule, the establishment can immediately reprocess the product using the full process schedule, use an appropriate alternate process schedule, or hold the product involved and have the deviation evaluated by a processing authority to assess the safety and stability of the product. Upon completion of the evaluation, the establishment is required to provide the inspection program employee with a complete description of the deviation along with all necessary supporting documentation, a copy of the evaluation report, and a description of the product disposition actions. If the process deviation is handled according to these requirements, there would be no noncompliance record written, and the process deviation would not be considered a deviation from a critical limit or an unforeseen hazard. If you need assistance in assessing the supporting documentation or effectiveness of the corrective actions, PDD can be contacted.

If the process deviation was not handled in accordance with the requirements of sections §318.308 or §381.308, it is regulatory noncompliance, and the establishment would also have to consider it as an unforeseen hazard. If the process deviation is considered to be an unforeseen hazard, the establishment must reassess it hazard analysis as required in 9 CFR 417.3(b) and have supporting documentation for the decisions made during the reassessment.

Process authorities are persons or organizations recognized as having the knowledge and expertise to develop thermal processing schedules. The decisions made by the process authorities generally are well documented and supported by science, and contribute significantly to the validation of the corrective actions. When there is a process deviation and the processing authority makes a disposition of the affected product, he/she should have supporting documentation for that decision. For example, if product were retorted short of the process schedule by one minute, the processing authority might be able to support the decision that the product is safe and will be stable because the process authority designed the system to have a safety factor and the support documentation shows that there is a safety factor of one minute designed into the process schedule. If you are not provided with the scientific basis for the decision made by the process authority in response to corrective actions, you should request a copy of the support documentation. If the support documentation appears to be inadequate (e.g., doesn't address the specific corrective action), there is noncompliance with the canning regulations and concerns with the safety and stability of the product. If you have reason to question the corrective actions taken by the establishment, you should contact your District Office (DO). The DO may send an EIAO to review the effectiveness of the corrective actions taken by the establishment.

Documentation and Enforcement in Canning Operations

You should follow the instructions in FSIS Directive 5000.1 when you find a regulatory noncompliance with the canning regulatory requirements. An NR should be issued to the establishment citing 9 CFR 417.5(a)(1) as the relevant HACCP regulation and also citing the relevant canning regulation. This is considered to be recordkeeping noncompliance because the establishment is failing to comply with the parameters of its

supporting documentation (meeting the requirements of the canning regulations) for its hazard analysis. The 03D01 or 03D02 is the appropriate procedure code. Recordkeeping would be the noncompliance indicator used for the noncompliances associated with the canning regulations because the canning regulations serve as supporting documentation for the decision made in the hazard analysis that the food safety hazards associated with microbiological contamination are not likely to occur. Inspection personnel are to link NRs when there is **ANY** noncompliance with the canning regulations. When you determine that a trend of noncompliance exists, you are to contact your DO, through supervisory channels, and ask that it issue an Notice of Intended Enforcement (NOIE) to the establishment as described in 9 CFR 500.4. We will cover documentation and enforcement in more detail later in this training.

Note: The canning regulations were written prior to the HACCP regulations. Current Agency regulatory policy in the HACCP environment does not usually require approval of establishment programs. There are currently 7 instances for in the canning regulations which use terminology such as Administrator approval, Program approval, or area supervisor. These are found in §318.301(f)(2), §318.304(e), §318.305(h)(2), and §318.309(d)(1)(i) & (viii); (d)(2)(i) & (ii). The approvals are no longer required. For example, the canning regulations state that a copy should be provided to the IIC, however when operating in the HACCP regulatory thought process, you would expect that the establishment would make the records available to the IIC when requested.

WORKSHOP: Inspection Verification of Canning Regulations

1. You have recently been assigned to a canning establishment. You review the hazard analysis and HACCP plan. You determine that the establishment has addressed biological hazards at each step in the hazard analysis with the statement "no microbiological hazards likely to occur – this establishment complies with the FSIS canning regulations". Your procedure schedule for today contains an 03DO2 procedure. You chose the specific production of yesterday's production lot of Beef Chili. You review the HACCP plan, and all HACCP records associated with monitoring, verification, and recordkeeping requirements. You note that pre-shipment records review is scheduled for 10 days from today, the date that the specific production is scheduled to be released from incubation. You see that there was no corrective action or reassessment applied to this specific production. What else would you review?

2. Describe how you would perform the **03D01** procedure in each of these situations. Then, describe how you would perform the **03D02** procedure in each of these situations.

a. An establishment that has chosen to address biological hazards by compliance with the canning regulations. The establishment has a hazard analysis but no HACCP plan because the hazard analysis did not reveal any food safety hazards reasonably likely to occur.

01:

02:

b. An establishment has chosen to address all hazards in the HACCP plan. Describe how this situation would differ from the one above.

01:

02:

Scenarios

3. You are an inspector at an establishment producing canned beef stew that uses 9 CFR Subpart G as supporting documentation. The process schedule states that the meat and potato ingredient size of ½ inch cubes, sauce viscosity, and fully hydrated vegetables are critical factors. The establishment purchases meat, potatoes, and dried vegetables. The establishment cuts the meat and potatoes to the specified size and hydrates the vegetables using its hydration procedure.

One day, the QA manager indicates that the establishment received some complaints and returned containers for product produced 2 months previous. Management indicates that a few cases of the product are at the on-site warehouse. You and the QA manager go to the warehouse and examine the remaining product and observe that a large number of containers are swollen. The QA manager took some containers for examination. You call the FSIS Western Laboratory for sampling instructions. The lab requests that you send 4 abnormal and 4 normal-appearing containers for analysis. You observe that the QA manager implements control of the product at the establishment. You take and send the samples for analysis at the FSIS laboratory.

A week and a half later you receive a copy of the report from the PDD indicating that there is a potential food safety hazard associated with the product due to spore-forming rods in the product. Additionally, the DO and the establishment are notified by the Recall Management Division of OFO and the establishment is requested to recall the affected product due to a potential health hazard resulting from under-processing.

a. What would you expect the establishment to do?

Based on the reassessment performed after the deviation, the establishment determined that the dehydrated vegetables that were used were dried differently than the process traditionally used by the vendor. The establishment traditionally received vegetables that were freeze-dried but for the process in question the vegetables were air-dried. In testing the vegetables, the establishment found that the hydration procedure followed for the freeze-dried vegetables is inadequate to hydrate air-dried vegetables. Based on this finding, the establishment decided to develop purchase specifications to purchase only freeze-dried vegetables.

b. What regulation(s) apply to this situation?

c. Is there noncompliance, if so, what is the regulatory citation?

d. Would an NR be issued?

4. Your PS for today lists procedure 03D02. This establishment addresses microbiological contamination in the hazard analysis by complying with the canning regulations. You proceed to the QA office to begin your verification to determine if the plant is in compliance with the canning regulations for lot of whole chicken in broth packed in 603 x 708 cans that was produced two days ago. Since you are conducting the 02 procedure on product that was retorted two days ago, you will use the recordkeeping component.

You review the processing and production records such as the retort operation log, time/temperature recording charts, and critical factor records (if any) associated with the lot of whole chicken in broth to verify that the plant has complied with the canning requirements in §381.306, §381.307(a) and (b), and §381.308. You find that all of the required information has been recorded but there is no documentation that management reviewed the processing and production records to ensure completeness and to determine whether the product received the process schedule.

a. List the specific requirements that you will verify:

During your review of the processing records, you find that the process temperature dropped from 245°F to 242°F for approximately four minutes on the time/temperature recording chart and for retort #4. The process schedule on the corresponding retort operation log was 100°F (I.T)/245°F (retort temperature)/75 (process minutes) for 603 x 708 cans of whole chicken in broth. The process schedule on file was the same one as documented on the retort operation log. The establishment did not have an alternate process schedule on file for processing whole chicken in broth at 242°F. This drop in temperature was not noted (no comment) by the operator on either the retort operation log or time/temperature recording chart. No action was documented on the retort operation log or recording chart.

b. Based on your observation, is there noncompliance with the canning regulations? If so, please cite the canning regulation.

You request any other information from the establishment that would support product safety, particularly, if it had any documentation that the process deviation was detected and the product segregated and placed on hold, until the deviation is reviewed and

cleared by a processing authority. The establishment is unable to provide any further information. You ask for distribution records and determine that the product has left the control of the establishment.

c. What do you do next?

d. Would you take an immediate withholding action?

e. Is there evidence that the establishment produced and shipped adulterated product?

f. If you determined that there was regulatory noncompliance, complete the following NR.

The request for this information is voluntary. It is needed to monitor defects found in this inspection system. It is used by FSIS to determine whether establishments are in compliance. 9 CFR 301 and 9 CFR 381. FORM APPROVED OMB No. 0583-0089. OMB DISCLOSURE STATEMENT: Public reporting burden for this collection of information is estimated to average 7 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, Room 404-W, Washington, DC 20250: and to the Office of Information and Regulatory Affairs, Office of Management and Budget.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
NONCOMPLIANCE RECORD

TYPE OF NONCOMPLIANCE

☐ Food Safety ☐ Other Consumer Protection

1. DATE	2. RECORD NO.	3. ESTABLISHMENT NO.

4. TO (Name and Title)	5. PERSONNEL NOTIFIED

6. RELEVANT REGULATION(S)

7. SECTION/PAGE OF EST. PRODEDURE PLAN	HACCP	SSOP	OTHER
☐			

8. ISP CODE	9. NONCOMPLIANCE CLASSIFICATION INDICATORS
☐	

10. DESCRIPTION OF NONCOMPLIANCE:

☐
☐
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☐
☐
☐

11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE

You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR.

12. PLANT MANAGEMENT RESPONSE: (Immediate action(s)):

13. PLANT MANAGEMENT RESPONSE: *(Further planned action(s)):*

This document serves as written notification of your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.

14. SIGNATURE OF PLANT MANAGEMENT	15. DATE
16. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE	17. DATE

Decision-making

Next in the regulatory process is decision-making. In the decision-making thought process you will determine whether or not the establishment is in compliance with the regulatory requirements. If noncompliance exists, then you will determine whether an inadequate system exists.

Noncompliance Determination

HACCP noncompliance is the failure to meet ***any*** of the regulatory requirements of 9 CFR Part 417: monitoring, verification, recordkeeping, corrective actions, and reassessment. If a HACCP noncompliance occurs, the establishment is expected to take immediate and further planned actions.

Before you determine whether or not you should document the failure to meet the regulatory requirements as a noncompliance, you should consider the following questions.

1. Has the establishment already identified the failure to meet regulatory requirements or deviations from critical limits?

2. If product is involved, has the establishment ensured product safety?

3. Has the establishment taken immediate and further planned actions to correct the failure to meet regulatory requirements, or has it taken the 9 CFR 417.3 corrective and preventive measures to address the deviations or unforeseen hazard?

4. Is a trend developing (i.e., has the establishment carried out the actions in 1 through 3 above for similar situations)?

If the answer is **yes** to **1, 2, and 3** and **no** to **question 4**, then there is **no noncompliance that you would document**, because the establishment has already identified and addressed the situation. You will document on the Procedure Schedule that the procedure was performed and no other action is necessary. Not writing an NR in this situation will not adversely affect your ability to track developing trends since the establishment's response to a deviation will provide the corrective actions. An establishment's failure to follow through on corrective actions or further planned actions could lead to recurring noncompliances and would warrant an NR in recurring situations.

If the answer is **no** to **questions 1, 2, or 3,** or **yes** to **question 4**, then there is a **noncompliance that you would document**.

►Examples of Noncompliance Determinations

The following are examples of situations that will require a determination of noncompliance.

Example 1: *While performing an 01 HACCP procedure records review, you find that an establishment employee missed a calibration procedure. You then find that the establishment found the error during its records verification, demonstrated product safety with other records, and took immediate and further planned actions for the noncompliance by re-training the employee. Also, you looked at previous NRs and determined that the establishment had not missed a calibration check in over a year. In this situation no NR is necessary, even though there was a missed calibration check, and the 01 procedure is marked as performed.*

However, if you find that actions were not in place, and that the missed calibration check and correction had occurred several times recently, you may determine that a trend for verification/calibration noncompliance has developed. In this case you will issue an NR and discuss this trend with establishment management during the weekly meeting.

Example 2: *While performing an 01 HACCP procedure records review, you find that an establishment employee missed a 9:00 a.m. monitoring check and find no indication that the establishment identified the missed monitoring check. You write an NR for the 01 procedure. Then you perform an 02 procedure and find that the product was shipped without a pre-shipment review. In this situation you would write an NR that explains this noncompliance. Next you would determine whether the establishment can provide other documentation that establishes product safety. If the establishment cannot demonstrate product safety, you would take action in accordance with the Rules of Practice, 9 CFR Part 500.*

Example 3: *While performing the 01 HACCP procedure records review, you observe that an establishment employee recorded a deviation from a critical limit on the monitoring record. You verify that the corrective actions taken by the establishment meet the requirements of §417.3(a). There is no regulatory noncompliance, and an NR is not necessary.*

Example 4: *While performing an 02 procedure records review for a lot of canned product, you see in the records that an establishment employee missed a can teardown check at 10:00 a.m. You continue to review the records and find that at pre-shipment review the establishment identified the missing check and took the action to demonstrate product safety relevant to the missed can teardown check. In this situation no NR is necessary even though there was a missed teardown check, and the 02 procedure is marked as performed.*

However, if you find that actions were not in place, and that the missed teardown check and correction had occurred several times recently, you may determine that a trend for canning regulation noncompliance has developed. In this case you will issue an NR and discuss this trend with establishment management during the weekly meeting.

If the establishment cannot demonstrate product safety, you would take action in accordance with the Rules of Practice, 9 CFR Part 500.

If the establishment is found in compliance with the regulatory requirements, you would stop and mark “performed” on the Procedure Schedule. If the establishment is not in compliance with the regulatory requirements, then you have found regulatory non-compliance and should document this on an NR. Before completing your decision making process, you should next consider whether an inadequate system exists.

Inadequate System Determination

If noncompliance is found, you need to determine if it indicates an **inadequate system**.

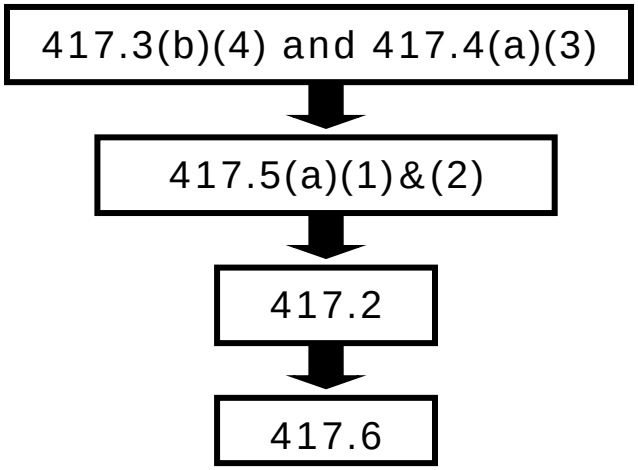
Sec. 417.6 Inadequate HACCP Systems.

A HACCP system may be found to be inadequate if:

(a) The HACCP plan in operation does not meet the requirements set forth in this part;
(b) Establishment personnel are not performing tasks specified in the HACCP plan;
(c) The establishment fails to take corrective actions, as required by Sec. 417.3 of this part;
(d) HACCP records are not being maintained as required in Sec. 417.5 of this part; or
(e) Adulterated product is produced or shipped.

To determine the plant's HACCP system adequacy, you must consider more than the HACCP plan. All available evidence and supporting documentation must be taken into account. You should evaluate other systems within the plant (SSOP, in-plant testing programs, etc.). Depending on the problems identified, the establishment may need to reassess the HACCP plan. For example, if an establishment has not identified *E. coli* O157:H7 as a food safety hazard likely to occur in its dry fermented sausage process and is testing outside the HACCP plan or SSOP and gets a positive result, a reassessment of its HACCP plan and hazard analysis is required by 9 CFR 417.3(b)(4) and 417.4(a)(3). The establishment is required to support the decisions made during the reassessment as specified in §417.5(a)(1)&(2).

It is your responsibility to verify that the establishment is meeting these requirements. If the establishment did not reassess its HACCP plan and hazard analysis as required by §417.3(b)(4) and §417.4(a)(3) and/or does not have the supporting documentation required by§417.5(a)(1)&(2), you cannot determine that the HACCP plan is meeting the requirements of §417.2, therefore the HACCP system may be determined to be inadequate as described in §417.6.



To determine if there is an inadequate system you need to answer the following questions.

►1. Does the HACCP plan meet the regulatory requirements of Part 417?

If the establishment is not implementing all or some of its program, it has not met regulatory requirements. For example, if an establishment is not maintaining **any** records associated with its HACCP plan, the establishment is not monitoring critical limits at any CCP, the establishment did not reassess the HACCP plan when required, or the establishment did not modify its HACCP plan when it no longer met the requirements---then the establishment has not met the regulatory requirements. Therefore, you are unable to determine whether or not the establishment is producing adulterated product, and, therefore the HACCP system is inadequate. In these cases, the HACCP system would be considered inadequate because it did not meet the regulatory requirements of Part 417.

If the answer is **no** to question 1, this may be indicative of an **inadequate system**.

►2. Was adulterated product produced or shipped?

If the HACCP system did not prevent the production and distribution of adulterated product, it is an inadequate system. If you determine that the establishment failed to meet a critical limit for a CCP and did not take the corrective actions as per Section §417.3 of the Federal regulations, and the establishment has performed its pre-shipment review, the HACCP system is inadequate.

If the answer is **yes** to question 2, this may be indicative of an **inadequate system**.

►3. Is there a trend in establishment noncompliance?

You should observe trends in noncompliance when determining whether an establishment's HACCP system is inadequate. If two or more NRs have descriptions of noncompliance indicating that similar problems are recurring, there may be a trend indicating the HACCP system is inadequate.

There is no specific number of incidents which determines a trend. Because there will be a variety of processing environments and HACCP plans, FSIS cannot establish that a specific number of the same or similar incidents of noncompliance necessarily supports an inadequate system. Therefore, you must thoroughly analyze and document noncompliance trends that may support a determination. When reviewing a possible trend in incidents of noncompliance, you must closely review the descriptions of noncompliance contained in Block 10 of the NR form. You should not solely rely on the number of marked noncompliance classification indicators. Only through careful analysis of written descriptions of noncompliance can you determine whether there is a trend indicating that a HACCP system may be inadequate.

If the answer is **yes** to question 3, this may be indicative of an **inadequate system**.

Action to Take If an Inadequate System Exists

If you determine that an **inadequate system** exists, then you must take action.

- You notify the District Office.
- If you determine that adulterated product has been produced and shipped, you would take an immediate withholding action, according to the Rules of Practice.

The main point to remember is to contact the District Office if you believe an inadequate system exists. We will cover these enforcement actions in more detail in later sections.

Documentation – Completing a Noncompliance Record (NR)

When documenting noncompliance on a Noncompliance Record (NR), do the following.

- Identify each noncompliance.
- Be specific and thorough, including time and location.
- Explain that plant management has received notification.
- State any regulatory control actions you took.

If you need further information about completing the NR, please consult FSIS Directive 5400.5.

When you determine that a HACCP noncompliance has occurred, you will complete a Noncompliance Record (NR), which will include marking the appropriate noncompliance indicator.

►HACCP Noncompliance Indicators

There are four noncompliance indicators for HACCP noncompliance: **monitoring, verification, recordkeeping,** and **corrective action.**

1. Monitoring

You will use the monitoring noncompliance indicator when there is noncompliance with the monitoring requirement. The monitoring noncompliance indicator would be marked if:

a. The establishment is not monitoring the critical limit at the frequency stated in the HACCP plan.

b. The establishment is not monitoring the critical limit using the prescribed procedures in the HACCP plan.

c. A deviation from a critical limit exists that the establishment has no way of detecting.

Monitoring Noncompliance Example: *You are verifying monitoring at the establishment's cooking CCP in a semi-dry sausage establishment. The establishment has a monitoring procedure of taking two temperatures at the completion of the cooking cycle for each smokehouse. You decide to perform review and observation, and proceed to the smokehouse area. You observe the smokehouse operator take only one temperature and record it. You look at the record and see that for most of the lots cooked today, only one temperature is recorded.*

2. Verification

The verification noncompliance indicator should be used when:

1. The establishment is not conducting the verification activities as described in the HACCP plan.

2. The establishment is not conducting the verification activities at the frequencies prescribed in the HACCP plan.

3. The establishment has a positive FSIS *E. coli* O157:H7, *Listeria*, or *Salmonella* sampling result in its RTE product.

Verification Noncompliance Example: *You are performing the 03F01 procedure in a jerky establishment, and have selected to verify the verification requirements. The jerky HACCP plans call for records review verification of monitoring records to be conducted daily. You review recent records and observe that for the last week, there are no verification records review results recorded. You gather more information and determine that the verification was not performed. (If it had been performed, but not recorded, then the verification noncompliance indicator is not appropriate.)*

3. Corrective Action

The corrective action noncompliance indicator should be used when corrective actions taken by the establishment in response to a deviation from a critical limit, or unforeseen hazard, did not meet the requirements of §417.3 because they did not:

1. Adequately address identifying and eliminating the cause of the deviation.

2. Include measures to ensure that the CCP is under control after a deviation occurs.

3. Include measures to prevent the deviation or unforeseen hazard from recurring.

4. Include appropriate disposition of the product.

5. Conduct a reassessment, if an unforeseen hazard was identified.

Corrective Action Noncompliance Example: *You are performing the 03D01 procedure at an establishment which produces meals in retortable pouches. You realize that you should verify the corrective actions whenever a deviation occurs. You regularly review the corrective action logs and ask QC personnel about any current corrective actions that are taking place. Today you observed that the QC department has placed a hold on a lot and you decide to investigate. You see that this morning's monitoring log for the metal detection equipment recorded a deviation, the equipment did not operate properly when checked with the seeded sample. You review the corrective action log and see that it includes documentation of the deviation, that all effected product is being held, with a notation showing it is to be destroyed. There is no documentation that the*

cause of the deviation was identified and eliminated, that the CCP is under control, or that measures were taken to prevent the deviation from recurring.

4. Recordkeeping

The recordkeeping noncompliance indicator should be used when:

1. The monitoring records do not include the actual times, temperatures, or other quantifiable values, the calibration of process monitoring instruments, corrective actions, verification procedures and results, product identity, signature or initials of the person making the entry, or the date the record is made.

2. The establishment does not have the decision-making documents associated with the selection and development of the CCPs and critical limits, and documents supporting both the monitoring and verification procedures and frequencies.

3. The establishment did not conduct the pre-shipment review.

4. The establishment is not retaining HACCP records for the required length of time.

5. The establishment does not have controls to ensure the integrity of computer-maintained records.

Recordkeeping Noncompliance Example: *You are performing the 03F01 procedure in a dry sausage operation and have randomly selected to verify the establishment recordkeeping requirement for pH at the fermentation CCP. You review the HACCP plan and find that the monitoring procedure is that QC will take three pieces from each smokehouse, check the pH of each, and record the results. The critical limit is 4.9 or less. You review the current fermentation log.*

Fermentation log		*Date: second shift*	
Time	*pH*	*Temperature*	*Monitor initials*
1:00 pm lot c	*4.9, 4.8, 4.8*	*109. 110, 108*	✓
1:29 pm lot d	*4.8, 4.7, 4.8*	*111, 110, 110*	
1:58 pm lot f	*4.9, 4.9, 4.8*	*109, 110, 109*	*FT*

Based on your observations, you determine that this part of the recordkeeping requirement is not in compliance because the date is not recorded and the monitor did not initial the results.

Workshop: Noncompliance

Refer to the module and to FSIS Directive 5000.1 to complete the following questions.

1. You are performing an 03F01 at a dry and semi-dry sausage establishment that you have recently rotated into. You have chosen to verify the recordkeeping requirements. You review the hazard analysis.

Process Step	Food Safety Hazard	Likely to occur?	Basis	Preventive measures	CCP
Raw meat storage	B – Pathogens present in meat may grow if temperature not properly maintained. C – none P – none	No	Temperature control program		

You know that an EIAO has performed a food safety assessment at this establishment in the past, which included an evaluation of this program. You also realize that per Directive 5000.2, you should request to review the records produced under this program on a regular basis. You review the program, which states “both room and product temperature in the raw meat storage will be monitored and recorded 3 times every day.” You review the records associated with the last week, and note that for each day there is only one set of temperatures recorded.

What do you determine? What would you do next?

If you determine there is noncompliance, cite the appropriate regulation and write a brief summary of what you would record in block 10.

2. Read the following NRs. Circle any documentation in the NR which needs improvement. After each NR, explain how the NR could be better written.

The request *for* this information is voluntary. It is needed to monitor defects found in this inspection system. It is used by FSIS to determine whether establishments are in compliance. 9 CFR 301 and 9 CFR 381. FORM APPROVED OMB No. 0583-0089. OMB DISCLOSURE STATEMENT: Public reporting burden *for* this collection of information is estimated to average 7 minutes per response, including the time *for* reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions *for* reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, Room 404-W, Washington, DC 20250: and to the Office of Information and Regulatory Affairs, Office of Management and Budget.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
NONCOMPLIANCE RECORD

TYPE OF NONCOMPLIANCE

☒ Food Safety ☐ Other Consumer Protection

1. DATE	2. RECORD NO.	3. ESTABLISHMENT NO.
TODAY	**0026-2005-675**	**00038 M/1**

4. TO (*Name and Title*)	5. PERSONNEL NOTIFIED
Mr. John Doe, Plant Manager	**Ms. Jane Doe, Processing Supervisor**

6. RELEVANT REGULATION(S)
417.3

7. SECTION/PAGE OF EST. PRODEDURE PLAN	HACCP	SSOP	OTHER
	X		

8. ISP CODE	9. NONCOMPLIANCE CLASSIFICATION INDICATORS
03F01	**HACCP-Corrective Action**

10. DESCRIPTION OF NONCOMPLIANCE:

At approximately 9:20 a.m., while reviewing the Oven Temperature and Humidity monitoring record for the lethality step (CCP 2) dated 3-26-05, I observed that the recorded result for the 2:36 p.m. check exceeded the limit printed at the top of the record. In the comments column next to the monitoring result "see corrective action log" was recorded. I reviewed the plant's corrective action log. The plant's recorded corrective actions for this deviation did not meet all of the corrective actions required by the regulations. This document serves as written notification that failure to comply with regulatory requirements could result in additional regulatory or administrative action.

11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE

You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR.

12. PLANT MANAGEMENT RESPONSE: (Immediate action(s)):

13. PLANT MANAGEMENT RESPONSE: *(Further planned action(s)):*

This document serves as written notification of your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.

14. SIGNATURE OF PLANT MANAGEMENT	15. DATE
16. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE	17. DATE

The request *for* this information is voluntary. It is needed to monitor defects found in this inspection system. It is used by FSIS to determine whether establishments are in compliance. 9 CFR 301 and 9 CFR 381. FORM APPROVED OMB No. 0583-0089. OMB DISCLOSURE STATEMENT: Public reporting burden *for* this collection of information is estimated to average 7 minutes per response, including the time *for* reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions *for* reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, Room 404-W, Washington, DC 20250: and to the Office of Information and Regulatory Affairs, Office of Management and Budget.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
NONCOMPLIANCE RECORD

TYPE OF NONCOMPLIANCE

☒ Food Safety ☐ Other Consumer Protection

1. DATE	2. RECORD NO.	3. ESTABLISHMENT NO.
Today	**0026-2005-677**	**00038 M/1**

4. TO (*Name and Title*)	5. PERSONNEL NOTIFIED
Ms. Jane Doe, Plant Manager	**Mr. Jon Doe (Formulation Supervisor)**

6. RELEVANT REGULATION(S)
318.300

7. SECTION/PAGE OF EST. PRODEDURE PLAN	HACCP	SSOP	OTHER
	III/3		

8. ISP CODE	9. NONCOMPLIANCE CLASSIFICATION INDICATORS
03D01	**HACCP-Monitoring**

10. DESCRIPTION OF NONCOMPLIANCE:

At approximately 9:00am during the performance procedure 03D01 the following non-compliance was observed: While observing the formulation of one batch of beef stew to verify that the plant was measuring, controlling and recording the critical factors to ensure they were within the limits used to establish the process schedule as required by 9 CFR 318.303, I, Inspector Smith, found several pieces of raw diced beef to be larger than the maximum dice size of a ¼ inch listed as a critical factor in the process schedule. I found several pieces of beef to be 3/8 inch and some as large as ½ inch in greatest dimension. Upon review of the critical factor record, I found that the QA tech had a result of 3/8 inch recorded for two of the four batches that had already been produced.

11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE

You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR.

12. PLANT MANAGEMENT RESPONSE: (Immediate action(s)):

13. PLANT MANAGEMENT RESPONSE: *(Further planned action(s)):*

This document serves as written notification of your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.

14. SIGNATURE OF PLANT MANAGEMENT	15. DATE
16. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE	17. DATE

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE **NONCOMPLIANCE RECORD** **CONTINUATION SHEET**	Type of Noncompliance ☒ Food Safety ☐ Other Consumer Protection
1. Date **Today** 2. Record No **0026-2005-677**	3. Establishment No. **00038 M / 1**
4. To (*Name and Title*) **Ms. Jane Doe, Plant Manager**	5. Personnel Notified **Mr. Jon Doe (Formulation Supervisor)**
6. Relevant Regulation(s) **318.300**	
7. Relevant Section/Page of Establishment Procedure/Plan	| HACCP **III/3** | SSOP | OTHER ☐
8. ISP Code **03D01**	9. Noncompliance Classification Indicators **HACCP—Monitoring**

10. DESCRIPTION OF NONCOMPLIANCE

I informed Mr. Larry Doe, HACCP Coordinator, that this change in the ingredient and formulation could affect the heat penetration profile or sterilization value and needed to be reviewed by a processing authority as stated in 9 CFR 318.302(b)(2) and the failure to comply with the critical factor requirement was a process deviation to be handed in accordance with 9 CFR 318.308(b). Mr. Doe stopped the further production of the beef stew and said that the batch in process and the four batches of stew already produced would be segregated and placed n QA hold. Later in the day, I found 18 pallets of boxed beef stew (correct day and batch codes) segregated and on hold with QA tags in the finished product storage area.

11. Signature of Inspection Program Employee

Linking NRs

You should link NRs to provide notification to the establishment that the further planned actions are ineffective in preventing the noncompliance from recurring and that, if the trend continues, the repetitive noncompliance would support an enforcement action under the rules of practice. You should be linking NRs together only when the noncompliances are from the **same cause**.

How to Link NRs

When you link one NR to another, you should **document:**

- **The previous NR number** and **date.**
- The **further planned action** that was ineffective in preventing recurrence of the noncompliance.
- Any discussion with plant management, during the weekly meeting, concerning the trend.
- A **statement in Block 10** of the NR stating that **continued failure to meet regulatory requirements can lead to enforcement actions as described in 9 CFR 500.4.**

NRs should be linked **as they are issued**. Each noncompliance that you believe is linked to a previous noncompliance should be documented as linked at the time the NR is completed. Do not link the current noncompliance to more than one previous noncompliance.

You should continue to link NRs together that derive from the same cause **until you determine that enforcement action is necessary** to bring the establishment into compliance with the regulations. When you determine that enforcement action is necessary, you should contact the District Office and always keep your supervisor apprised of the situation.

Good judgment is necessary when determining which NRs to link together. Remember to follow the thought process, gather information by asking questions, assess the information, and make a sound, supportable conclusion. Some factors to consider are:

1. How much time has elapsed since the previous NR was written?
2. Was this noncompliance from the same cause as the previous NR?
3. Were the establishment's further planned actions implemented?
4. Were the establishment's further planned actions effective in reducing the frequency of these noncompliances?
5. Is the establishment continuing to implement better further planned actions?

6. Are there NRs over the past three months that should be linked to other NRs?

7. Do the NRs establish that there is a persistent problem in the plant's approach to addressing noncompliances (e.g., the establishment's procedures led to repeated noncompliances)?

Linking Example 1:
You issued an NR for the establishment not performing a monitoring procedure as specified in the HACCP plan. Two weeks later you observe, at a different CCP in the same HACCP plan, that the establishment does not perform the monitoring procedures as specified in the HACCP plan. You decide that these two noncompliances have the same cause (not performing monitoring according to the HACCP plan) and that you should link them in your documentation. You realize you could link these noncompliances even if it was across two different HACCP plans.

Linking Example 2: *You issued an NR when you took a measurement at CCP 3 and found that the critical limit was not met. Two months later, you observe that the establishment is not conducting the monitoring procedures as specified in the HACCP plan: they missed a monitoring check at CCP 2. Although these are both monitoring noncompliances and are both documented under the same procedure code, you determine that they are not from the same cause. You do not link them in your documentation.*

Linking Example 3: *You issued an NR when you observed that the establishment did not meet one of the recordkeeping requirements, there were no monitor's initials for one result. About four months later, you again observe that the establishment monitor did not initial one of the monitoring results. Although these two noncompliances both have the same cause, you determine that the establishment has shown a substantial period of compliance, and you decide not to link this NR to the previous one.*

Linking Example 4: *You issued an NR on September 2, when the establishment had a deviation, and the corrective actions taken did not meet 417.3. They did not implement measures to prevent the recurrence of the deviation, and they did not take appropriate measures to ensure that the CCP was under control after the actions were taken. On November 4, the establishment has another deviation at the same CCP, and as you verify the corrective actions you observe that the establishment did not implement measures to identify and eliminate the cause of the deviation, and they did not implement measures to prevent the recurrence of the deviation. You determine that although some time has lapsed, the establishment has* ***not*** *shown a substantial period of compliance. You determine that both of these noncompliances are due to the same cause, which is, not completing all parts of the requirements for corrective action, and you decide to link them in your documentation.*

You can contact your supervisor if you need assistance in making this decision. The in-plant inspection team can also contact PDD for assistance, if needed.

Workshop: Linking NRs

Refer to the module and to FSIS Directive 5000.1 to complete the following question.

Scenario:

A dry sausage establishment has a HACCP plan for pepperoni. Procedure 03E01 is on your procedure schedule. You review the HACCP plan and observe there are three CCPs. The critical limit identified for CCP-1, fermentation, is a 96°F internal product temperature with 85-90% relative humidity for 7 hours, and a product pH of 5.0 or less before the heat cycle. There is a heat treatment, CCP-2, that has the critical limit of at least 128°F internal product temperature for at least 60 minutes, followed by a 21 day drying step, CCP-3, with a critical limit of a room temperature between 55°F-57°F. You review the time/temperature recording chart for a specific production of pepperoni that was fermented and heated yesterday, and find that the temperature recorded on the chart did not remain at or above 128°F for the entire hour; it dropped to about 125°F several times during the heat cycle. When you ask Mr. John Doe, production supervisor, he tells you that "a slight drop in the internal temperature of the product during the heat cycle would not affect the safety of the pepperoni because the plant's process has additional microbiological interventions at the fermentation and drying steps".

You recall a similar situation happened about 3 weeks ago. You review the previous NR. It was record number 118-05, dated March 28, 2005. The corrective actions implemented in the previous situation included installing a new fan in the smokehouse air circulation system. You observe that today's situation involves a different smokehouse.

Workshop: Complete an NR for this noncompliance, blocks 8, 9 and 10 only. Then answer the following question, noting that as a training example, you do not have the amount of detailed data that you would have in real life.

What further actions would you take?

The request *for* this information is voluntary. It is needed to monitor defects found in this inspection system. It is used by FSIS to determine whether establishments are in compliance. 9 CFR 301 and 9 CFR 381. FORM APPROVED OMB No. 0583-0089. OMB DISCLOSURE STATEMENT: Public reporting burden *for* this collection of information is estimated to average 7 minutes per response, including the time *for* reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions *for* reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, Room 404-W, Washington, DC 20250: and to the Office of Information and Regulatory Affairs, Office of Management and Budget.

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE **NONCOMPLIANCE RECORD**		TYPE OF NONCOMPLIANCE ☐ Food Safety ☐ Other Consumer Protection
1. DATE	2. RECORD NO.	3. ESTABLISHMENT NO.
4. TO (Name and Title)		5. PERSONNEL NOTIFIED
6. RELEVANT REGULATION(S)		

7. SECTION/PAGE OF EST. PRODEDURE PLAN	HACCP	SSOP	OTHER
☐			

8. ISP CODE	9. NONCOMPLIANCE CLASSIFICATION INDICATORS
☐	

10. DESCRIPTION OF NONCOMPLIANCE:

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11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE

You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR.

12. PLANT MANAGEMENT RESPONSE: (Immediate action(s)):

13. PLANT MANAGEMENT RESPONSE: *(Further planned action(s)):*

This document serves as written notification of your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.

14. SIGNATURE OF PLANT MANAGEMENT	15. DATE
16. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE	17. DATE

Enforcement – Follow Rules of Practice

When a noncompliance determination is made, it may be necessary to take an **enforcement action** to prevent adulterated product from being produced and shipped. In accordance with the rules of practice, this enforcement action could be one of three types.

1. A "**regulatory control action**" is the retention of product, rejection of equipment or facilities, slowing or stopping of lines, or refusal to allow the processing of specifically identified product.

2. A "**withholding action**" is the refusal to allow the marks of inspection to be applied to products. A withholding action may affect all product in the establishment or product produced by a particular process.

3. A "**suspension**" is an interruption in the assignment of program employees to all or part of an establishment.

►Regulatory Control Actions

Regulatory control actions are not frequently used for HACCP regulatory noncompliance unless control is necessary to prevent shipment of contaminated or adulterated product.

Regulatory Control Action Example: *You are performing the 03F01 procedure at a large snack stick establishment, and have selected the monitoring requirement to verify. The HACCP plan for the lethality CCP states that product temperatures will be taken by QC personnel hourly and recorded. You take a product temperature measurement, which is not within the critical limits for this CCP. You look at the establishment's lethality log, and you observe that the most recent monitoring result was also not within critical limits. You observe no evidence that corrective action is being taken. You observe that there are no establishment supervisors in the area to notify about your findings. You take a regulatory control action, and put a retain tag on all available product in the area. Employees begin to stop production.*

►Withholding Action Without Prior Notice

There may be instances when it is necessary for you to take immediate enforcement actions to prevent imminent threat to public health, without giving the establishment prior notice. For example, if the establishment produced and shipped adulterated product, you would need to take an immediate withholding action. In these situations, first take the immediate withholding action, and then as soon as possible notify the District Office. For further information, refer to the Rules of Practice module.

Immediate Withholding Action Example: *You are reviewing records at a canning establishment which produces a variety of chili products in glass jars. You observe that the establishment has noted in the records that the canning process was reassessed about two weeks ago because of a change of ingredients vendor. You see a note that a new type of starch was substituted for the previous thickening agent. You ask whether the processing authority evaluated the process for potential changes needed in the*

process schedule. You are told "no, the vender explained that this starch worked BETTER so we determined that the process authority did not need to evaluate the new formula." You review processing records and realize that the product being released for distribution today is the first product made with the new starch. You proceed to the shipping area and determine that the product is being loaded onto trucks. You verify that pre-shipment review was completed, and that some of the product produced has already left the control of the establishment. You cannot determine at this point whether the establishment has produced and shipped adulterated product. You gather shipping information and any other details (product ID, amount, destination, etc.) you will need to communicate this situation to the District Office. You page your supervisor and call the DO. After discussion with District personnel, you notify the establishment that the marks of inspection are being withheld pending further instructions from your District Manager.

Notify the District Office

If you determine that an inadequate system may exist, you should notify the District Office. Provide the DO all of the information about the situation. You should request that a Notice of Intended Enforcement Action be issued to the establishment. The DO will provide direction about further actions you need to take. The DO may assign an EIAO to evaluate the establishment's HACCP system.

District Office Determines Enforcement Action

After evaluating all of the facts of the case, the District Office will determine the appropriate enforcement action based upon the rules of practice.

►Withholding and Suspension Actions With Prior Notification

Keep in mind that some withholding and suspension actions require prior notification according to the rules of practice. The most common withholding or suspension actions related to HACCP noncompliance are those in which the HACCP system is found inadequate due to **multiple or recurring noncompliances**. Withholding or suspending inspection for this cause does require prior notification to the establishment. The prior notice is in the form of a written Notice of Intended Enforcement Action (NOIE). Remember that a suspension may only be issued by a District Manager or higher FSIS official.

Enforcement Action Example: *You are a relief inspector and have been assigned to an establishment which produces several types of jerky. The lethality CCP for the jerky HACCP plan lists critical limits of a time and temperature combination of 141˚F for 12 minutes, and the percent relative humidity maintained at 90 percent or higher throughout cooking until the lethality is reached. Your procedure schedule includes an 03F01and you randomly select to verify recordkeeping. You review recent lethality records and observe that for one lot produced today, only time and temperature are recorded, not humidity. You ask the establishment whether it can support the safety of the product produced. The establishment cannot produce any record demonstrating that humidity was maintained as per the HACCP plan. You verify that the establishment is maintaining a hold on the affected product. You review recent NRs and find that there were two NRs written last week for the same reason, and that the regularly assigned inspector has documented the developing trend by linking the two previous NRs. You issue an NR for not conducting monitoring procedures as specified in the HACCP plan. You add appropriate documentation to the NR to link this noncompliance to the previous one. When you provide the NR to the establishment, you explain that documentation on NRs demonstrates that further enforcement actions may be necessary to bring the establishment into regulatory compliance. You contact the District Office to explain that repetitive NRs indicate a need to take further enforcement actions and request that a Notice of Intended Enforcement Action be issued to the establishment. After gathering evidence that the establishment cannot demonstrate that its process does not produce adulterated product, the DO advises you to take an immediate withholding action. The DO issues an NOIE to the establishment the next day.*

Recalls

Recalls are initiated when there is evidence of unsafe or adulterated product in commerce, for example, when a positive sample result is obtained for product that the establishment has shipped. The DO and possibly the RMD evaluate each situation on a case-by-case basis. More or less product may be determined “affected product” based on all considered factors (e.g., whether some or all products produced under the same or a substantially similar HACCP plan have been affected, what pathogens or toxins are involved, whether there have been any other incidents of contamination in the plant associated with the pathogen or toxin, and whether there have been persistent and recurring noncompliances in the plant).

The RMD is notified immediately if product has left the establishment’s control, and it coordinates any recall activities. You must determine the status of the products that were produced under the same HACCP plan in the same time frame as the sampled lot and report this back to the DO. The DO notifies the RMD (see FSIS Directive 8080.1, Recall of Meat and Poultry Products). RMD is notified so a press release can be issued and effectiveness checks can be performed. The establishment is expected to perform a voluntary recall of any unsafe product in commerce. If the establishment does not voluntarily recall product, the DO will coordinate actions to detain or seize affected product.

Workshop: Enforcement

Refer to the module and to FSIS Directive 5000.1 to complete the following questions.

1. You are the IIC at a small canning establishment which produces both an amenable meat spaghetti and non-amenable pasta with lobster cheese sauce. You are performing ISP procedure code 01B02.

a. The regulation sections that you are verifying regulatory compliance with are?

You observe various product contact surfaces in the formulation area. You see that some of the blending equipment appears to have product residue from the previous day's production. You inspect the interior surfaces of the blenders and find residue. You see what appears to be cheese sauce residue in several areas, and you see what appears to be tomato sauce residue in several other areas. You check the production records from the previous day, and determine that the establishment produced lobster cheese pasta in the morning, and meat spaghetti in the afternoon. The label of the meat spaghetti does not list any lobster (crustacean) or milk ingredients.

b. Are the conditions you observed creating an insanitary condition?

c. Are the conditions you observed contaminating product?

d. Is there a food safety hazard associated with the contaminated product?

e. You take official control of the blenders by placing a U.S. reject tag on them. What regulations give you the authority to take this action?

f. What statutes give you the authority to take this action? Explain in your own words the reasoning behind this authority.

g. What actions would you take next?

You review the HACCP plan and hazard analysis. The establishment found that food allergens were potential food safety hazards, but determined that they were not likely to occur in this process because the establishment has a food allergen control program which prevents the hazard.

h. Which corrective action regulation would apply in this situation?

As part of the 03D01 procedure, you decide to review the establishment's food allergen control program. You find that the establishment lists several daily in-plant checks and verification activities, and the associated documentation that will be kept. You request recent records and your review reveals that the food allergen control program verification activities are not being done at the frequency listed in the program. Records are also not available for some of the days.

i. Could this indicate an inadequate system?

j. How would you document what you have found? What procedure codes, regulations, and noncompliance indicators would you use?

k. What actions would you take next?

2. You have recently rotated into a new assignment which includes an establishment which produces several dried specialty meats. You review the hazard analysis and HACCP plan for a dried peppered beef product. You observe that the establishment considered pathogen growth during the drying process as a potential hazard, but decided it was not likely to occur based on following a prerequisite program for drying. The drying program contains control procedures for dry room temperature and relative humidity. You review the program and observe that for the peppered beef product, the dry room is to be maintained at 50°F and 60 percent relative humidity. The temperature and percent relative humidity are to be monitored and recorded 3 times per day. You review some recent records and observe that for the last week, the temperature and percent relative humidity were not monitored. You request documentation supporting the safety of the product in the dry room, but the establishment has no other records.

a. What regulations need to be considered?

b. Is there a HACCP noncompliance? Please explain your answer.

3. You are a relief inspector who has been assigned to cover a large establishment which produces not-heat treated shelf-stable salami. You review the documentation left by the regularly assigned inspector and find a list of 03E02 procedures which have been started but which could not be finished because the specific production (a lot) has not completed the last step in the process. You realize that one of the product lots, 2411, is on the list and should have finished drying, and decide to complete the 02 procedure. You review the HACCP plan, which states for the final CCP, drying, that the water activity of 3 pieces will be measured and recorded from each dry room at the end of the specified drying period. The 3 pieces will be selected from the slowest drying area of the dry room. The critical limit is .80 a_w or less. You ask if the establishment has conducted pre-shipment review, and the QC manager, Mr. Quincy Clark, says yes and shows you a record.

Drying		Date: *4-8-05*	
Lot	Dry room	Monitoring	Verification
2411	*5W*	*.78 RS 8:17 am*	
Corrective Action:			
Pre-shipment records review: *Quincy Clark, 4-8-05*			

You notice that there is only one monitoring result recorded. You notify Mr. Clark, and while you are making some notes about this, the monitor comes forward, produces the following notepad page, and states "I was interrupted and didn't finish transferring the numbers from my notepad."

.78, .78, .79 RS 8:17

What determinations do you make?

What other questions do you have?

If you determine there is a noncompliance, complete blocks 6, 8, 9 and 10 the following NR.

The request *for* this information is voluntary. It is needed to monitor defects found in this inspection system. It is used by FSIS to determine whether establishments are in compliance. 9 CFR 301 and 9 CFR 381. FORM APPROVED OMB No. 0583-0089. OMB DISCLOSURE STATEMENT: Public reporting burden *for* this collection of information is estimated to average 7 minutes per response, including the time *for* reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions *for* reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, Room 404-W, Washington, DC 20250: and to the Office of Information and Regulatory Affairs, Office of Management and Budget.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
NONCOMPLIANCE RECORD

TYPE OF NONCOMPLIANCE

☐ Food Safety ☐ Other Consumer Protection

1. DATE	2. RECORD NO.	3. ESTABLISHMENT NO.

4. TO (*Name and Title)*	5. PERSONNEL NOTIFIED

6. RELEVANT REGULATION(S)

7. SECTION/PAGE OF EST. PRODEDURE PLAN	HACCP	SSOP	OTHER
☐			

8. ISP CODE	9. NONCOMPLIANCE CLASSIFICATION INDICATORS
☐	

10. DESCRIPTION OF NONCOMPLIANCE:

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11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE

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Summary Workshop 1 - Canning

It is April 1, 2005, and procedure 03D02 is on your procedure schedule for a poultry canning establishment, P-42. This establishment does not have a HACCP plan. The establishment's hazard analysis revealed that there are no food safety hazards associated with physical and chemical contamination reasonably likely to occur in the process. It also made the determination in its hazard analysis that the food safety hazards associated with microbiological contamination are not reasonably likely to occur in its operations because it is following the applicable canning regulations. In this case the canning regulations act as supporting documentation for the decision the plant made in its hazard analysis. You decide to use the recordkeeping component and review records from March 30, 2005. You go the QC office and review the information below and the still retort operator's record and time/temperature recording chart on the following pages to verify that the establishment is complying with the canning regulations for a lot production. **Answer the questions after you review the information and records.**

Process Schedule on File

Product: Chicken ala King — Process in Minutes

Can Size	Net Wt.	J	f_h	F_0	I.T.°F.	R.T.240°F	245°F	250°F
307x409	20 oz.	1.6	66	7.0	100	125	110	95
					120	120	105	90
					140	115	100	85
					160	110	95	80
					180	100	85	75
					200	90	75	65
401x411	30 oz.	1.6	88	6.0	100	150	130	120
404x404					120	145	125	115
					140	135	120	105
					160	130	110	100
					180	115	100	90
					200	100	90	80

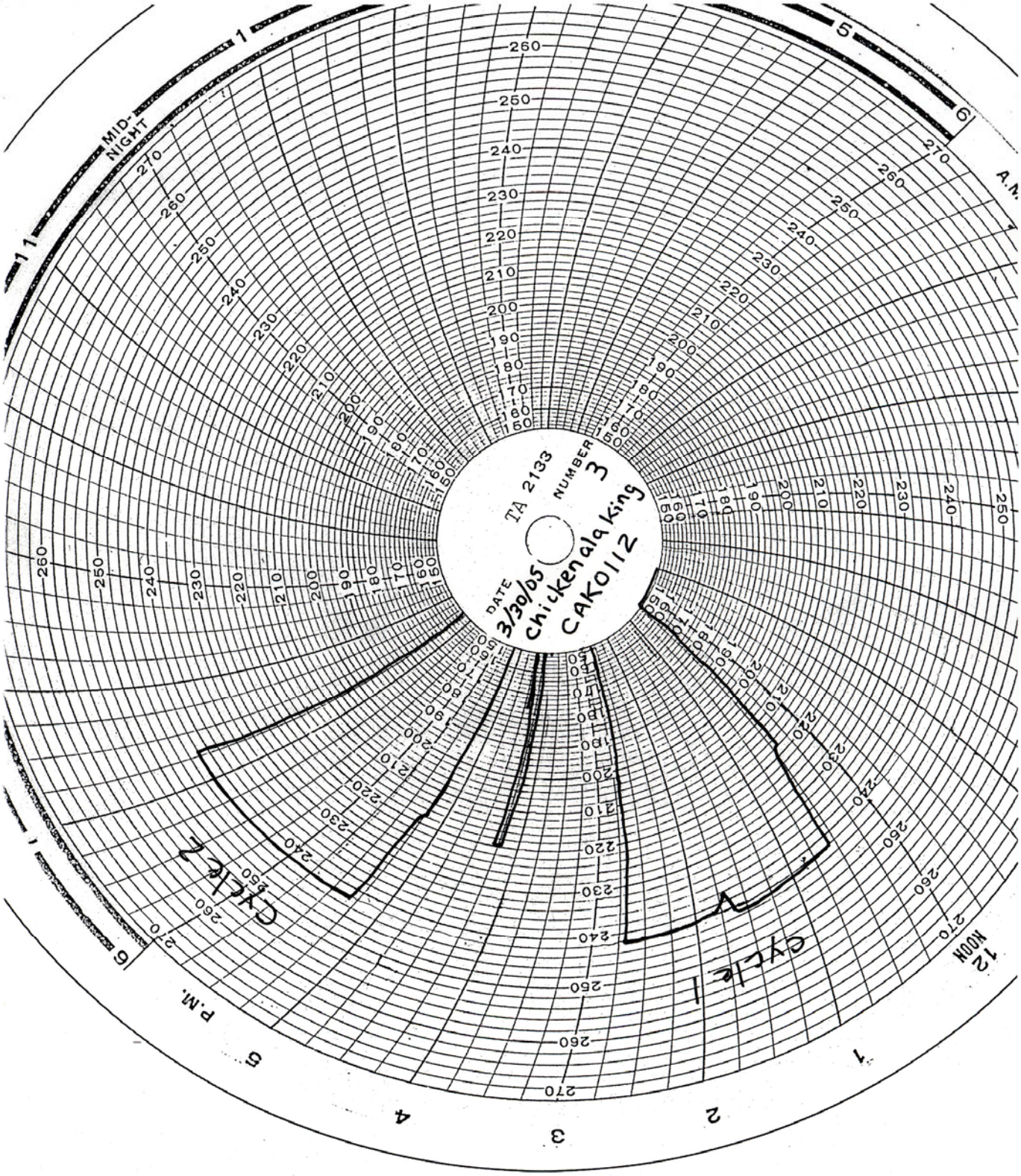
Vent Schedule on File

The vent valve must be fully open for the required time AND temperature after the steam is turned on. Water, drain and air valves must be closed. The timing of the venting period starts when the steam is turned on.

Venting through a 1 inch top vent (no dividers): Vent valve wide open for at least 5 minutes and to at least 230°F

STILL RETORT STERILIZING REPORT						DATE: 3/30/05
PRODUCT AND CODE 307X409 Chicken ala king (CAK0112)	**PROCESS** 125 min/240 °F	**INITIAL TEMP.** 100°F	**COOLING TEMP.** 105°F	**RETORT OPERATOR** PP		**DEPT.** 58
	RETORT NUMBER 1	**RETORT NUMBER** 2	**RETORT NUMBER** 1	**RETORT NUMBER** 2	**RETORT NUMBER** 3	**RETORT NUMBER** 3	**RETORT NUMBER** 3
I.T. °F	115	112	108	110	114	106	97
STEAM-ON	8:27	8:29	12:20	12:24	12:28	4:13	5:15
END VENT TIME	8:33	8:35	12:26	12:30	12:35	4:24	5:21
END VENT TEMP. °F	231	232	232	230	234	220	231
RETORT –UP	8:35	8:37	12:28	12.32	12:36		5:23
PROCESS	126 mins	127 mins	126 mins	126 mins	126 mins		
COOK TEMP. °F **MERCURY**	242	242	242	242	243		242
RECORDER	242	242	242	242	243		242
STEAM-OFF	10:41	10:44	2:34	2:38	2:42		
END OF COOL	11: 10	11:18	3:08	3:12	3:15		
NO. OF BASKETS	4	4	4	4	4	4	4
OPERATOR'S REMARKS						Boiler Down	
	RETORT NUMBER 4	**RETORT NUMBER** 5	**RETORT NUMBER**	**RETORT NUMBER**	**RETORT NUMBER**	**RETORT NUMBER**	**RETORT NUMBER**
I.T.°F	109	113					
STEAM-ON	9:16	9:20					
END VENT TIME	9: 22	9:25					
END VENT TEMP.	232	231					
RETORT –UP	9:24	9:27					
PROCESS	125 mins	127 mins					
COOK TEMP.°F **MERCURY**	242	243					
RECORDER	242	243					
STEAM-OFF	11:29	11:34					
END OF COOL	12:04	12:08					
NO. OF BASKETS	4	4					
OPERATOR'S REMARKS							

COMMENTS: BOILER WENT DOWN FOR ABOUT AN HOUR BEFORE THE LAST RETORT LOAD


TA 2133
NUMBER 3
DATE 3/30/05
Chickenala King
CAK0112
Cycle 1
Cycle 2
MID-NIGHT
NOON
A.M.
P.M.

a. What should you do first?

b. Has a noncompliance occurred?

c. Has a deviation in processing occurred?

d. Should a Noncompliance Record be generated? If so, what regulations should be entered in block 6 of the NR?

e. Should the incident be reported to the District Office?

Summary Workshop 2 – Jerky

It is April 3, 2005, and you have a 03F01 procedure scheduled at Establishment 38. You decide to verify the monitoring, verification, and recordkeeping requirements by using the recordkeeping component. You decide to use the records from the previous day to perform this procedure.

You look at the HACCP plan, the hazard analysis, and records provided, and determine compliance. You should gather information, assess the information, and determine regulatory compliance. There are three possible outcomes: compliance, noncompliance, or more information needed. Determine one of these outcomes for each requirement verified. If more information is needed, list the type of information needed and the concerns you are wanting addressed with this information.

1. Use the questions in FSIS Directive 5000.1 to gather information. The questions asked to verify the **monitoring** requirements specified in 9 CFR 417.2(c)(4) are:

a) Does the HACCP plan list the monitoring procedures and frequencies that are used to monitor each of the CCPs to ensure compliance with the critical limits?

b) Are the monitoring procedures being performed as described in the HACCP plan?

c) Are the monitoring procedures being performed at the frequencies for the CCPs listed in the HACCP plan?

d) Are the CLs met?

When you have gathered the information asking these questions, you should assess the information you gathered and make a supportable regulatory decision.

e) Is the monitoring requirement met?

f) Is there regulatory noncompliance with the monitoring requirement? If so, what is the noncompliance?

g) Do you need more information to determine monitoring compliance? If so, what type of information is needed and what concerns do you have?

2. Use the questions in FSIS Directive 5000.1 to gather information. The questions asked to verify the **verification** requirements specified in 9 CFR 417.2(c)(7) and 9CFR 417.4(a)(2)(i)(ii)(iii) are:

a) Does the HACCP plan contain procedures and frequencies for the calibration of the process-monitoring instruments?

b) Does the HACCP plan contain procedures and frequencies for direct observations of monitoring activities and corrective actions?

c) Does the HACCP plan list procedures and frequencies for the reviews of records generated and maintained in accordance with 9 CFR 417.5(a)(3)?

d) Does the HACCP plan list product sampling as a verification activity?

e) Are process-monitoring instrument calibration activities conducted as per the HACCP plan?

f) Are direct observation activities conducted as per the HACCP plan?

g) Are records generated in accordance with 9 CFR 417.5(a)(3) being reviewed by the establishment?

When you have gathered the information asking these questions, you should assess the information you gathered and make a supportable regulatory decision.

h) From what we have considered so far, is the verification requirement met?

i) Do you need more information to determine verification compliance? If so, what type of information is needed and what concerns do you have?

3. Use the questions in FSIS Directive 5000.1 to gather information. The questions asked to verify the **recordkeeping** requirements specified in 9 CFR 417.2(c)(6)are:

a) Does the HACCP plan set out a recordkeeping system that documents the monitoring of the CCP?

b) Do the records contain actual values and observations obtained during monitoring?

4. Use the questions in FSIS Directive 5000.1 to gather information. The questions asked to verify the **recordkeeping** requirements specified in 9 CFR 417.5(a)(1), 417.5(a)(2) are:

a) Does the establishment have the supporting documentation for the decisions made in the hazard analysis?

b) Does the establishment have the decision-making documents associated with the selection of each CCP?

c) Do the documents explain why the establishment selected that location for the CCP?

d) Is there a control at the identified point in the process that will prevent, eliminate, or reduce to acceptable levels the identified hazards?

e) Does the establishment have scientific, technical, or regulatory support for the critical limit?

f) Does the support appear creditable?

g) Does the establishment have documents supporting the monitoring procedures and frequencies listed in the HACCP plan?

h) Does the establishment have documents supporting the verification procedures and frequencies listed in the HACCP plan? Do the documents support what the establishment has done?

i) If the establishment has supporting documents for these decisions, does the documentation support the decisions?

5. Use the questions in FSIS Directive 5000.1 to gather information. The questions asked to verify the **recordkeeping** requirements specified in 9 CFR 417.5(a)(3) are:

a) Do the records document the monitoring of CCPs and their critical limits?

b) Do the records include actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan?

c) Do the monitoring, verification, and corrective action records include product codes, product name or identity, or slaughter productions lot, and the date the record was made?

d) Are the verification procedures and results of those procedures documented?

e) Is the time recorded when the verification activity was performed?

f) Does the record contain the date the record was made?

g) Are the process-monitoring calibration procedures and results being recorded?

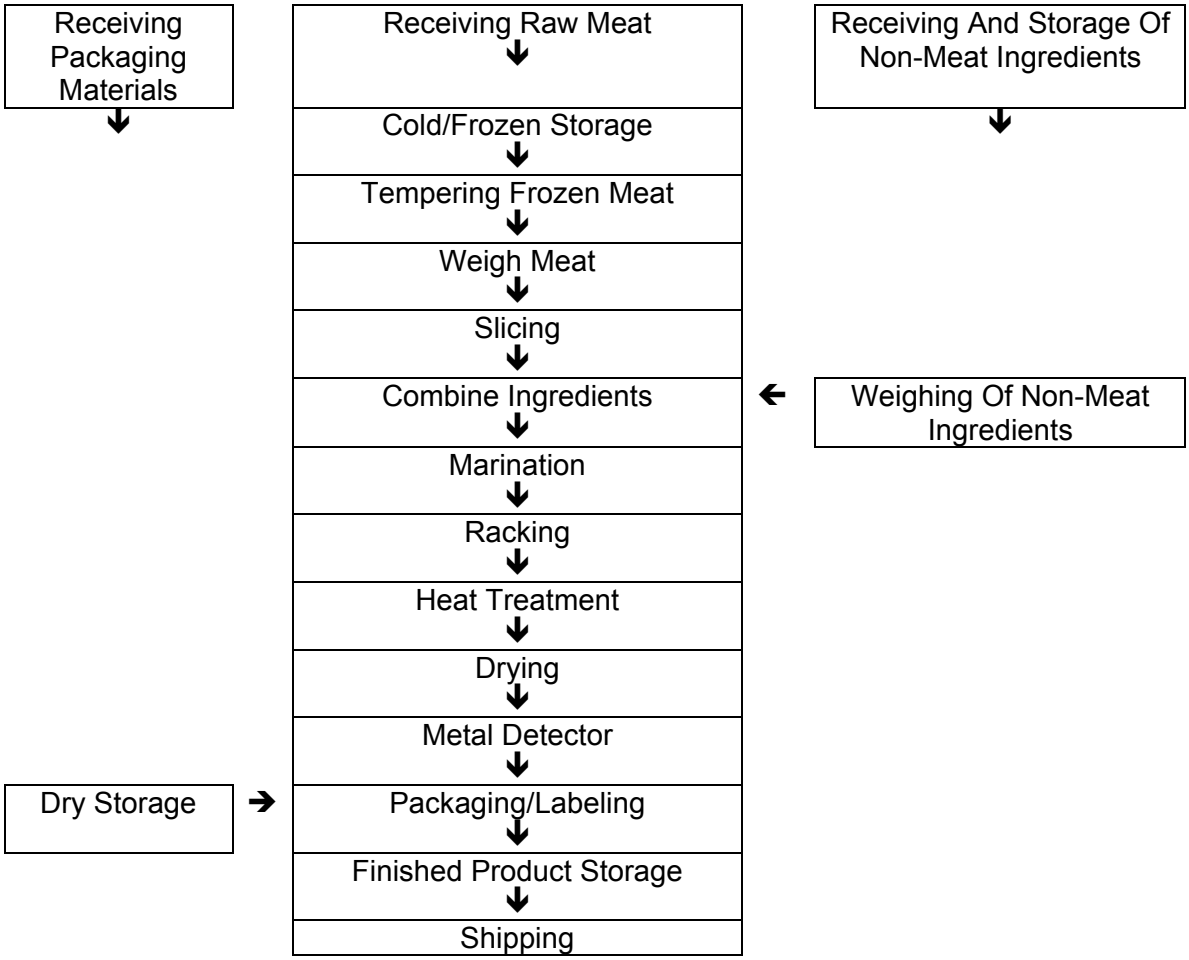
When you have gathered the information asking these questions, you should assess the information you gathered and make a supportable regulatory decision.

h) Is the recordkeeping requirement met?

i) Is there regulatory noncompliance with the recordkeeping requirement? If so, what is the noncompliance?

j) Do you need more information to determine recordkeeping compliance? If so, what type of information is needed and what concerns do you have?

Beef Jerky Flow Diagram



No product is reworked back into the process

Product Description: Jerky
Common name: Beef Jerky; Teriyaki Beef Jerky, Hot-N-Spicy Beef Jerky, Western Barbeque Beef Jerky, Store Brand X Beef Jerky How is it to be used: Consumed as packaged, ready-to-eat, shelf-stable Type of package: 3, and 6 oz plastic bags Length of shelf life: 8 months non-refrigerated Where sold: Distributed wholesale and sold at retail Labeling instructions: Refrigerate after opening

Beef Jerky Hazard Analysis					
Process Step	**Food Safety Hazard**	**Reasonably Likely to Occur?**	**Basis**	**If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level?**	**Critical Control Point**
Receiving packaging materials	B – None C – Packaging material not acceptable for intended use P – None	No	Letters of guaranty are received from all suppliers of packaging materials		
Receiving non-meat ingredients	B – None C – Food ingredients not acceptable for intended use P – None	No	Letters of guaranty are received from all suppliers of food ingredients		
Dry storage of packaging materials and food ingredients	B – None C – None P – None				
Receiving – raw meat	B – Pathogens (*Salmonella, Listeria monocytogenes, E. coli* O157:H7) C – None P – Foreign materials such as metal fragments	Yes No	Pathogens may be present on incoming raw product Plant records show that there has been no incidence of foreign materials in products received into the plant	Pathogens will be controlled at a subsequent step through heat treatment and drying	

Beef Jerky Hazard Analysis					
Process Step	**Food Safety Hazard**	**Reasonably Likely to Occur?**	**Basis**	**If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level?**	**Critical Control Point**
Cold/frozen storage of meat	B – Pathogens (*Salmonella, Listeria monocytogenes, E. coli* O157:H7) C – None P – None	No	Pathogens are not likely to grow if the product is maintained at proper temperature.	Prerequisite program in place to prevent pathogen growth from being likely to occur. Pathogens will be controlled at a subsequent step through heat treatment and drying.	
Tempering frozen meat	B – None C – None P – None				
Weigh meat	B – None C – None P – None				
Slicing	B – None C – None P – Metal Contamination	No	Plant records show that there has been no incidence of metal contamination in the process.		
Weigh non-meat ingredients	B – None C – Excessive level of nitrite P – None	No	Prerequisite program in place to prevent addition of greater than allowed amount of nitrite.		
Combine ingredients	B – None C – None P – None				

Beef Jerky Hazard Analysis					
Process Step	**Food Safety Hazard**	**Reasonably Likely to Occur?**	**Basis**	**If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level?**	**Critical Control Point**
Marination	B – None C – None P – None				
Racking	B – None C – None P – None				
Heat treatment	B – Pathogens (*Salmonella, Listeria monocytogenes, E. coli* O157:H7, *Staphylococcus aureus*) C – None P – None	Yes	Potential survival and growth of pathogens and toxigeneses from *S. aureus* with inadequate process time/temperature/humidity.	Heat treatment using appropriate time/temperature/humidity to produce lethality.	1
Drying	B – Pathogens (*Listeria monocytogenes, Staphylococcus aureus*) C – None P – None	Yes	*L. monocytogenes* can grow if a_w above 0.92 and *S. aureus* growth & toxigeneses can occur if *S. aureus* survived heat treatment.	Low water activity precludes bacterial pathogen growth. The a_w required to prevent growth of *S. aureus* (0.86) is lower than that for other pathogens.	2

Beef Jerky Hazard Analysis					
Process Step	**Food Safety Hazard**	**Reasonably Likely to Occur?**	**Basis**	**If Yes in Column 3, What Measures Could be Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level?**	**Critical Control Point**
Packaging/Labeling	B – Pathogen contamination and subsequent growth (*Listeria monocytogenes)* C – None P – None	No	Potential post-lethality exposure to *Lm*. SSOPs prevent contamination. Growth precluded by previous drying step – water activity of product is much less than 0.92 minimum required for *Lm* growth. The drying process meets the criteria described in 9 CFR 430.4 for Alternative 2.		
Finished product storage	B – None C – None P – None				
Shipping	B – None C – None P – None				

Beef Jerky HACCP plan				*Suzanne Ortega 7-8-04*	
CCP# and Location	Critical Limits	Monitoring Procedures and Frequency	HACCP Records	Verification Procedures and Frequency	Corrective Actions
1 Heat Treatment	Cooked to an oven temperature of ≥ 180°F for ≥ 2 hours with ≥ 90% humidity throughout the cook	Oven temperature monitored with dry bulb thermometer every 30 minutes throughout each cooking period and recorded Humidity monitored by comparison of wet and dry bulb thermometers every 30 minutes throughout the cook and recorded (Wet bulb temperature must be within 4.5°F of the dry bulb temperature) Time cook starts and time end recorded	Cook log Thermometer Calibration log	Maintenance supervisor will verify that the wet bulb water wick well contains the appropriate amount of water prior to startup Once per shift the QA supervisor will review the Cook log Once per shift the QA supervisor will observe the smokehouse operator perform the monitoring activity	Will meet 9 CFR 417

2 Drying	Water activity of ≤ 0.80	Water activity checks will be done by separately placing 25 gram portions of 3 product samples from each lot in a water activity meter and the results will be recorded on the cook log	Cook Log Corrective action log Water Activity Meter Calibration log	QA technician will check all water activity meters used for monitoring for accuracy daily against a known standard (methodology reference on file) and calibrate when necessary QA supervisor will review the cook log once per shift Once per week QA supervisor will observe the QA technician perform the monitoring activity	Will meet 9 CFR 417

You review the following establishment records:

Cook Log

Date: *4-1-05*			**Product ID**: *lot 1423*			**Smokehouse #**: *9*
	Time	**Oven Temp Dry**	**Oven Temp Wet**	**Difference For % RH**	**Monitor**	**Verification***
start	*8:25 am*	*182*	*178*	*4*	*IC*	
	9:34	*184*	*181*	*3*	*IC*	
	9:58	*185*	*181*	*4*	*IC*	
end	*11:03*	*185*	*181*	*4*	*IC*	
Comments: *End dry time 2:34 pm IC*						*RR, 6:00 pm, DG*
Water Activity : date, time, monitor, results						
4-2-05, 3:20 pm, MR .75, .74, .76						
Pre-shipment review: *Larry Gastille 4-3-05*						
***Verification- DO= direct observation and results per HACCP plan RR= records review and results per HACCP plan**						

Cook Log

Date: *4-1-05*			**Product ID**: *lot 1424*			**Smokehouse #**: *8*
	Time	**Oven Temp Dry**	**Oven Temp Wet**	**Difference For % RH**	**Monitor**	**Verification***
start	*9:10*	*182*	*178*	*4*	*IC*	
	9:43	*184*	*180*	*4*	*IC*	
	10:04	*184*	*180*	*4*	*IC*	
	10:33	*184*	*181*	*3*	*IC*	
	10:50	*185*	*181*	*4*	*IC*	
end	*11:15*	*185*	*181*	*4*	*IC*	
Comments: *End dry time 3:19 pm*						
						RR, 6:04 pm, DG
Water Activity: date, time, monitor, results						
4-2-05, 3:50 pm, MR .76, .75, .76						*DO, LG, 4-2-05*
Preshipment review: *Larry Gastille 4-3-05*						
***Verification- DO= direct observation and results per HACCP plan RR= records review and results per HACCP plan**						

Water Activity Calibration Log			**Criteria within ±.003 of each Control**			
Date	**Time**	**Meter #**	**a_w NACL (.753)**	**a_w distilled H_2O (1.000)**	**Adjustment needed?**	**Initials**
4-2-05	*2:50 pm*	*1*	*.755*	*1.000*	*no*	*MR*
4-2-05	*3:10 pm*	*2*	*.754*	*1.000*	*no*	*MR*
Aw of control solutions (salt and water) conducted at 77°F						

In addition, you review one part of the establishment's supporting documentation, on the following pages.

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April 2007

Updated Compliance Guideline

Quick Guide on Processing Jerky

and

Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Plants

Quick Guide on Processing Jerky

The Compliance Guideline for Meat and Poultry Jerky lists seven (7) processing steps in the production of meat and poultry jerky where some level of microbial intervention can be applied to maximize lethality. While it may not be necessary for some establishments to apply all seven of these steps, the lethality treatment and drying steps must be used in all processes to ensure that a safe product is produced.

Lethality treatment: For meat jerky, use of the time-temperature combinations provided in the lethality compliance guidelines (Appendix A of the final rule "Performance Standards for the Production of Certain Meat and Poultry Products"; http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/95-033F/95-033F_Appendix_A.htm) can be used to ensure the safety of the product. For poultry jerky, the minimum internal temperatures listed in the lethality compliance guidelines of 160°F for uncured poultry (see complete Compliance Guideline regarding 155°F for cured and smoked poultry) can be used to achieve an adequate lethality. The time-temperature combinations listed in the "Time-Temperature Tables For Cooking Ready-To-Eat Poultry Products" can also be used for lethality.

The 90% humidity parameter must be applied throughout the lethality treatment for meat and poultry jerky if the lethality compliance guidelines (Appendix A) are used as supporting documentation. The humidity must be maintained at ≥90% for the time that the product is heated at the temperature specified in Appendix A.

Some simple and practical measures that can be used to aid in meeting the humidity parameters in the lethality compliance guidelines include:

- Sealing the oven dampers to provide a closed system and to prevent moisture loss.
- Adding humidity to the system by placing one or more shallow, wide pans of water in the oven or by injecting steam in the oven.

The establishment is expected to measure and maintain the relative humidity during the lethality treatment. The process should be monitored using wet and dry bulb thermometers. The use of wet and dry bulb measurements can be used to determine relative humidity (http://home.fuse.net/clymer/water/wet.html).

Drying: After the lethality treatment, the product is dried to meet a water activity level that will stabilize the finished product for food safety purposes. A water activity critical limit for stabilization of 0.85 or lower should control growth of all bacterial pathogens of concern. The finished product must also meet the moisture protein ration (MPR) product standard.

Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Plants

Purpose

This document is intended to provide updated guidance and information for the small and very small meat and poultry plants that manufacture jerky. It is not intended to set any regulatory requirements.

Background

Meat or poultry jerky is a ready-to-eat (RTE), dried product that is generally considered to be shelf-stable (i.e., it does not require refrigeration after proper processing). In the early fall of 2003, FSIS found that producers of meat and poultry jerky may not be adequately processing jerky to achieve the lethality necessary to produce a safe product.

FSIS identified two points in jerky processing where producers need to improve.

1. Ensuring an adequate lethality

If the requirement for moist cooking is not achieved, heat treatment alone may not be enough to meet the lethality performance standards. Processors that use dry heat to both heat and dry their product will not achieve adequate lethality during the heating process because the product dries prematurely, and the lethality process stops. Buege et al. (2006) and Faith et al. (1998) demonstrated that this failure would occur through studies in which an adequate lethality was not achieved by a slow temperature rise or by a long time at sub-lethal temperatures.

2. Using water activity and not Moisture Protein Ratio (MPR)

FSIS is aware that some manufacturers rely upon the maximum moisture protein ratio (MPR), rather than water activity, for determining whether their process adequately dries the jerky to produce a shelf-stable product. Water activity, however, as measured by laboratory analysis, is the more appropriate indicator to verify that the jerky is properly dried. Water activity is a better measure of available water for microbial growth than MPR. Minimizing available water (e.g., achieving a water activity of 0.85 or less) is critical for controlling the growth of pathogens. However, an MPR of 0.75:1 or less remains part of the standard of identity for jerky. Thus, an MPR of 0.75:1 or less is necessary to call the product "jerky," but it is not sufficient to ensure a safe product.

Definition of Lethality treatment: The process step or steps used to destroy pathogenic microorganisms on or in a product to make the product safe for human consumption.

Lethality Compliance Guidelines for Jerky

In general, jerky processin includes slicing or forming the meat or poultry, marinating, heating, and then drying the strips. The purpose of the heating step is to apply a lethality treatment to kill or reduce the numbers of microorganisms. Drying the jerky stabilizes the final product and prevents the growth of microorganisms, especially toxigenic microorganisms such as *Staphylococcus aureus*. Some processors combine the heating and drying procedures into one step. However, it is **critical** that the heating step includes adequate humidity before the jerky is dried.

If the times and temperatures in the lethality compliance guidelines (Appendix A of the final rule "Performance Standards for the Production of Certain Meat and Poultry Products"; http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/95-033F/95-033F_Appendix_A.htm) are used, it is critical that the humidity criteria be rigorously followed during the cooking/heating (lethality) steps. Note:

- A was developed for large mass meat products, not thin strips of meat.
- The humidity parameters in Appendix A cannot be maintained in a home-style dehydrator. However, processes that can achieve an adequate reduction of *Salmonella* and *E. coli* O157:H7 in dehydrators are described in the studies by Buege et al. (2006), and Harrison et al. (2006).

The following are general or common processing steps used in jerky production. Although an establishment's process may not include all these steps, the **lethality treatment and drying must be utilized to produce a safe product**. The intervention step may be required for those processes that do not achieve an adequate lethality. The steps listed as heating and drying are consecutive steps. Drying should closely follow heating. Heating is used to achieve lethality of harmful microorganisms, and drying is used to stabilize the product.

Step 1 - Strip preparation: Whole muscle is sliced or ground; ground product is formed into strips. (Some jerky is formed.)

Step 2 – Marination: The strips are then marinated in a solution that often contains salt, sugar, and flavoring ingredients.

Step 3 - Interventions: Antimicrobial interventions, before and after marinating the strips of raw product, have been shown to increase the level of pathogen reduction beyond that achieved by heating alone. Some heating processes may not deliver an adequate lethality and, thus, may require an additional intervention step to ensure product safety. Examples of such interventions are:

- Preheating the meat or poultry jerky strips in the marinade to a minimum internal temperature of 160°F will provide an immediate reduction of *Salmonella* (Harrison and Harrison, 1996). Heating in the marinade may produce an unacceptable flavor for some products; however, other liquids such as water could be used. The times and temperatures in the lethality compliance guidelines could be used for preheating in

the liquid.

- Dipping the product in 5 % acetic acid for 10 minutes before placing it in the marinade can augment the log reduction effects of drying but not enough to eliminate pathogens (Calicioglu, 2002 & 2003). This intervention may also result in an undesirable flavor.

- Dipping the product in 1:2 or 1:3 mixtures of calcium sulfate (Mionix Safe$_2$ O™) and water for 30 seconds can increase the level of reduction of *Salmonella*, *Listeria monocytogenes*, and *Escherichia coli* O157:H7 above that achieved with no pretreatment. Pretreatment with acidified sodium chlorite (Keeper®) at concentrations between 500 and 1,200 ppm also was effective. These pretreatments were effective in both dehydrators and smokehouse processing. (Harrison et al., 2006)

Step 4 - <u>Lethality treatment:</u> The establishment needs to control, reduce, or eliminate the biological hazards identified in its hazard analysis. For meat and poultry jerky, these hazards will most likely include the microbiological hazards from *Salmonella* spp., *Listeria monocytogenes,* and *Staphylococcus aureus*. For beef jerky, *Escherichia coli* O157:H7 may also be a hazard reasonably likely to occur. In recent years, several jerky products have been found to be adulterated with *Salmonella* and *Escherichia coli* O157:H7.

For meat jerky, use of the time-temperature combinations provided in the lethality compliance guidelines (Appendix A) should help to ensure the safety of the product. These time-temperature combinations are based on experiments that were done with ground beef without added salt or sugar. Added salt, sugar, or other substances that reduce water activity will increase the heat resistance of bacteria in a product. However, time and experience have shown that the time-temperature combinations in the lethality compliance guidelines have been sufficient to produce safe products even with both salt and sugar added, but the **humidity during heating is a critical factor**.

For poultry jerky, to produce a safe product, producers can use the minimum internal temperatures listed in the lethality compliance guidelines of 160°F for uncured poultry or 155°F for cured and smoked poultry. The required reduction of *Salmonella* also can be achieved by using one of the time-temperature combinations listed in the "Time-Temperature Tables for Cooking Ready-to-Eat Poultry Products" (on the FSIS website at http://www.fsis.usda.gov/OPPDE/rdad/FSISNotices/RTE_Poultry_Tables.pdf). **NOTE: If highly pathogenic avian influenza (HPAI) virus H5N1 is identified as a hazard reasonably likely to occur, cured and smoked poultry should be cooked to at least 158°F or a time and temperature combination that achieves a 7-log $_{10}$ reduction of *Salmonella*** as listed in the "Temperature Tables For Cooking Ready-To-Eat Poultry Products," posted on the FSIS website above. However, here again, **humidity during heating is a critical factor** regardless of which compliance guideline is used. As with meat jerky, the time- temperature combinations would be sufficient to produce safe products with both salt and sugar additives if the processor uses the humidity parameters applicable to beef as described below.

Some simple and practical measures that can be used to aid in meeting the humidity parameters in the lethality compliance guidelines include:

- Seal the oven
  Close the oven dampers to provide a closed system and prevent moisture loss. In order to ensure that moisture is not lost, **the establishment is expected to measure and maintain the relative humidity at ≥90% for the specified period of time.**

- Add humidity
  - Place one or more shallow, wide pans of hot water in the oven to provide humidity in the system. Conduct a test run to determine whether the water evaporates.
  - Injecting steam or a fine water mist in the oven can also add humidity. In either case, the use of a wet bulb thermometer, in addition to the dry bulb thermometer, would enable the operator to determine whether adequate humidity is being applied.

- Monitor humidity
  Use a wet bulb thermometer in combination with a dry bulb thermometer. A basic wet bulb thermometer can be prepared by fitting a wet, moisture-wicking cloth around a dry bulb thermometer. To maintain a wet cloth during the process, submerse an end of the cloth in a water supply. The cloth must remain wet during the entire cooking step and should be changed daily, especially if smoke is applied. The use of a wet bulb thermometer is especially important for production at high altitudes or areas of low humidity where evaporation is facilitated.

The humidity parameters must be followed for meat and poultry jerky if the lethality compliance guidelines (Appendix A) are used as supporting documentation. The time-temperature tables are based on wet-heat. **Without humidity the product will dry, and the bacteria will become more heat resistant** (Goepfert, 1970; Goodfellow and Brown, 1978; Faith, N.G. et al. 1998). As long as proper humidity is maintained, the level of pathogen reduction attained by using the lethality compliance guidelines for cooking poultry or whole beef should be sufficient to provide a safe product.

If the lethality compliance guidelines are used, the **relative humidity must be maintained above 90 percent throughout the cooking or thermal heating process**, unless an establishment can provide documentation that its process can achieve an adequate lethality with less humidity. With adequate humidity, small mass products such as jerky should heat rapidly and attain the necessary time and temperature to meet the compliance guideline criteria for lethality. The humidity criterion, “50 percent of the cooking time but in no case not less than one hour,” in Appendix A is not applicable to jerky.

The heating temperature and humidity (e.g., steam) are critical for achieving adequate lethality. If the heating chamber does not have high humidity, then most of the applied

heat will be absorbed by the moisture evaporating from the product and the product will not attain a lethal temperature until most of the moisture is gone. As the water activity is reduced, the heat resistance (D value) of the bacteria increases (Goepfert, 1970). Thus, if adequate humidity is not maintained during heating, the time needed at a particular temperature to eliminate *Salmonella* will be greatly increased. It is crucial that the processor prevent drying of the product until a lethal time-temperature combination is attained. The humidity requirement must be applied during the first part of the heating process, before any drying occurs. If humidity is not applied for a sufficient amount of time, the product will lose moisture, and the concentration of any solutes, such as sugar or salt, will increase with the decrease in water. Both the drying of the product and the increase in solute concentration will increase the heat resistance of bacteria, including *Salmonella*.

The process should be monitored using wet and dry bulb thermometers (values in Appendix A are wet bulb product temperature values). The use of wet and dry bulb measurements can be used to determine relative humidity (http://home.fuse.net/clymer/water/wet.html). For example, readings that show a difference of 2°F between the wet and dry bulbs might indicate approximately 94% relative humidity. Wet and dry bulb temperatures should not differ by more than 4.5°F. A temperature difference greater than 4.5°F indicates a relative humidity of approximately 86% and shows that the needed minimum relative humidity (90%) is not being maintained. A recent study by Buege et al. (2006) emphasized the importance of wet bulb measurements in controlling the process. The web page "Safe Processing of Meat and Poultry Jerky" (http://www.ext.vt.edu/pubs/foods/458-501/458-501.html) provides examples of constructing a wet bulb thermometer, calibrating the thermometer, and placement of the thermometer in a piece of jerky. (Note: The example for calibrating the thermometer in ice water described on the web page may not guarantee accuracy at oven temperatures).

At high altitudes, the amount of humidity in the chamber necessary to achieve a given log reduction of bacteria may need to be increased. Processing failures in the manufacture of jerky have occurred in establishments located at high altitudes.

Step 5 – Drying: After the lethality treatment, the product is dried to meet a water activity level that will stabilize the finished product for food safety purposes. If the product is insufficiently dried, *S. aureus* and mold are potential hazards. These organisms are not expected to grow in properly dried products. A water activity critical limit for stabilization of 0.85 or lower should control growth of all bacterial pathogens of concern. The finished product must also meet the MPR product standard.

Consequently, the establishment should verify the water activity to demonstrate that the product has attained the critical limit for shelf stability. Water activity is the key to determining the proper level of drying. The water activity can vary greatly at any given MPR (as a result of the presence and level of different solutes, such as sugar and salt). Therefore, a laboratory test for water activity should be used to verify proper drying.

Step 6 – Post-drying heat step: Heat the dried product in a 275°F oven for 10 minutes. This heating has the potential to reduce *Salmonella* levels by approximately 2 logs from the level of reduction achieved during initial heat step (Harrison et al., 2001). This step may be needed for processes that do not result in an adequate reduction of *Salmonella* through the initial heating process.

Step 7 - Handling: The establishment's Sanitation SOPs (9 CFR 416) should ensure that product is properly handled to prevent re-contamination or cross-contamination of the meat and poultry products by the bacterial pathogens of concern.

Validating Customized Processes

Establishments, or their processing authorities, may develop customized processes that achieve an appropriate reduction of pathogens throughout the product. These customized processes are based on a scientific rationale and supported by experimental data. Establishments develop their customized processes by using:

- information obtained from the literature,
- unpublished studies that are scientifically valid, or
- comparison of methods used by the establishment with established procedures that have been validated to achieve the required $\log_{10}$ reduction of pathogens.

At a minimum, a validation study for a microbiological food safety hazard should:

- identify the hazard,
- indicate the $\log_{10}$ reduction achieved for the specified pathogens,
- describe how the $\log_{10}$ reduction of the pathogen was achieved or determined,
- specify the actual processing conditions (e.g., time, temperature, and humidity),
- list critical ingredients (e.g., salt, sugar, and cure), and
- list the critical product characteristics (e.g., pH, water activity, and fat content).

If validation is needed for more than one product, the study should be designed around products with similar characteristics, ingredients, and processing procedures. Consider factors such as:

- Salt, sugar, or other substances that reduce water activity may increase the heat resistance of bacteria; and
- Additives may have a bactericidal effect and would limit the validation to products that contain the additive.

NOTE: Alternative or custom processes must be validated (9 CFR 417.4).

Challenge studies are excellent means to validate processes. Validation by a challenge study is based on a scientific rationale and provides the necessary data to determine the $\log_{10}$ reduction of the target pathogen. Pathogen challenge studies should be conducted in a testing laboratory and not in the processing plant environment. Product sampling

results, based on historical data alone, should not be used to validate these procedures because they do not provide information on the incoming pathogen load and, consequently, the level of pathogen reduction achieved is unknown. Challenge studies should be equivalent to peer-reviewed scientific literature. All of the critical elements need to be included to permit evaluation or confirmation of the results.

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NR Documentation Review

The request *for* this information is voluntary. It is needed to monitor defects found in this inspection system. It is used by FSIS to determine whether establishments are in compliance. 9 CFR 301 and 9 CFR 381. FORM APPROVED OMB No. 0583-0089. OMB DISCLOSURE STATEMENT: Public reporting burden *for* this collection of information is estimated to average 7 minutes per response, including the time *for* reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions *for* reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, Room 404-W, Washington, DC 20250: and to the Office of Information and Regulatory Affairs, Office of Management and Budget.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
NONCOMPLIANCE RECORD

TYPE OF NONCOMPLIANCE

☒ Food Safety ☐ Other Consumer Protection

1. DATE	2. RECORD NO.	3. ESTABLISHMENT NO.
Today	**0026-2005-675**	**00038 M/1**

4. TO (*Name and Title*)	5. PERSONNEL NOTIFIED
Mr. John Doe, Plant Manager	**Ms. Jane Doe, Processing Supervisor**

6. RELEVANT REGULATION(S)

417.3(a)(4)

7. SECTION/PAGE OF EST. PRODEDURE PLAN	HACCP	SSOP	OTHER
	II/2		

8. ISP CODE	1. NONCOMPLIANCE CLASSIFICATION INDICATORS
03F01	**HACCP-Corrective Action**

10. DESCRIPTION OF NONCOMPLIANCE:

At approximately 9:20 a.m., while performing procedure 03F01, I reviewed the Oven Temperature and Humidity monitoring record, dated 3-26-05, for the jerky lethality step (CCP 2). I observed that the recorded result for the 2:36 p.m. monitoring check exceeded the critical limit in the HACCP plan. Relative humidity of 90% or higher throughout the 2hr cook cycle is one of the stated critical limits. To be at or above 90%, the difference between the wet bulb and dry bulb thermometers cannot exceed 4.5° F. The recorded result for the 2:36 p.m. check was 6.3° F. In the comments column next to the monitoring result "see corrective action log" was recorded.

11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE

You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR.

12. PLANT MANAGEMENT RESPONSE: (Immediate action(s)):

13. PLANT MANAGEMENT RESPONSE: *(Further planned action(s)):*

This document serves as written notification of your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.

14. SIGNATURE OF PLANT MANAGEMENT	15. DATE
16. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE	17. DATE

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE **NONCOMPLIANCE RECORD** **CONTINUATION SHEET**	Type of Noncompliance [X] Food Safety [ ] Other Consumer Protection

1. Date	2. Record No	3. Establishment No.
Today	**0026-2005-675**	**00038 M / 1**

4. To (Name and Title)	5. Personnel Notified
Mr. John Doe, Plant Manager	**Ms. Jane Doe, Processing Supervisor**

6. Relevant Regulation(s)

417.3(a)(4)

7. Relevant Section/Page of Establishment Procedure/Plan	HACCP	SSOP	OTHER
	II/2		

8. ISP Code	9. Noncompliance Classification Indicators
03F01	**HACCP--Corrective Action**

10. DESCRIPTION OF NONCOMPLIANCE

I reviewed the plant's corrective action log dated 3-26-05. The plant's recorded corrective actions for this deviation did not meet all of the corrective actions required by the 9 CFR 417.3(a). Measures to ensure that product injurious to health or otherwise adulterated did not enter commerce were not documented. I asked Ms. Jane Doe, QA Supervisor, if any action was taken against the jerky to ensure that it was safe for distribution. She could not provide any evidence that the jerky was segregated and held or had its safety evaluated. I reviewed the plant's pre-shipment review file. The pre-shipment review for the lot of jerky had not been conducted. The lot (same code as on the monitoring record) of packaged jerky was located in the finished product storage room and U.S. retained with tags #567385 and #567386. Ms. Jane Doe was orally notified of the regulatory control action and the basis for the action in accordance 9 CFR 500.2(b).

11. Signature of Inspection Program Employee

NR Documentation Review

The request *for* this information is voluntary. It is needed to monitor defects found in this inspection system. It is used by FSIS to determine whether establishments are in compliance. 9 CFR 301 and 9 CFR 381. FORM APPROVED OMB No. 0583-0089. OMB DISCLOSURE STATEMENT: Public reporting burden *for* this collection of information is estimated to average 7 minutes per response, including the time *for* reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions *for* reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, Room 404-W, Washington, DC 20250: and to the Office of Information and Regulatory Affairs, Office of Management and Budget.

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
NONCOMPLIANCE RECORD

TYPE OF NONCOMPLIANCE

☒ Food Safety ☐ Other Consumer Protection

1. DATE	2. RECORD NO.	3. ESTABLISHMENT NO.
Today	**0026-2005-677**	**00038 M/1**

4. TO (Name and Title)	5. PERSONNEL NOTIFIED
Ms. Jane Doe, Plant Manager	**Mr. Jon Doe (Formulation Supervisor)**

6. RELEVANT REGULATION(S)

417.5(a)(1); 318.302(b)(2); 318.303(a)(5)

7. SECTION/PAGE OF EST. PRODEDURE PLAN	HACCP	SSOP	OTHER
	III/3		

8. ISP CODE	9. NONCOMPLIANCE CLASSIFICATION INDICATORS
03D01	**HACCP-Recordkeeping**

10. DESCRIPTION OF NONCOMPLIANCE:

At approximately 9:00am during the performance procedure 03D01 the following non-compliance was observed: While observing the formulation of one batch of beef stew to verify that the plant was measuring, controlling and recording the critical factors to ensure they were within the limits used to establish the process schedule as required by 9 CFR 318.303, I, Inspector Smith, found several pieces of raw diced beef to larger than the maximum dice size of a ¼ inch listed as a critical factor in the process schedule. I found several pieces of beef to be 3/8 inch and some as large as ½ inch in greatest dimension. Upon review of the critical factor record, I found that the QA tech had a result of 3/8 inch recorded for two of the four batches that had already been produced.

11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE

You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR.

12. PLANT MANAGEMENT RESPONSE: (Immediate action(s)):

13. PLANT MANAGEMENT RESPONSE: *(Further planned action(s)):*

This document serves as written notification of your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.

14. SIGNATURE OF PLANT MANAGEMENT	15. DATE
16. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE	17. DATE

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE **NONCOMPLIANCE RECORD** **CONTINUATION SHEET**	Type of Noncompliance ☒ Food Safety ☐ Other Consumer Protection
1. Date **Today**	2. Record No **0026-2005-677**
3. Establishment No. **00038 M / 1**	
4. To (*Name and Title*) **Ms. Jane Doe, Plant Manager**	5. Personnel Notified **Mr. Jon Doe (Formulation Supervisor)**
6. Relevant Regulation(s) **417.5(a)(1); 318.302(b)(2); 318.303(a)(5)**	
7. Relevant Section/Page of Establishment Procedure/Plan **III/3**	| HACCP | SSOP | OTHER
8. ISP Code **03D01**	9. Noncompliance Classification Indicators **HACCP—Recordkeeping**

10. DESCRIPTION OF NONCOMPLIANCE

I informed Mr. Larry Doe, HACCP Coordinator, that this change in the ingredient and formulation could affect the heat penetration profile or sterilization value and needed to be reviewed by a processing authority as stated in 9 CFR 318.302(b)(2) and the failure to comply with the critical factor requirement was a process deviation to be handled in accordance with 9 CFR 318.308(b). Mr. Doe stopped the further production of the beef stew and said that the batch in process and the four batches of stew already produced would be segregated and placed on QA hold. Later in the day, I found 18 pallets of boxed beef stew (correct day and batch codes) segregated and on hold with QA tags in the finished product storage area.

11. Signature of Inspection Program Employee

Appendix 1

Bonus Canning Regulations Workshop

Read each statement, refer to the canning regulations, and determine if the statement is either true or false. Note the regulation reference where the information is found. For each false statement please provide a short explanation as to why the answer is false.

1. EVERY empty container shall be evaluated by the establishment to ensure that all containers are clean and free of defects.

2. A closure technician should visually examine the double seams of rigid containers EVERY HOUR.

3. A teardown examination of the double seams formed by each closing machine head shall be performed at a frequency SUFFICIENT to ensure proper closure.

4. Visual examinations of semirigid or flexible container heat seals will be performed only BEFORE heat processing.

5. The maximum time lapse between closing and initiation of the thermal processing shall be four hours.

6. The establishment must have an approved process schedule for EACH canned meat or poultry product packed.

7. If there is a change in the formulation, ingredients, or treatments, the PROCESSING AUTHORITY shall make amendments to the process schedule.

8. The IIC SHALL MAINTAIN a record concerning all aspects of the development of the process schedule.

9. Letters from processing authorities recommending all process schedules shall be maintained on file by the establishment.

10. ALL critical factors specified in the process schedule shall be measured, controlled, and recorded.

11. The process schedule must be POSTED OR MADE AVAILABLE to the thermal processsing sytem operator.

12. Traffic control is important to prevent product from bypassing the thermal processing operation.

13. Each basket, crate, or similar vehicle containing unprocessed product, or at least one visible container in each vehicle, shall be plainly and conspicuously marked with a heat-sensitive indicator that will visually indicate whether such unit has been thermally processed.

14 The intitial temperature is the temperature of the contents of the HOTTEST container to be processed.

15. The TEMPERATURE/TIME RECORDING DEVICE shall be used as a reference instrument for indicating the process temperature.

16. The temperature recording chart should be adjusted to agree with, but shall never be HIGHER than, the known accurate indicating temperature device.

17. Horizontal still retorts shall be equipped with perforated steam spreaders that extend the FULL LENGTH of the retort.

18. Bleeders on steam retorts shall be CLOSED during come-up time and must be OPEN during the cooking time.

19. There shall NOT be a measurable residual of sanitizer in the water at the discharge point of the cooling canal.

20. The indicating temperature device and temperature recorder shall be read at the SAME TIME AT LEAST ONCE during process timing and the observed temperatures recorded when processing in steam with batch retorts.

21. When processing in steam with batch agitating retorts, the establishment must also record the functioning of the condensate bleeder and the retort or reel speed.

22. Atmospheric cookers, batch type systems, require that MOST of the critical factors of the process schedule be recorded.

23. Charts from temperature/time recording devices SHALL INCLUDE the container code.

24. All entries shall be made NO LATER THAN ONE WORKING DAY after the actual process.

25. The establishment shall maintain a record identifying the initial distribution of the finished product.

26. When at least TWO OR MORE critical factors do not comply with the process schedule, it shall be considered a deviation in processing.

27. When retort jams for breakdowns occur in a continuous rotary retort DURING THE PROCESSING operation, all containers shall be given an emergency still process before the retort is cooled or the retort shall be cooled promptly and all containers removed and either reprocessed, repacked and reprocessed, or destroyed.

28. The incubation temperature shall be maintained at 35 degrees C plus or minus 2.8 degrees C.

29. From EACH LOAD of product processed in a BATCH-TYPE thermal processing system, the establishment shall select AT LEAST ONE container for incubation.

30. For CONTINUOUS ROTARY retorts, the establishment shall select AT LEAST ONE container per 1,000 for incubation.

Appendix 2

Random Number Generator

You can use an FSIS computer to select a random number. This is one way to randomly select the regulatory requirements to verify during the 01 procedure. You will need to randomly select a number between one and three to represent which of the three regulatory requirements you are going to verify. Remember that you may also choose to verify more than one regulatory requirement. You can use the random number generator to choose any amount of random numbers.

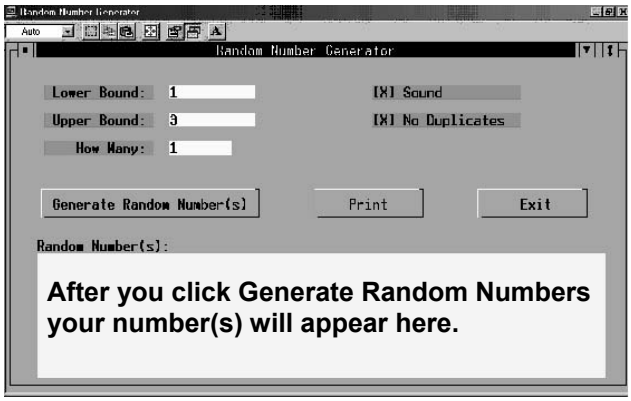
1-Monitoring
2-Verification
3-Recordkeeping

Here are some instructions on how to do this on your computer.

- Go to Start
- Select FSIS Applications
- Select Other Tools
- Select Random Number Generator
- In Lower Bound enter the lowest number in the group of numbers you are randomly selecting from.
- In Upper Bound enter the highest number in the group of numbers you are randomly selecting from.
- In How Many enter the number of random numbers you want to generate.
- Click on Generate Random Numbers.

Example: To select one out of the three regulatory requirements:

- Enter “1” in Lower Bound
- Enter “3” in Upper Bound
- Enter “1” in How Many
- Then click Generate Random Numbers.
- To select two of the three regulatory requirements, repeat the same instructions, but enter “2” in How Many.



Appendix 3

FSIS Directives and Notices

FSIS Directive 5000.1, Rev. 3, Verifying an Establishment's Food Safety System, 6/24/08

FSIS Directive 5000.2, Rev. 1, Review of Establishment Data by Inspection Program Personnel, 6/19/08

FSIS Directive 5400.5, Inspection System Activities, 11-21-97

FSIS Directive 7310.5 Presence of Foreign Material in Meat or Poultry Products, 5/30/03

FSIS Directive 7355.1, Rev. 2, Use of Sample Seals for Laboratory Samples and Other Applications, 12/3/02

FSIS Directive 8080.1, Rev 4, Recall of Meat and Poultry Products7/29/04

FSIS Directive 10,200.1, Accessing Laboratory Sample Information via LEARN, 7/19/01

FSIS Directive 10,210.1, Amend 6, Unified Sampling Form, 12/18/03

FSIS Directive 10,230.2, Amend , Procedures for Collecting and Submitting Domestic Samples for Microbiological Analyses, 9/4/92

FSIS Directive10,240.4, Rev.2 Verification Procedures for Consumer Safety Inspectors for the *Listeria monocytogenes (Lm)* Regulation and *Lm* Sampling Programs, 2/3/09

FSIS Directive10,600.1, Sample Shipment Procedures, 10/6/83

FSIS Notice 5-01, 1-24-01 District Manager Responsibilities in Assessing an Establishments Response to a "Notice of Intended Enforcement" (NOIE)

FSIS Notice 36-01, 9-5-01 Rules of Practice

FSIS Notice 37-01, 9-5-01 Making determinations about whether product is produced or shipped under part 417 HACCP Regulations

FSIS Notice 02-05, Availability of updates of the generic HACCP model for heat treated, shelf-stable meat and poultry products and the compliance guideline for meat and poultry jerky, 1/12/2005

FSIS Notice 16-05, Time and Temperature Tables for Cooking Ready-To-Eat Poultry Products, 3/2/05

FSIS Directives and Notices are available on FSIS website: http://www.fsis.usda.gov/

FSRE modules, upcoming course schedules, and other training information, are available on the FSIS Regional Training website:
http://www.fsis.usda.gov/FSIS_Employees/Regional_Training/index.asp

Other References

FDA Compliance Policy Guide, Statement of Policy for Labeling and Preventing Cross-contact of Common Food Allergens., and Allergen Inspection Guideline, FDA website. http://www.fda.gov/ora

American Meat Institute Foundation. 1997. Good Manufacturing Practices for Fermented Dry and Semi-Dry Sausage Products.

Blankenship, L.C. 1978, Survival of a *Salmonella Typhimuriam* experimental contaminant during cooking of beef roasts. Appl. Environ. Microblio. 35:1160.

Buchanan, R.L, *et. al*. 1994. Non-thermal Inactivation Models for *Listeria monocytogenes*. J. Food Sci. 59:179-88.

Centers for Disease Control and Prevention (CDC), Division of Bacterial and Mycotic Diseases, Disease Information, http://www.cdc.gov/health/default.htm

Code of Federal Regulations, online
http://www.gpoaccess.gov/cfr/index.html

FDA, Food Microbiological Control, 1998, available through FSIS, CEDL Lending Library

FSIS Food Standards and Labeling Policy Book

FSIS Guideline No. 6, A Glossary of Meat and Poultry Terms, April 1992

FSIS Microbiological Hazard Identification Guide for Meat and Poultry Components of Products Produced by Very Small Plants, August 26, 1999, FSIS website

FSIS, Policy Development Division, Frequently Asked Questions, FSIS website

FSIS Policy Development Division, IKE Scenarios, FSIS website

FSIS Small and Very Small Plant Outreach materials at
http://www.fsis.usda.gov/Science/small_very_small_plant_outreach/index.asp
(202) 690-0520

FSIS Website
http://www.fsis.usda.gov/

Goepfert, J. M., I. K. Iskander and C.H. Amundson. 1970. Relation of the heat resistance of salmonellae to the water activity of the environment. Appl. Microbiol. 19(3):429-33.

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Guidance on the Procedures for Joint Food Safety and Inspection Service (FSIS) and Food and Drug Administration (FDA) Approval of Ingredients and Sources of Radiation Used in the Production of Meat and Poultry Products, FSIS website

Guidebook for the Preparation of HACCP Plans and Generic HACCP Models, September 1999, FSIS website

Institute of Food Technologists, Evaluation and Definition of Potentially Hazardous Foods, A Report of the Institute of Food Technologists for the Food and Drug Administration of the U.S. Department of Health and Human Services, December 31, 2001, http://www.foodprotect.org/pdf/hazard_foods/front.pdf

Lopez, A. 1987. A complete course in canning and related processes. 3 vols. The Canning Trade, Inc., Baltimore. (canning reference)

National Research Council. National Academy of Sciences. 1985. An evaluation of the role of microbiological criteria for foods and food ingredients. National Academy Press, Washington, D.C.

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Pflug, I.J. 1987. Calculating FT-values for heat preservation of shelf-stable, low-acid canned foods using the straight-line semilogarithmic model. Journal of Food Protection 50:608-620.

Stevenson, K.E., & Bernard, D.T., 1999. *HACCP: A systematic approach to food safety, a comprehensive manual for developing and implementing a hazard analysis and critical control point plan*. The Food Processors Institute.

Stumbo, C.R. 1973. Thermobacteriology in food processing, 2d. ed. Academic Press, New York. (canning reference)

Townsend, C.T.; Esty, J.R.; Baselt, F. C. 1938. Heat-resistance studies on spores of putrefactive anaerobes in relation to determination of safe processes for canned foods. Food Research 3:323-346.

Supporting Documentation Materials for HACCP Decisions, Prepared for the Food Safety and Inspection Service, USDA, by Mary Kay Folk and Lynn Knipe, Ph. D., Department of Animal Sciences and Food Science and Technology, The Ohio State University, September 2002.
http://www.ag.ohio-state.edu/~meatsci/HACCPsupport.html

USDA, ARS Pathogen Modeling Program at http://www.arserrc.gov/mfs/pathogen.htm.

Appendix 4 Regulations

Canning Regulations

Please note these are the livestock regulations. The poultry regulations (381.300) are not included because they are identical.

Subpart G-Canning and Canned Products

Sec. 318.300 Definitions.

(a) Abnormal container. A container with any sign of swelling or product leakage or any evidence that the contents of the unopened container may be spoiled

. (b) Acidified low acid product. 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 unless data are available from the establishment's processing authority demonstrating that a longer time period is safe.

(c) Bleeders. Small orifices on a retort through which steam, other gasses, and condensate are emitted from the retort throughout the entire thermal process.

(d) Canned product. A meat 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. Unless otherwise specified, the term ``product'' as used in this subpart G shall mean ``canned product.''

(e) Closure technician. The individual(s) identified by the establishment as being trained to perform specific container integrity examinations as required by this subpart and designated by the establishment to perform such examinations.

(f) Code lot. All production of a particular product in a specific size container marked with a specific container code.

(g) Come-up time. The elapsed time, including venting time (if applicable), between the introduction of the heating medium into a closed retort and the start of process timing.

(h) Critical factor. Any characteristic, condition or aspect of a product, container, or procedure that affects the adequacy of the process schedule. Critical factors are established by processing authorities.

(i) Headspace. That portion of a container not occupied by the product.

(1) Gross headspace. The vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the top edge of the container (i.e., the flange of an unsealed can, the top of the double seam on a sealed can, or the top edge of an unsealed jar).

(2) Net headspace. The vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the inside surface of the lid.

(j) Hermetically sealed containers. Air-tight containers which are designed and intended to protect the contents against the entry of microorganisms during and after thermal processing.

(1) Rigid container. A container, the shape or contour of which, when filled and sealed, is neither affected by the enclosed product nor deformed by external mechanical pressure of up to 10 pounds per square inch gauge (0.7 kg/cm\2\) (i.e., normal firm finger pressure).

(2) Semirigid container. A container, the shape or contour of which, when filled and sealed, is not significantly affected by the enclosed product under normal atmospheric temperature and pressure, but can be deformed by external mechanical pressure of less than 10 pounds per square inch gauge (0.7 kg/cm\2\) (i.e., normal firm finger pressure).

(3) Flexible container. A container, the shape or contour of which, when filled and sealed, is significantly affected by the enclosed product.

(k) Incubation tests. Tests in which the thermally processed product is kept at a specific temperature for a specified period of time in order to determine if outgrowth of microorganisms occurs.

(l) Initial temperature. The temperature, determined at the initiation of a thermal process cycle, of the contents of the coldest container to be processed.

(m) Low acid product. A canned product in which any component has a pH value above 4.6.

(n) Process schedule. The thermal process and any specified critical factors for a given canned product required to achieve shelf stability.

(o) Process temperature. The minimum temperature(s) of the heating medium to be maintained as specified in the process schedule.

(p) Process time. The intended time(s) a container is to be exposed to the heating medium while the heating medium is at or above the process temperature(s).

(q) Processing authority. The person(s) or organization(s) having expert knowledge of thermal processing requirements for foods in hermetically sealed containers, having access to facilities for making such determinations, and designated by the establishment to perform certain functions as indicated in this subpart.

(r) Program employee. Any inspector or other individual employed by the Department or any cooperating agency who is authorized by the Secretary to do any work or perform any duty in connection with the Program (see Sec. 301.2(f)).

(s) Retort. A pressure vessel designed for thermal processing of product packed in hermetically sealed containers.

(t) Seals. Those parts of a semirigid container and lid or of a flexible container that are fused together in order to hermetically close the container.

(u) Shelf stability. 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. Shelf stability and shelf-stable are synonymous with commercial sterility and commercially sterile, respectively.

(v) Thermal process. The heat treatment necessary to achieve shelf stability as determined by the establishment's processing authority. It is quantified in terms of:

(1) Time(s) and temperature(s); or

(2) Minimum product temperature.

(w) Venting. The removal of air from a retort before the start of process timing.

(x) Water activity. The ratio of the water vapor pressure of the product to the vapor pressure of pure water at the same temperature.

Sec. 318.301 Containers and closures

(a) Examination and cleaning of empty containers. (1) Empty containers, closures, and flexible pouch roll stock shall be evaluated by the establishment to ensure that they are clean and free of structural defects and damage that may affect product or container integrity. Such an examination should be based upon a statistical sampling plan.

(2) All empty containers, closures, and flexible pouch roll stock shall be stored, handled, and conveyed in such a manner that will prevent soiling and damage that could affect the hermetic condition of the sealed container.

(3) Just before filling, rigid containers shall be cleaned to prevent incorporation of foreign matter into the finished product. Closures, semirigid containers, preformed

flexible pouches, and flexible pouch roll stock contained in original wrappings do not need to be cleaned before use.

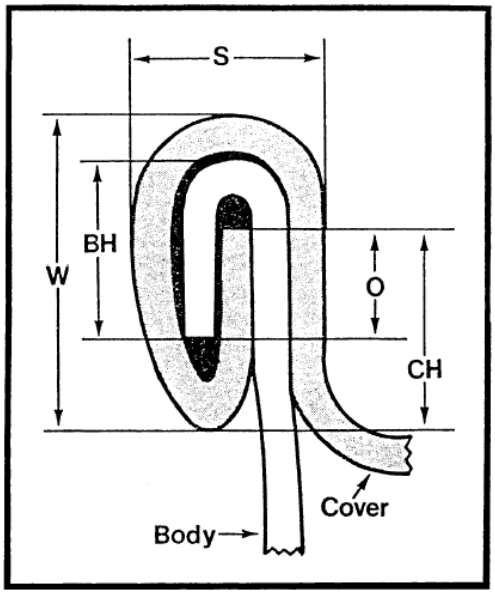
(b) Closure examinations for rigid containers (cans)--(1) Visual examinations. A closure technician shall visually examine the double seams formed by each closing machine head. When seam defects (e.g., cutovers, sharpness, knocked down flanges, false seams, droops) are observed, necessary corrective actions, such as adjusting or repairing the closing machine, shall be taken. In addition to the double seams, the entire container shall be examined for product leakage or obvious defects. A visual examination shall be performed on at least one container from each closing machine head, and the observations, along with any corrective actions, shall be recorded. Visual examinations shall be conducted with sufficient frequency to ensure proper closure and should be conducted at least every 30 minutes of continuous closing machine operation. Additional visual examinations shall be made by the closure technician at the beginning of production, immediately following every jam in the closing machine and after closing machine adjustment (including adjustment for changes in container size).

(2) Teardown examinations. Teardown examinations of double seams formed by each closing machine head shall be performed by a closure technician at a frequency sufficient to ensure proper closure. These examinations should be made at intervals of not more than 4 hours of continuous closing machine operation. At least one container from each closing head shall be examined on the packer's end during each regular examination period. Examination results along with any necessary corrective actions, such as adjusting or repairing the closing machine, shall be promptly recorded by the closure technician. The establishment shall have container specification guidelines for double seam integrity on file and available for review by Program employees. A teardown examination of the can maker's end shall be performed on at least one container selected from each closing machine during each examination period except when teardown examinations are made on incoming empty containers or when, in the case of self-manufactured containers, the containers are made in the vicinity of the establishment and the container plant records are made available to Program employees. Additional teardown examinations on the packer's end should be made at the beginning of production, immediately following every jam in a closing machine and after closing machine adjustment (including adjustment for a change in container size). The following procedures shall be used in teardown examinations of double seams: (i) One of the following two methods shall be employed for dimensional measurements of the double seam.

(a) Micrometer measurement. For cylindrical containers, measure the following dimensions (Figure 1) at three points approximately 120 degrees apart on the double seam excluding and at least one-half inch from the side seam juncture:

(1) Double seam length--W;
(2) Double seam thickness--S;
(3) Body hook length--BH; and
(4) Cover hook length--CH.

Maximum and minimum values for each dimensional measurement shall be recorded by the closure technician.



(b) Seamscope or seam projector. Required measurements of the seam include thickness, body hook, and overlap. Seam thickness shall be obtained by micrometer. For cylindrical containers, at least two locations, excluding the side seam juncture, shall be used to obtain the required measurements.

(ii) Seam tightness. Regardless of the dimensional measurement method used to measure seam dimensions, at a minimum, the seam(s) examined shall be stripped to assess the degree of wrinkling.

(iii) Side seam juncture rating. Regardless of the dimensional measurement method used to measure seam dimensions, the cover hook shall be stripped to examine the cover hook droop at the juncture for containers having side seams.

(iv) Examination of noncylindrical containers. Examination of noncylindricalcontainers (e.g., square, rectangular, ``D''-shaped, and irregularly-shaped) shall be conducted as described in paragraphs (b)(2) (i), (ii), and (iii) of this section except that the required dimensional measurements shall be made on the double seam at the points listed in the establishment's container specification guidelines.

(c) Closure examinations for glass containers--(1) Visual examinations. A closure technician shall visually assess the adequacy of the closures formed by each closing machine. When closure defects, such as loose or cocked caps, fractured or cracked containers and low vacuum jars, are observed, necessary corrective actions, such as adjusting or repairing the closing machine shall be taken and recorded. In addition to the closures, the entire container shall be examined for defects. Visual examinations shall be made with sufficient frequency to ensure proper closure and should be conducted at least every 30 minutes of continuous closing machine operation. Additional visual examinations shall be made by the closure technician and the observations recorded at
the beginning of production, immediately following every jam in the closing machine, and after closing machine adjustment (including adjustment for a change in container size).

(2) Closure examinations and tests. Depending upon the container and closure, tests shall be performed by a closure technician at a frequency sufficient to ensure proper closure. These examinations should be made either before or after thermal processing and at intervals of not more than 4 hours of continuous closing

machine operation. At least one container from each closing machine shall be examined during each regular examination period. Examination results along with any necessary corrective actions, such as adjusting or repairing the closing machine, shall be promptly recorded by the closure technician. The establishment shall have specification guidelines for closure integrity on file and available for review by Program employees. Additional closure examinations should be made at the beginning of production, immediately following every jam in the closing machine, and after closing machine adjustment (including adjustment for a change in container size).

(d) Closure examinations for semirigid and flexible containers--(1) Heat seals--(i) Visual examinations. A closure technician shall visually examine the seals formed by each sealing machine. When sealing defects are observed, necessary corrective actions, such as adjusting or repairing the sealing machine, shall be taken and recorded. In addition to examining the heat seals, the entire container shall be examined for product leakage or obvious defects. Visual examinations shall be performed before and after the thermal processing operation and with sufficient frequency to ensure proper closure. These examinations should be conducted at least in accordance with a statistical sampling plan. All defects noted and corrective actions taken shall be promptly recorded.

(ii) Physical tests. Tests determined by the establishment as necessary to assess container integrity shall be conducted by the closure technician at a frequency sufficient to ensure proper closure. These tests shall be performed after the thermal processing operation and should be made at least every 2 hours of continuous production. The establishment's acceptance guidelines for each test procedure shall be on file and available for review by Program employees. Test results along with any necessary corrective actions, such as adjusting or repairing the sealing machine, shall be recorded.

(2) Double seams on semirigid or flexible containers shall be examined and the results recorded as provided in paragraph (b) of this section. Any additional measurements specified by the container manufacturer shall also be made and recorded.

(e) Container coding. Each container shall be marked with a permanent, legible, identifying code mark. The mark shall, at a minimum, identify in code the product (unless the product name lithographed or printed elsewhere on the container) and the day and year the product was packed.

(f) Handling of containers after closure. (1) Containers and closures shall be protected from damage which may cause defects that are likely to affect the hermetic condition of the containers. The accumulation of stationary containers on moving conveyors should be minimized to avoid damage to the containers.

(2) The maximum time lapse between closing and initiation of thermal processing shall be 2 hours. However, the Administrator may specify a shorter period of time when considered necessary to ensure product safety and stability. A longer period of time between closing and the initiation of thermal processing may be permitted by the Administrator.

Sec. 318.302 Thermal processing.

(a) Process schedules. Prior to the processing of canned product for distribution in commerce, an establishment shall have a process schedule (as defined in Sec. 318.300(n) of this subpart) for each canned meat product to be packed by the establishment.

(b) Source of process schedules. (1) Process schedules used by an establishment shall be developed or determined by a processing authority.

(2) Any change in product formulation, ingredients, or treatments that are not already incorporated in a process schedule and that may adversely affect either the product heat penetration profile or sterilization value requirements shall be evaluated by the establishment's processing authority. If it is determined that any such change adversely affects the adequacy of the process schedule, the processing authority shall amend the process schedule accordingly.

(3) Complete records concerning all aspects of the development or determination of a process schedule, including any associated incubation tests, shall be made available by the establishment to the Program employee upon request.

(c) Submittal of process information. (1) Prior to the processing of canned product for distribution in commerce, the establishment shall provide the inspector at the establishment with a list of the process schedules (including alternate schedules) along with any additional applicable information, such as the retort come-up operating procedures and critical factors.

(2) Letters or other written communications from a processing authority recommending all process schedules shall be maintained on file by the establishment. Upon request by Program employees, the establishment shall make available such letters or written communications (or copies thereof). If critical factors are identified in the process schedule, the establishment shall provide the inspector with a copy of the procedures for measuring, controlling, and recording these factors, along with the frequency of such measurements, to ensure that the critical factors remain within the limits used to establish the process schedule. Once submitted, the process schedules and associated critical factors and the procedures for measuring (including the frequency), controlling, and recording of critical factors shall not be changed without the prior written submittal of the revised procedures (including supporting documentation) to the inspector at the establishment.

Sec. 318.303 Critical factors and the application of the process schedule.

Critical factors specified in the process schedule shall be measured, controlled and recorded by the establishment to ensure that these factors remain within the limits used to establish the process schedule. Examples of factors that are often critical to process schedule adequacy may include:

(a) General. (1) Maximum fill-in weight or drained weight;

(2) Arrangement of pieces in the container;

(3) Container orientation during thermal processing;

(4) Product formulation;

(5) Particle size;

(6) Maximum thickness for flexible, and to some extent semirigid containers during thermal processing;

(7) Maximum pH;

(8) Percent salt;

(9) Ingoing (or formulated) nitrite level (ppm);

(10) Maximum water activity; and

(11) Product consistency or viscosity.

(b) Continuous rotary and batch agitating retorts. (1) Minimum headspace; and

(2) Retort reel speed.

(c) Hydrostatic retorts. (1) Chain or conveyor speed.

(d) Steam/air retorts. (1) Steam/air ratio; and

(2) Heating medium flow rate.

Sec. 318.304 Operations in the thermal processing area.

(a) Posting of processes. Process schedules (or operating process schedules) for daily production, including minimum initial temperatures and operating procedures for thermal processing equipment, shall be posted in a conspicuous place near the thermal processing equipment. Alternatively, such information shall be available to the thermal processing system operator and the inspector.

(b) Process indicators and retort traffic control. A system for product traffic control shall be established to prevent product from bypassing the thermal processing operation. Each basket, crate or similar vehicle containing unprocessed product, or at least one visible container in each vehicle, shall be plainly and conspicuously marked with a heat sensitive indicator that will visually indicate whether such unit has been thermally processed. Exposed heat sensitive indicators attached to container vehicles shall be removed before such vehicles are refilled with unprocessed product. Container loading systems for crateless retorts shall be designed to prevent unprocessed product from bypassing the thermal processing operation.

(c) Initial temperature. The initial temperature of the contents of the coldest container to be processed shall be determined and recorded by the establishment at the time the processing cycle begins to assure that the temperature of the contents of every container to be processed is not lower than the minimum initial temperature specified in the process schedule. Thermal processing systems which subject the filled and sealed containers to water at any time before process timing begins shall be operated to assure that such water will not lower the temperature of the product below the minimum initial temperature specified in the process schedule.

(d) Timing devices. Devices used to time applicable thermal processing operation functions or events, such as process schedule time, come-up time and retort venting, shall be accurate to assure that all such functions or events are achieved. Pocket watches and wrist watches are not considered acceptable timing devices. Analog and digital clocks are considered acceptable. If such clocks do not display seconds, all required timed functions or events shall have at least a 1-minute safety factor over the specified thermal processing operation times. Temperature/time recording devices shall correspond within 15 minutes to the time of the day recorded on written records required by Sec. 318.306.

(e) Measurement of pH. Unless other methods are approved by the Administrator, potentiometric methods using electronic instruments (pH meters) shall be used for making pH determinations when a maximum pH value is specified as a critical factor in a process schedule.

Sec. 318.305 Equipment and procedures for heat processing systems.

(a) Instruments and controls common to different thermal processing systems--(1) Indicating temperature devices. Each retort shall be equipped with at least one indicating temperature device that measures the actual temperature within the retort. The indicating temperature device, not the temperature/time recording device, shall be used as the reference instrument for indicating the process temperature.

(i) Mercury-in-glass thermometers. A mercury-in-glass thermometer shall have divisions that are readable to 1F °(or 0.5C°) and whose scale contains not more than 17F°/inch (or 4.0C°/cm) of graduated scale. Each mercury-in-glass thermometer shall be tested for accuracy against a known accurate standard upon installation and at least once a year to ensure its accuracy. Records that specify the date, standard used, test method, and the person or testing authority performing the test shall bymaintained on file by the establishment and made available to Program employees. A mercury-in-glass thermometer that has a divided mercury column or that cannot be adjusted to the standard shall be repaired and tested for accuracy before further use, or replaced.

(ii) Other devices. Temperature-indicating devices, such as resistance temperature detectors, used in lieu of mercury-in-glass thermometers, shall meet known, accurate standards for such devices when tested for accuracy. The records of such testing shall be available to FSIS program employees.

(2) Temperature/time recording devices. Each thermal processing system shall be equipped with at least one temperature/time recording device to provide a permanent record of temperatures within the thermal processing system. This recording device may be combined with the steam controller and may be a recording/controlling instrument. When compared to the known accurate indicating temperature device, the recording accuracy shall be equal to or better than 1F °(or 0.5C°) at the process temperature. The temperature recording chart should be adjusted to agree with, but shall never be higher than, the known accurate indicating temperature device. A means of preventing unauthorized changes in the adjustment shall be provided. For example, a lock or a notice from management posted at or near the recording device warning that only authorized persons are permitted to make adjustments, are satisfactory means for preventing unauthorized changes. Air-operated temperature controllers shall have adequate filter systems to ensure a supply of clean, dry air. The recorder timing mechanism shall be accurate.

(i) Chart-type devices. Devices using charts shall be used only with the correct chart. Each chart shall have a working scale of not more than 55F°/inch (or 12C°/cm) within a range of 20F °(or 11C°) of the process temperature. Chart graduations shall not exceed 2F degrees (or 1C degree) within a range of 10F degrees (or 5C degrees) of the process temperature. Multipoint plotting chart-type devices shall print temperature readings at intervals that will assure that the parameters of the process time and process temperature have been met. The frequency of recording should not exceed 1-minute intervals. (ii) Other devices. Temperature/time recording devices or procedures used in lieu of chart-type devices must meet known accurate standards for such devices or procedures when tested for accuracy. Such a device must be accurate enough for ensuring that process time and temperature parameters have been met.

(3) Steam controllers. Each retort shall be equipped with an automatic steam controller to maintain the retort temperature. This may be a recording/controlling instrument when combined with a temperature/time recording device.

(4) Air valves. All air lines connected to retorts designed for pressure processing in steam shall be equipped with a globe valve or other equivalent-type valve or piping arrangement that will prevent leakage of air into the retort during the process cycle.

(5) Water valves. All retort water lines that are intended to be closed during a process cycle shall be equipped with a globe valve or other equivalent-type valve or piping arrangement that will prevent leakage of water into the retort during the process cycle.

(b) Pressure processing in steam--(1) Batch still retorts. (i) The basic requirements and recommendations for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section. Additionally, bulb sheaths or probes of indicating temperature devices and probes of temperature/time recording devices shall be installed either within the retort shell or in external wells attached to the retort. External wells shall be connected to the retort through at least a \3/4\ inch (1.9 cm) diameter opening and equipped with a \1/16\ inch (1.6 mm) or larger bleeder opening so located as to provide a constant flow of steam past the length of the bulb or probe. The bleeder for external wells shall emit steam continuously during the entire thermal processing period. (ii) Steam controllers are required as described under paragraph (a)(3) of this section.

(iii) Steam inlet. The steam inlet to each retort shall be large enough to provide steam for proper operation of the retort, and shall enter at a point to facilitate air removal during venting.

(iv) Crate supports. Vertical still retorts with bottom steam entry shall employ bottom retort crate supports. Baffle plates shall not be used in the bottom of retorts.

(v) Steam spreader. Perforated steam spreaders, if used, shall be maintained to ensure they are not blocked or otherwise inoperative. Horizontal still retorts shall be equipped with perforated steam spreaders that extend the full length of the retort unless the adequacy of another arrangement is documented by heat distribution data or other documentation from a processing authority. Such information shall be maintained on file by the establishment and made available to Program employees for review.

(vi) Bleeders and condensate removal. Bleeders, except those for external wells of temperature devices, shall have \1/8\ inch (or 3 mm) or larger openings and shall be wide open during the entire process, including the come-up time. For horizontal still retorts, bleeders shall be located within approximately 1 foot (or 30 cm) of the outermost locations of containers at each end along the top of the retort. Additional bleeders shall be located not more than 8 feet (2.4 m) apart along the top. Bleeders may be installed at positions other than those specified above, as long as the establishment has heat distribution data or other documentation from the manufacturer or from a processing authority demonstrating that the bleeders accomplish removal of air and circulate the steam within the retort. This information shall be maintained on file by the establishment and made available to Program employees for review. All bleeders shall be arranged in a way that enables the retort operator to observe that they are functioning properly. Vertical retorts shall have at least one bleeder opening located in the portion of the retort opposite the steam inlet. All bleeders shall be arranged so that the retort operator can observe that they are functioning properly. In retorts having a steam inlet above the level of the lowest container, a bleeder shall be installed in the bottom of the retort to remove condensate. The condensate bleeder shall be so arranged that the retort operator can observe that it is functioning properly. The condensate bleeder shall be checked with sufficient frequency to ensure adequate removal of condensate. Visual checks should be performed at intervals of not more than 15 minutes and the results recorded. Intermittent condensate removal systems shall be equipped with an automatic alarm system that will serve as a continuous monitor of condensate bleeder functioning. The automatic alarm system shall be tested at the beginning of each shift for proper functioning and the results recorded. If the alarm system is not functioning properly, it must be repaired before the retort is used.

(vii) Stacking equipment--(a) Equipment for holding or stacking containers in retorts. Crates, trays, gondolas, carts, and other vehicles for holding or stacking product containers in the retort shall be so constructed to ensure steam circulation during the venting, come-up, and process times. The bottom of each vehicle shall have perforations at least 1 inch (2.5 cm) in diameter on 2 inch (or 5 cm) centers or the equivalent unless the adequacy of another arrangement is documented by heat distribution data or other documentation from a processing authority and such information is maintained on file by the establishment and made available to Program employees for review.

(b) Divider plates. Whenever one or more divider plates are used between any two layers of containers or placed on the bottom of a retort vehicle, the establishment shall have on file documentation that the venting procedure allows the air to be removed from the retort before timing of the thermal process is started. Such documentation shall be in the form of heat distribution data or documentation from a processing authority. This information shall be made available to Program employees for review.

(viii) Bleeder and vent mufflers. If mufflers are used on bleeders or vent systems, the establishment shall have on file documentation that the mufflersdo not impede the removal of air from the retort. Such documentation shall consist of either heat distribution data or documentation from the muffler manufacturer or from a processing authority. This information shall be made available to Program employees for review.

(ix) Vents--(a) Vents shall be located in that portion of the retort opposite the steam inlet and shall be designed, installed, and operated in such a way that air is removed from the retort before timing of the thermal process is started. Vents shall be controlled by a gate, plug cock, or other full-flow valve which shall be fully opened to permit rapid removal of air from retorts during the venting period.

(b) Vents shall not be connected to a closed drain system without an atmospheric break in the line. Where a retort manifold connects several pipes from a single retort, the manifold shall be controlled by a gate, plug cock, or other full-flow valve and the manifold shall be of a size such that the cross-sectional area of the manifold is larger than the total cross-sectional area of all connecting vents. The discharge shall not be connected to a closed drain without an atmospheric break in the line. A manifold header connecting vents or manifolds from several still retorts shall lead to the atmosphere. The manifold header shall not be controlled by a valve and shall be of a size such that the cross-sectional area is at least equal to the total cross-sectional area of all connecting retort manifold pipes from the maximum number of retorts to be vented simultaneously.

(c) Some typical installations and operating procedures are described below. Other retort installations, vent piping arrangements, operating procedures or auxiliary equipment such as divider plates may be used provided there is documentation that the air is removed from the retort before the process is started. Such documentation shall be in the form of heat distribution data or other documentation from the equipment manufacturer or processing authority. This information shall be maintained on file by the establishment and made available to Program employees for review.

(d) For crateless retort installations, the establishment shall have heat distribution data or other documentation from the equipment manufacturer or from a processing authority that demonstrates that the venting procedure used accomplishes the removal of air and condensate. This information shall be maintained on file by the establishment and made available to Program employees for review.

(e) Examples of typical installations and operating procedures that comply with the requirements of this section are as follows:

(1) Venting horizontal retorts.

(i) Venting through multiple 1 inch (2.5 cm) vents discharging directly to the atmosphere.

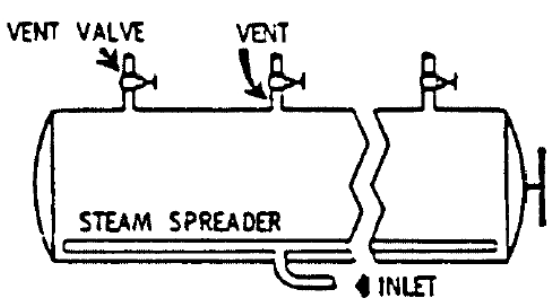


Figure 1.

Specifications (Figure 1): One, 1-inch (2.5 cm) vent for every 5 feet (1.5 m) of retort length, equipped with a gate, plug cock, or other full-flow valve and discharging to

atmosphere. The end vents shall not be more than 2\1/2\ feet (or 75 cm) from ends of retort. Venting method (Figure 1): Vent valves shall be wide open for at least 5 minutes and to at least 225 °F (or 107 °C), or at least 7 minutes and to at least 220 °F (or 104.5 °C).

(ii) Venting through multiple 1 inch (2.5 cm) vents discharging through a manifold to the atmosphere.

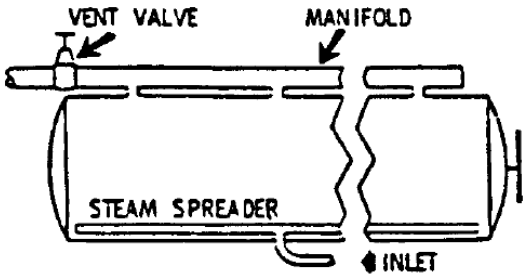


Figure 2.

Specifications (Figure 2): One, 1-inch (2.5 cm) vent for every 5 feet (1.5 m) of retort length; vents not over 2\1/2\ feet (or 75 cm) from ends of retort; size of manifold for retorts less than 15 feet (4.6 m) in length, 2\1/2\ inches (6.4 cm), and for retorts 15 feet (4.6 m) and over in length, 3 inches (7.6 cm). Venting method (Figure 2): The manifold vent gate, plug cock, or other full-flow valve shall be wide open for at least 6 minutes and to at least 225 °F (or 107 °C) or for at least 8 minutes and to at least 220 °F (or 104.5 °C).

(iii) Venting through water spreaders.

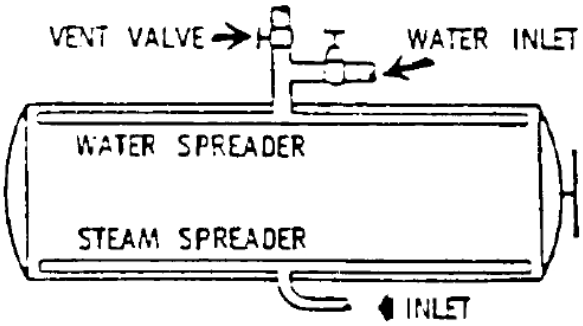


Figure 3.

Specifications (Figure 3): Size of vent and vent valve. For retorts less than 15 feet (4.6 m) in length, 2 inches (or 5 cm); for retorts 15 feet (4.6 m) and over in length, 2\1/2\ inches (6.4 cm).

Size of water spreader (Figure 3): For retorts less than 15 feet (4.6 m) in length, 1\1/2\ inches (3.8 cm); for retorts 15 feet (4.6 m) and over in length, 2 inches (or 5 cm). The number of holes shall be such that their total cross-sectional area is equal to the cross-sectional area of the vent pipe inlet.

Venting method (Figure 3): The gate, plug cock, or other full-flow valve on the water spreader vent shall be wide open for at least 5 minutes and to at least 225 °F (or 107 °C), or for at least 7 minutes and to at least 220 °F (or 104.5 °C).

(iv) Venting through a single 2\1/2\ inch (6.4 cm) top vent for retorts not exceeding 15 feet (4.6 m) in length.

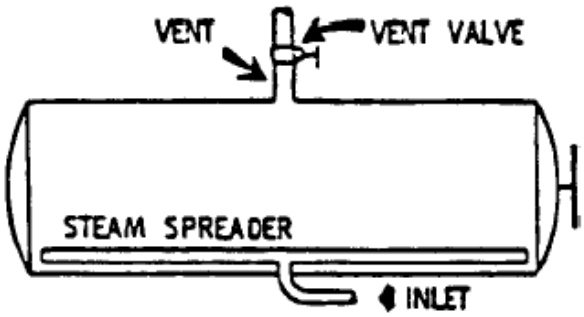


Figure 4.

Specifications (Figure 4): A 2\1/2\ inch (6.4 cm) vent equipped with a 2\1/2\ inch (6.4 cm) gate, plug cock, or other full-flow valve and located within 2 feet (61 cm) of the center of the retort.

Venting method (Figure 4): The vent valve shall be wide open for at least 4 minutes and to at least 220 °F (or 104.5 °C).

(2) Venting vertical retorts.

(i) Venting through a 1\1/2\ inch (3.8 cm) overflow.

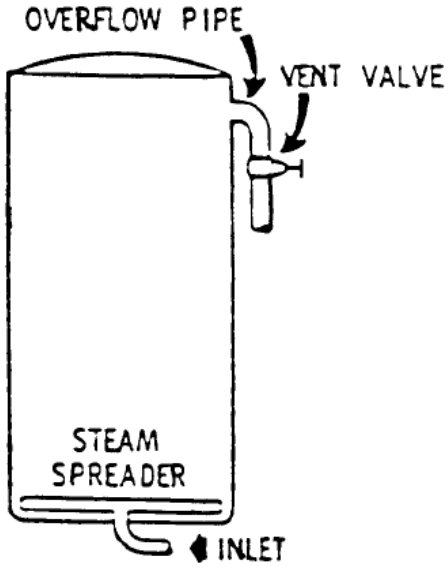


Figure 5.

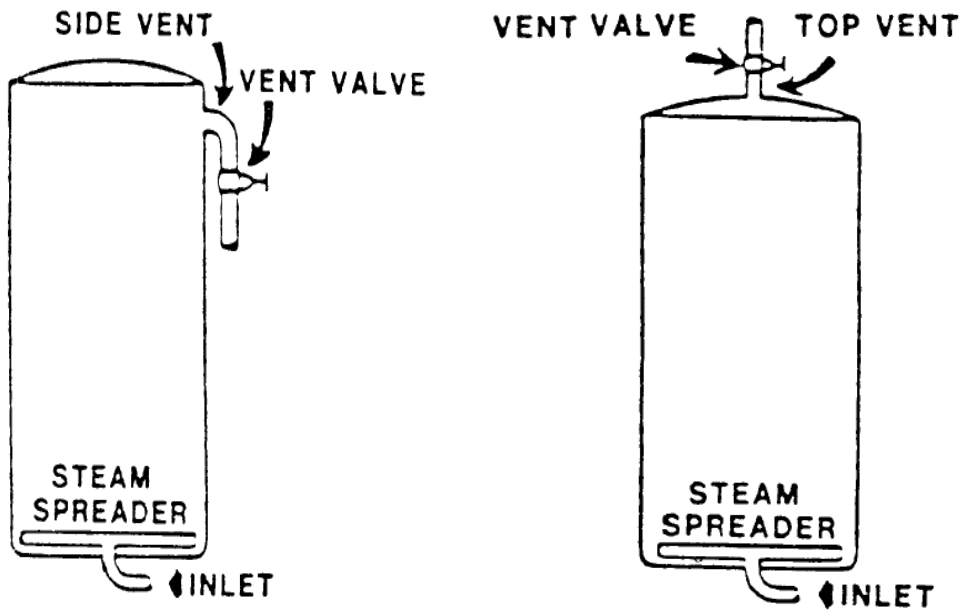
Figure 5

Specifications (Figure 5): A 1\1/2\ inch (3.8 cm) overflow pipe equipped with a 1\1/2\ inch (3.8 cm) gate, plug cock, or other full-flow valve and with not more than 6 feet (1.8

m) of 1\1/2\ inch (3.8 cm) pipe beyond the valve before a break to the atmosphere or to a manifold header.

Venting method (Figure 5): The vent valve shall be wide open for at least 4 minutes and to at least 218 °F (or 103.5 °C), or for at least 5 minutes and to at least 215 °F (or 101.5 °C).

(ii) Venting through a single 1 inch (2.5 cm) side or top vent.



Specifications (Figure 6 or 7): A 1 inch (2.5 cm) vent in lid or top side, equipped with a gate, plug cock, or other full-flow valve and discharging directly into the atmosphere or to a manifold header.

Venting method (Figure 6 or 7): The vent valve shall be wide open for at least 5 minutes and to at least 230 °F (110 °C), or for at least 7 minutes and to at least 220 °F (or 104.5 °C).

(2) Batch agitating retorts. (i) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section. Additionally, bulb sheaths or probes of indicating temperature devices and probes of temperature/time recording devices shall be installed either within the retort shell or in external wells attached to the retort. External wells shall be connected to the retort through at least a \3/4\ inch (1.9 cm) diameter opening and equipped with a \1/16\ (1.6 mm) or larger bleeder opening so located as to provide a constant flow of steam past the length of the bulbs or probes. The bleeder for external wells shall emit steam continuously during the entire thermal processing period.

(ii) Steam controllers are required as described in paragraph (a)(3) of this section.

(iii) Steam inlet. The steam inlet to each retort shall be large enough to provide steam for proper operation of the retort and shall enter at a point(s) to facilitate air removal during venting.

(iv) Bleeders. Bleeders, except those for external wells of temperature devices, shall be \1/8\ inch (or 3 mm) or larger and shall be wide open during the entire process including the come-up time. Bleeders shall be located within approximately 1 foot (or 30

cm) of the outermost location of containers, at each end along the top of the retort. Additional bleeders shall be located not more than 8 feet (2.4 m) apart along the top. Bleeders may be installed at positions other than those specified above, as long as the establishment has heat distribution data or other documentation from the manufacturer or from a processing authority that the bleeders accomplish removal of air and circulate the steam within the retort. This information shall be maintained on file by the establishment and made available to Program employees for review. All bleeders shall be arranged in a way that enables the retort operator to observe that they are functioning properly.

(v) Venting and condensate removal. The air in the retort shall be removed before processing is started. Heat distribution data or other documentation from the manufacturer or from the processing authority who developed the venting procedure shall be kept on file by the establishment and made available to Program employees for review. At the time the steam is turned on, the drain shall be opened to remove steam condensate from the retort. A bleeder shall be installed in the bottom of the retort to remove condensate during retort operation. The condensate bleeder shall be so arranged that the retort operator can observe that it is functioning properly. The condensate bleeder shall be checked with sufficient frequency to ensure adequate removal of condensate. Visual checks should be performed at intervals of not more than 15 minutes and the results recorded. Intermittent condensate removal systems shall be equipped with an automatic alarm system that will serve as a continuous monitor of condensate bleeder functioning. The automatic alarm system shall be tested at the beginning of each shift for proper functioning and the results recorded. If the alarm system is not functioning properly, it must be repaired before the retort is used.

(vi) Retort or reel speed timing. The retort or reel speed shall be checked before process timing begins and, if needed, adjusted as specified in the process schedule. In addition, the rotational speed shall be determined and recorded at least once during process timing of each retort load processed. Alternatively, a recording tachometer can be used to provide a continuous record of the speed. The accuracy of the recording tachometer shall be determined and recorded at least once per shift by checking the retort or reel speed using an accurate stopwatch. A means of preventing unauthorized speed changes on retorts shall be provided. For example, a lock or a notice from management posted at or near the speed adjustment device warning that only authorized persons are permitted to make adjustments are satisfactory means of preventing unauthorized changes.

(vii) Bleeder and vent mufflers. If mufflers are used on bleeders or vent systems, the establishment shall have documentation that the mufflers do not impede the removal of air from the retort. Such documentation shall consist of either heat distribution data or documentation from the muffler manufacturer or from a processing authority. This information shall be maintained on file by the establishment and made available to Program employees for review. (3) Continuous rotary retorts. (i) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section. Additionally, bulb sheaths or probes of indicating temperature devices and probes of temperature/time recording devices shall be installed either within the retort shell or in external wells attached to the retort. External wells shall be connected to the retort through at least a \3/4\ inch (1.9 cm) diameter opening and equipped with a \1/16\ inch (1.6 mm) or larger bleeder opening so located as to provide a constant flow of steam past the length of the bulbs or probes. The bleeder for external wells shall emit steam continuously during the entire thermal processing period.

(ii) Steam controllers are required as described in paragraph (a)(3) of this section.

(iii) Steam inlet. The steam inlet to each retort shall be large enough to provide steam for proper operation of the retort, and shall enter at a point(s) to facilitate air removal during venting.

(iv) Bleeders. Bleeders, except those for external wells of temperature devices, shall be \1/8\ inch (3.2 mm) or larger and shall be wide open during the entire process, including the come-up time. Bleeders shall be located within approximately 1 foot (or 30 cm) of the outermost location of containers at each end along the top of the retort. Additional bleeders shall be located not more than 8 feet (2.4 m) apart along the top of the retort. Bleeders may be installed at positions other than those specified above, as long as the establishment has heat distribution data or other documentation from the manufacturer or a processing authority that the bleeders accomplish removal of air and circulate the steam within the retort. This information shall be maintained on file by the establishment and made available to Program employees for review. All bleeders shall be arranged so that the retort operator can observe that they are functioning properly.

(v) Venting and condensate removal. The air in the retort shall be removed before processing is started. Heat distribution data or other documentation from the manufacturer or from the processing authority who deve!oped the venting procedure shall be kept on file by the establishment and made available to Program employees for review. At the time the steam is turned on, the drain shall be opened to remove steam condensate from the retort. A bleeder shall be installed in the bottom of the shell to remove condensate during the retort operation. The condensate bleeder shall be so arranged that the retort operator can observe that it is functioning properly. The condensate bleeder shall be checked with sufficient frequency to ensure adequate removal of condensate. Visual checks should be performed at intervals of not more than 15 minutes and the results recorded. Intermittent condensate removal systems shall be equipped with an automatic alarm system that will serve as a continuous monitor of condensate bleeder functioning. The automatic alarm system shall be tested at the beginning of each shift for proper functioning and the results recorded. If the alarm system is not functioning properly, it must be repaired before the retort is used.

(vi) Retort speed timing. The rotational speed of the retort shall be specified in the process schedule. The speed shall be adjusted as specified, and recorded by the establishment when the retort is started, and checked and recorded at intervals not to exceed 4 hours to ensure that the correct retort speed is maintained. Alternatively, a recording tachometer may be used to provide a continuous record of the speed. If a recording tachometer is used, the speed shall be manually checked against an accurate stopwatch at least once per shift and the results recorded. A means of preventing unauthorized speed changes on retorts shall be provided. For example, a lock or a notice from management posted at or near the speed adjustment device warning that only authorized persons are permitted to make adjustments are satisfactory means of preventing unauthorized changes.

(vii) Bleeders and vent mufflers. If mufflers are used on bleeders or vent systems, the establishment shall have documentation that the mufflers do not impede the removal of air from the retort. Such documentation shall consist of either heat distribution data or other documentation from the muffler manufacturer or from a processing authority. This information shall be maintained on file by the establishment and made available to Program employees for review.

(4) Hydrostatic retorts. (i) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section. Additionally, indicating temperature devices shall be located in the steam dome near the steam/water interface. Where the process schedule specifies maintenance of particular water temperatures in the hydrostatic water legs, at least one

indicating temperature device shall be located in each hydrostatic water leg so that it can accurately measure water temperature and be easily read. The temperature/time recorder probe shall be installed either within the steam dome or in a well attached to the dome. Each probe shall have a \1/16\ inch (1.6 mm) or larger bleeder opening which emits steam continuously during the processing period. Additional temperature/time recorder probes shall be installed in the hydrostatic water legs if the process schedule specifies maintenance of particular temperatures in these water legs.

(ii) Steam controllers are required as described in paragraph (a)(3) of this section.

(iii) Steam inlet. The steam inlets shall be large enough to provide steam for proper operation of the retort.

(iv) Bleeders. Bleeder openings \1/4\ inch (or 6 mm) or larger shall be located in the steam chamber(s) opposite the point of steam entry. Bleeders shall be wide open and shall emit steam continuously during the entire process, including the come-up time. All bleeders shall be arranged in such a way that the operator can observe that they are functioning properly.

(v) Venting. Before the start of processing operations, the retort steam chamber(s) shall be vented to ensure removal of air. Heat distribution data or other documentation from the manufacturer or from a processing authority demonstrating that the air is removed from the retort prior to processing shall be kept on file at the establishment and made available to Program employees for review.

(vi) Conveyor speed. The conveyor speed shall be calculated to obtain the required process time and recorded by the establishment when the retort is started. The speed shall be checked and recorded at intervals not to exceed 4 hours to ensure that the correct conveyor speed is maintained. A recording device may be used to provide a continuous record of the conveyor speed. When a recording device is used, the speed shall be manually checked against an accurate stopwatch at least once per shift by the establishment. A means of preventing unauthorized speed changes of the conveyor shall be provided. For example, a lock or a notice from management posted at or near the speed adjustment device warning that only authorized persons are permitted to make adjustments are satisfactory means of preventing unauthorized changes.

(vii) Bleeders and vent mufflers. If mufflers are used on bleeders or vent systems, the establishment shall have documentation that the muffler do not impede the removal of air from the retort. Such documentation shall consist of either heat distribution data or other documentation from the muffler manufacturer or from a processing authority. This information shall be maintained on file by the establishment and made available to Program employees for review.

(c) Pressure processing in water--(1) Batch still retorts. (i) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a)(1) and (2) of this section. Additionally, bulbs or probes of indicating temperature devices shall be located in such a position that they are beneath the surface of the water throughout the process. On horizontal retorts, the indicating temperature device bulb or probe shall be inserted directly into the retort shell. In both vertical and horizontal retorts, the indicating temperature device bulb or probe shall extend directly into the water a minimum of 2 inches (or 5 cm) without a separable well or sleeve. In vertical retorts equipped with a recorder/controller, the controller probe shall be located at the bottom of the retort below the lowest crate rest in such a position that the steam does not strike it directly. In horizontal retorts so equipped, the controller probe shall be located between the water surface and the horizontal plane passing through the center of the retort so that there is no opportunity for direct steam impingement on the controller probe. Air-operated temperature controllers shall have filter systems to ensure a supply of clean, dry air.

(ii) Pressure recording device. Each retort shall be equipped with a pressure recording device which may be combined with a pressure controller.

(iii) Steam controllers are required as described in paragraph (a)(3) of this section.

(iv) Heat distribution. Heat distribution data or other documentation from the equipment manufacturer or a processing authority demonstrating uniform heat distribution within the retort shall be kept on file at the establishment and made available to Program employees for review.

(v) Crate supports. A bottom crate support shall be used in vertical retorts. Baffle plates shall not be used in the bottom of the retort.

(vi) Stacking equipment. For filled flexible containers and, where applicable, semirigid containers, stacking equipment shall be designed to ensure that the thickness of the filled containers does not exceed that specified in the process schedule and that the containers do not become displaced andoverlap or rest on one another during the thermal process.

(vii) Drain valve. A nonclogging, water-tight drain valve shall be used. Screens shall be installed over all drain openings.

(viii) Water level. There shall be a means of determining the water level in the retort during operation (i.e., by using a gauge, electronic sensor, or sight glass indicator). For retorts requiring complete immersion of containers, water shall cover the top layer of containers during the entire come-up time and thermal processing periods and should cover the top layer of containers during cooling. For retorts using cascading water or water sprays, the water level shall be maintained within the range specified by the retort manufacturer or processing authority during the entire come-up, thermal processing, and cooling periods. A means to ensure that water circulation continues as specified throughout the come-up, thermal processing, and cooling periods shall be provided. The retort operator shall check and record the water level at intervals to ensure it meets the specified processing parameters.

(ix) Air supply and controls. In both horizontal and vertical still retorts, a means shall be provided for introducing compressed air or steam at the pressure required to maintain container integrity. Compressed air and steam entry shall be controlled by an automatic pressure control unit. A nonreturn valve shall be provided in the air supply line to prevent water from entering the system. Overriding air or steam pressure shall be maintained continuously during the come-up, thermal processing, and cooling periods. If air is used to promote circulation, it shall be introduced into the steam line at a point between the retort and the steam control valve at the bottom of the retort. The adequacy of the air circulation for maintaining uniform heat distribution within the retort shall be documented by heat distribution data or other documentation from a processing authority, and such data shall be maintained on file by the establishment and made available to Program employees for review.

(x) Water recirculation. When a water recirculation system is used for heat distribution, the water shall be drawn from the bottom of the retort through a suction manifold and discharged through a spreader that extends the length or circumference of the top of the retort. The holes in the water spreader shall be uniformly distributed. The suction outlets shall be protected with screens to keep debris from entering the recirculation system. The pump shall be equipped with a pilot light or a similar device to warn the operator when it is not running, and with a bleeder to remove air when starting operations. Alternatively, a flow-meter alarm system can be used to ensure proper water circulation. The adequacy of water circulation for maintaining uniform heat distribution within the retort shall be documented by heat distribution or other documentation from a processing authority and such data shall be maintained on file by the establishment and made available to Program employees for review. Alternative methods for recirculation

of water in the retort may be used, provided there is documentation in the form of heat distribution data or other documentation from a processing authority maintained on file by the establishment and made available to Program employees for review.

(xi) Cooling water entry. In retorts for processing product packed in glass jars, the incoming cooling water should not directly strike the jars, in order to minimize glass breakage by thermal shock.

(2) Batch agitating retorts. (i) The basic requirements and recommendations for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section. Additionally, the indicating temperature device bulb or probe shall extend directly into the water without a separable well or sleeve. The recorder/controller probe shall be located between the water surface and the horizontal plane passing through the center of the retort so that there is no opportunity for steam to directly strike the controller bulb or probe.

(ii) Pressure recording device. Each retort shall be equipped with a pressurerecording device which may be combined with a pressure controller.

(iii) Steam controllers are required as described in paragraph (a)(3) of this section.

(iv) Heat distribution. Heat distribution data or other documentation from the equipment manufacturer or a processing authority shall be kept on file by the establishment and made available to Program employees for review.

(v) Stacking equipment. All devices used for holding product containers (e.g., crates, trays, divider plates) shall be so constructed to allow the water to circulate around the containers during the come-up and thermal process periods.

(vi) Drain valve. A nonclogging, water-tight drain valve shall be used. Screens shall be installed over all drain openings.

(vii) Water level. There shall be a means of determining the water level in the retort during operation (i.e., by using a gauge, electronic sensor, or sight glass indicator). Water shall completely cover all containers during the entire come-up, thermal processing, and cooling periods. A means to ensure that water circulation continues as specified throughout the come-up, thermal processing, and cooling periods shall be provided. The retort operator shall check and record the adequacy of the water level with sufficient frequency to ensure it meets the specified processing parameters.

(viii) Air supply and controls. Retorts shall be provided with a means for introducing compressed air or steam at the pressure required to maintain container integrity. Compressed air and steam entry shall be controlled by an automatic pressure control unit. A nonreturn valve shall be provided in the air supply line to prevent water from entering the system. Overriding air or steam pressure shall be maintained continuously during the come-up, thermal processing, and cooling periods. If air is used to promote circulation, it shall be introduced into the steam line at a point between the retort and the steam control valve at the bottom of the retort. The adequacy of the air circulation for maintaining uniform heat distribution within the retort shall be documented by heat distribution data or other documentation from a processing authority, and such data shall be maintained on file by the establishment and made available to Program employees for review.

(ix) Retort or reel speed timing. The retort or reel speed timing shall be checked before process timing begins and, if needed, adjusted as specified in the process schedule. In addition, the rotational speed shall be determined and recorded at least once during process timing of each retort load processed. Alternatively, a recording tachometer can be used to provide a continuous record of the speed. The accuracy of the recording tachometer shall be determined and recorded at least once per shift by the establishment by checking the retort or reel speed using an accurate stopwatch. A means of preventing unauthorized speed changes on retorts shall be provided. For

example, a lock or a notice from management posted at or near the speed adjustment device warning that only authorized persons are permitted to make adjustments are satisfactory means of preventing unauthorized changes.

(x) Water recirculation. If a water recirculation system is used for heat distribution, it shall be installed in such a manner that water will be drawn from the bottom of the retort through a suction manifold and discharged through a spreader which extends the length of the top of the retort. The holes in the water spreader shall be uniformly distributed. The suction outlets shall be protected with screens to keep debris from entering the recirculation system. The pump shall be equipped with a pilot light or a similar device to warn the operator when it is not running and with a bleeder to remove air when starting operations. Alternatively, a flow-meter alarm system can be used to ensure proper water circulation. The adequacy of water circulation for maintaining uniform heat distribution within the retort shall be documented by heat distribution data or other documentation from a processing authority, and such data shall be maintained on file by the establishment and made available to Program employees for review. Alternative methods for recirculation of water in the retort may be used provided there is documentationin the form of heat distribution data or other documentation from a processing authority maintained on file by the establishment and made available to Program employees for review.

(xi) Cooling water entry. In retorts for processing product packed in glass jars, the incoming cooling water should not directly strike the jars, in order to minimize glass breakage by thermal shock.

(d) Pressure processing with steam/air mixtures in batch retorts.

(1) The basic requirements for indicating temperature devices and temperature/time recording devices are described in paragraphs (a) (1) and (2) of this section. Additionally, bulb sheaths or probes for indicating temperature devices and temperature/time recording devices or controller probes shall be inserted directly into the retort shell in such a position that steam does not strike them directly.

(2) Steam controllers are required as described in paragraph (a)(3) of this section.

(3) Recording pressure controller. A recording pressure controller shall be used to control the air inlet and the steam/air mixture outlet.

(4) Circulation of steam/air mixtures. A means shall be provided for the circulation of the steam/air mixture to prevent formation of low-temperature pockets. The efficiency of the circulation system shall be documented by heat distribution data or other documentation from a processing authority, and such data shall be maintained on file by the establishment and made available to Program employees for review. The circulation system shall be checked to ensure its proper functioning and shall be equipped with a pilot light or a similar device to warn the operator when it is not functioning. Because of the variety of existing designs, reference shall be made to the equipment manufacturer for details of installation, operation, and control.

(e) Atmospheric cookers--(1) Temperature/time recording device. Each atmospheric cooker (e.g., hot water bath) shall be equipped with at least one temperature/time recording device in accordance with the basic requirements described in paragraph (a)(2) of this section.

(2) Heat distribution. Each atmospheric cooker shall be equipped and operated to ensure uniform heat distribution throughout the processing system during the thermal process. Heat distribution data or other documentation from the manufacturer or a processing authority demonstrating uniform heat distribution within the cooker shall be kept on file by the establishment and made available to Program employees for review.

(f) Other systems. All other systems not specifically delineated in this section and used for the thermal processing of canned product shall be adequate to produce shelf-stable products consistently and uniformly.

(g) Equipment maintenance. (1) Upon installation, all instrumentation and controls shall be checked by the establishment for proper functioning and accuracy and, thereafter, at any time their functioning or accuracy is suspect.

(2) At least once a year each thermal processing system shall be examined by an individual not directly involved in daily operations to ensure the proper functioning of the system as well as all auxiliary equipment and instrumentation. In addition, each thermal processing system should be examined before the resumption of operation following an extended shutdown.

(3) Air and water valves that are intended to be closed during thermal processing shall be checked by the establishment for leaks. Defective valves shall be repaired or replaced as needed.

(4) Vent and bleeder mufflers shall be checked and maintained or replaced by the establishment to prevent any reduction in vent or bleeder efficiency.

(5) When water spreaders are used for venting, a maintenance schedule shall be developed and implemented to assure that the holes are maintained at their original size.

(6) Records shall be kept on all maintenance items that could affect the adequacy of the thermal process. Records shall include the date and type of maintenance performed and the person conducting the maintenance.

(h) Container cooling and cooling water. (1) Potable water shall be used for cooling except as provided for in paragraphs (h) (2) and (3) of this section.

(2) Cooling canal water shall be chlorinated or treated with a chemical approved by the Administrator as having a bactericidal effect equivalent to chlorination. There shall be a measurable residual of the sanitizer in the water at the discharge point of the canal. Cooling canals shall be cleaned and replenished with potable water to prevent the buildup of organic matter and other materials.

(3) Container cooling waters that are recycled or reused shall be handled in systems that are so designed, operated, and maintained so there is no buildup of microorganisms, organic matter, and other materials in the systems and in the waters. System equipment, such as pipelines, holding tanks and cooling towers, shall be constructed and installed so that they can be cleaned and inspected. In addition, the establishment shall maintain, and make available to Program employees for review, information on at least the following:

(i) System design and construction;

(ii) System operation including the rates of renewal with fresh, potable water and the means for treating the water so that there is a measurable residual of an acceptable sanitizer, per paragraph (h)(2) of this section, in the water at the point where the water exits the container cooling vessel;

(iii) System maintenance including procedures for the periodic cleaning and sanitizing of the entire system; and

(iv) Water quality standards, such as microbiological, chemical and physical, monitoring procedures including the frequency and site(s) of sampling, and the corrective actions taken when water quality standards are not met.

(i) Post-process handling of containers Containers shall be handled in a manner that will prevent damage to the hermetic seal area. All worn and frayed belting, can retarders, cushions, and the like shall be replaced with nonporous materials. To minimize container abrasions, particularly in the seal area, containers should not remain stationary on

moving conveyors. All post-process container handling equipment should be kept clean so there is no buildup of microorganisms on surfaces in contact with the containers.

Sec. 318.306 Processing and production records.

At least the following processing and production information shall be recorded by the establishment: date of production; product name and style; container code; container size and type; and the process schedule, including the minimum initial temperature. Measurements made to satisfy the requirements of Sec. 318.303 regarding the control of critical factors shall be recorded. In addition, where applicable, the following information and data shall also be recorded:

(a) Processing in steam--(1) Batch still retorts. For each retort batch, record the retort number or other designation, the approximate number of containers or the number of retort crates per retort load, product initial temperature, time steam on, the time and temperature vent closed, the start of process timing, time steam off, and the actual processing time. The indicating temperature device and the temperature recorder shall be read at the same time at least once during process timing and the observed temperatures recorded.

(2) Batch agitating retorts. In addition to recording the information required for batch, still steam retorts in paragraph (a)(1) of this section, record the functioning of the condensate bleeder(s) and the retort or reel speed.

(3) Continuous rotary retorts. Record the retort system number, the approximate total number of containers retorted, product initial temperature, time steam on, the time and temperature vent closed, time process temperature reached, the time the first can enters and the time the last can exits the retort. The retort or reel speed shall be determined and recorded at intervals not to exceed 4 hours. Readings of the indicating temperature device(s) and temperature recorder(s) shall be made and recorded at the time the first container enters the retort and thereafter with sufficient frequency to ensurecompliance with the process schedule. These observations should be made and recorded at intervals not exceeding 30 minutes of continuous retort operation. Functioning of the condensate bleeder(s) shall be observed and recorded at the time the first container enters the retort and thereafter as specified in Sec. 318.305(b)(3)(v).

(4) Hydrostatic retorts. Record the retort system number, the approximate total number of containers retorted, product initial temperature, time steam on, the time and temperature vent(s) closed, time process temperature reached, time first containers enter the retort, time last containers exit the retort, and, if specified in the process schedule, measurements of temperatures in the hydrostatic water legs. Readings of the temperature indicating device, which is located in the steam/water interface, and the temperature recording device shall be observed and the temperatures recorded at the time the first containers enter the steam dome. Thereafter, these instruments shall be read and the temperatures recorded with sufficient frequency to ensure compliance with the temperature specified in the process schedule and should be made at least every hour of continuous retort operation. Container conveyor speed, and for agitating hydrostatic retorts, the rotative chain speed, shall be determined and recorded at intervals of sufficient frequency to ensure compliance with the process schedule and should be performed at least every 4 hours.

(b) Processing in water--(1) Batch still retorts. For each retort batch, record the retort number or other designation, the approximate number of containers or number of retort crates per retort load, product initial temperature, time steam on, the start of process timing, water level, water recirculation rate (if critical), overriding pressure maintained, time steam off, and actual processing time. The indicating temperature device and the

temperature recorder shall be read at the same time at least once during process timing and the observed temperatures recorded.

(2) Batch agitating retorts. In addition to recording the information required in paragraph (b)(1) of this section, record the retort or reel speed.

(c) Processing in steam/air mixtures. For each retort batch, record the retort number or other designation, the approximate number of containers or number of retort crates per retort load, product initial temperature, time steam on, venting procedure, if applicable, the start of process timing, maintenance of circulation of the steam/air mixture, air flow rate or forced recirculation flow rate (if critical), overriding pressure maintained, time steam off, and actual processing time. The indicating temperature device and the temperature recorder shall be read at the same time at least once during process timing and the observed temperatures recorded.

(d) Atmospheric cookers--(1) Batch-type systems. For each cooker batch, record the cooker number or other designation and the approximate number of containers. In addition, record all critical factors of the process schedule such as cooker temperature, initial temperature, the time the thermal process cycle begins and ends, hold time, and the final internal product temperature.

(2) Continuous-type systems. Record the cooker number or other designation, the time the first containers enter and the last containers exit a cooker, and the approximate total number of containers processed. In addition, record all critical factors of the process schedule such as the initial temperature, cooker speed, and final internal product temperature.

Sec. 318.307 Record review and maintenance.

(a) Process records. Charts from temperature/time recording devices shall be identified by production date, container code, processing vessel number or other designation, and other data as necessary to enable correlation with the records required in Sec. 318.306. Each entry on a record shall be made at the time the specific event occurs, and the recording individual shall sign or initial each record form. No later than 1 working day after the actual process, the establishment shall review all processing and production records to ensure completeness and to determine if all product received the process schedule. All records, including the temperature/time recorder charts and critical factor control records, shall be signed or initialed and dated by the person conducting the review. All processing and production records required in this subpart shall be made available to Program employees for review.

(b) Automated process monitoring and recordkeeping. Automated process monitoring and recordkeeping systems shall be designed and operated in a manner that will ensure compliance with the applicable requirements of Sec. 318.306.

(c) Container closure records. Written records of all container closure examinations shall specify the container code, the date and time of container closure examination, the measurement(s) obtained, and any corrective actions taken. Records shall be signed or initialed by the container closure technician and shall be reviewed and signed by the establishment within 1 working day after the actual production to ensure that the records are complete and that the closing operations have been properly controlled. All container closure examination records required in this subpart shall be made available to Program employees for review.

(d) Distribution of product. Records shall be maintained by the establishment identifying initial distribution of the finished product to facilitate, if necessary, the segregation of specific production lots that may have been contaminated or are otherwise unsound for their intended use.

(e) Retention of records. Copies of all processing and production records required in Sec. 318.306 shall be retained for no less than 1 year at the establishment, and for an additional 2 years at the establishment or other location from which the records can be made available to Program employees within 3 working days.

Sec. 318.308 Deviations in processing.

(a) Whenever the actual process is less than the process schedule or when any critical factor does not comply with the requirements for that factor as specified in the process schedule, it shall be considered a deviation in processing.

(b) Deviations in processing (or process deviations) must be handled according to:

(1)(i) A HACCP plan for canned product that addresses hazards associated with microbial contamination, or,

(ii) Alternative documented procedures that will ensure that only safe and stable product is shipped in commerce; or

(iii) Paragraph (d) of this section.

(c) [Reserved]

(d) Procedures for handling process deviations where the HACCP plan for thermally processed/commercially sterile product does not address food safety hazards associated with microbial contamination, where there is no approved total quality control system, or where the establishment has no alternative documented procedures for handling process deviations.

(1) Deviations identified in-process. If a deviation is noted at any time before the completion of the intended process schedule, the establishment shall:

(i) Immediately reprocess the product using the full process schedule; or

(ii) Use an appropriate alternate process schedule provided such a process schedule has been established in accordance with Sec. 318.302 (a) and (b) and is filed with the inspector in accordance with Sec. 318.302(c); or

(iii) Hold the product involved and have the deviation evaluated by a processing authority to assess the safety and stability of the product. Upon completion of the evaluation, the establishment shall provide the inspector the following:

(a) A complete description of the deviation along with all necessary supporting documentation;

(b) A copy of the evaluation report; and

(c) A description of any product disposition actions, either taken or proposed.

(iv) Product handled in accordance with paragraph (d)(1)(iii) of this section shall not be shipped from the establishment until the Program has reviewed all of the information submitted and approved the product disposition actions.

(v) If an alternate process schedule is used that is not on file with the inspector or if an alternate process schedule is immediately calculated and used, the product shall be set aside for further evaluation in accordance with paragraphs (d)(1)(iii) and (iv) of this section.

(vi) When a deviation occurs in a continuous rotary retort, the product shall be handled in accordance with paragraphs (d)(1)(iii) and (iv) of this section or in accordance with the following procedures:

(a) Emergency stops.

(1) When retort jams or breakdowns occur during the processing operations, all containers shall be given an emergency still process (developed per Sec. 318.302(b)) before the retort is cooled or the retort shall be cooled promptly and all containers removed and either reprocessed, repacked and reprocessed, or destroyed. Regardless of the procedure used, containers in the retort intake valve and in transfer valves between retort shells at the time of a jam or breakdown shall be removed and either

reprocessed, repacked and reprocessed and or destroyed. Product to be destroyed shall be handled as ``U.S. Inspected and Condemned'', as defined in Sec. 301.2(ttt) of this subchapter, and disposed of in accordance with part 314 of this subchapter.

(2) The time the retort reel stopped and the time the retort is used for an emergency still retort process shall be noted on the temperature/time recording device and entered on the other production records required in Sec. 318.306.

(b) Temperature drops. When the retort temperature drops below the temperature specified in the process schedule, the reel shall be stopped and the following actions shall be taken:

(1) For temperature drops of less than 10 °F (or 5.5 °C) either, (i) all containers in the retort shall be given an emergency still process (developed per Sec. 318.302(b)) before the reel is restarted; (ii) container entry to the retort shall be prevented and an emergency agitating process (developed per Sec. 318.302(b)) shall be used before container entry to the retort is restarted; or (iii) container entry to the retort shall be prevented and the reel restarted to empty the retort. The discharged containers shall be reprocessed, repacked and reprocessed, or destroyed. Product to be destroyed shall be handled as ``U.S. Inspected and Condemned'', as defined in Sec. 318.2(ee) of this subchapter, and disposed of in accordance with part 314 of this subchapter.

(2) For temperature drops of 10 °F (or 5.5 °C) or more, all containers in the retort shall be given an emergency still process (developed per Sec. 318.302(b)). The time the reel was stopped and the time the retort was used for a still retort process shall be marked on the temperature/time recording device by the establishment and entered on the other production records required in Sec. 318.306. Alternatively, container entry to the retort shall be prevented and the reel restarted to empty the retort. The discharged containers shall be either reprocessed, repacked and reprocessed, or destroyed. Product to be destroyed shall be handled as ``U.S. Inspected and Condemned'', as defined in Sec. 301.2(ee) of this subchapter, and disposed of in accordance with part 314 of this subchapter.

(2) Deviations identified through record review. Whenever a deviation is noted during review of the processing and production records required by Sec. 318.307 (a) and (b), the establishment shall hold the product involved and the deviation shall be handled in accordance with paragraphs (d)(1) (iii) and (iv) of this section.

(e) Process deviation file. The establishment shall maintain full records regarding the handling of each deviation. Such records shall include, at a minimum, the appropriate processing and production records, a full description of the corrective actions taken, the evaluation procedures and results, and the disposition of the affected product. Such records shall be maintained in a separate file or in a log that contains the appropriate information. The file or log shall be retained in accordance with Sec. 318.307(e) and shall be made available to Program employees upon request.

Sec. 318.309 Finished product inspection.

(a) Finished product inspections must be handled according to:

(1) A HACCP plan for canned product that addresses hazards associated with microbiological contamination;

(2) An FSIS-approved total quality control system;

(3) Alternative documented procedures that will ensure that only safe and stable product is shipped in commerce; or

(4) Paragraph (d) of this section.

(b)-(c) [Reserved]

(d) Procedures for handling finished product inspections where the HACCP plan for thermally processed/commercially sterile product does not address food safety hazards

associated with microbial contamination, where there is no approved total quality control system, or where the establishment has no alternative documented procedures for handling process deviations.

(1) Incubation of shelf stable canned product--(i) Incubator. The establishment shall provide incubation facilities which include an accurate temperature/time recording device, an indicating temperature device, a means for the circulation of the air inside the incubator to prevent temperature variations, and a means to prevent unauthorized entry into the facility. The Program is responsible for the security of the incubator.

(ii) Incubation temperature. The incubation temperature shall be maintained at 95+-5 °F (35+-2.8 °C). If the incubation temperature falls below 90 °F (or 32 °C) or exceeds 100 °F (or 38 °C) but does not reach 103 °F (or 39.5 °C), the incubation temperature shall be adjusted within the required range and the incubation time extended for the time the sample containers were held at the deviant temperature. If the incubation temperature is at or above 103 °F (or 39.5 °C) for more than 2 hours, the incubation test(s) shall be terminated, the temperature lowered to within the required range, and new sample containers incubated for the required time.

(iii) Product requiring incubation. Shelf stable product requiring incubation includes:

(a) Low acid products as defined in Sec. 318.300(m); and

(b) Acidified low acid products as defined in Sec. 318.300(b).

(iv) Incubation samples. (a) From each load of product processed in a batch-type thermal processing system (still or agitation), the establishment shall select at least one container for incubation.

(b) For continuous rotary retorts, hydrostatic retorts, or other continuous-type thermal processing systems, the establishment shall select at least one container per 1,000 for incubation.

(c) Only normal-appearing containers shall be selected for incubation.

(v) Incubation time. Canned product requiring incubation shall be incubated for not less than 10 days (240 hours) under the conditions specified in paragraph (d)(1)(ii) of this section.

(vi) Incubation checks and record maintenance. Designated establishment employees shall visually check all containers under incubation each working day and the inspector shall be notified when abnormal containers are detected. All abnormal containers should be allowed to cool before a final decision on their condition is made. For each incubation test the establishment shall record at least the product name, container size, container code, number of containers incubated, in and out dates, and incubation results. The establishment shall retain such records, along with copies of the temperature/time recording charts, in accordance with Sec. 318.307(e).

(vii) Abnormal containers. The finding of abnormal containers (as defined in Sec. 318.300(a)) among incubation samples is cause to officially retain at least the code lot involved.

(viii) Shipping. No product shall be shipped from the establishment before the end of the required incubation period except as provided in this paragraph or paragraph (b) or (c) of this section. An establishment wishing to ship product prior to the completion ofthe required incubation period shall submit a written proposal to the area supervisor. Such a proposal shall include provisions that will assure that shipped product will not reach the retail level of distribution before sample incubation is completed and that product can be returned promptly to the establishment should such action be deemed necessary by the incubation test results. Upon receipt of written approval from the area supervisor, product may be routinely shipped provided the establishment continues to comply with all requirements of this subpart.

(2) Container condition--(i) Normal containers. Only normal-appearing containers shall be shipped from an establishment as determined by an appropriate sampling plan or other means acceptable to Program employees.

(ii) Abnormal containers. When abnormal containers are detected by any means other than incubation, the establishment shall inform the inspector, and the affected code lot(s) shall not be shipped until the Program has determined that the product is safe and stable. Such a determination will take into account the cause and level of abnormals in the affected lot(s) as well as any product disposition actions either taken or proposed by the establishment.

Sec. 318.310 Personnel and training.

All operators of thermal processing systems specified in Sec. 318.305 and container closure technicians shall be under the direct supervision of a person who has successfully completed a school of instruction that is generally recognized as adequate for properly training supervisors of canning operations.

Sec. 318.311 Recall procedure.

Establishments shall prepare and maintain a current procedure for the recall of all canned product covered by this subpart. Upon request, the recall procedure shall be made available to Program employees for review.

9 CFR 430, Requirements for Specific Classes of Product

9 CFR 430.1, Definitions.

Antimicrobial agent. A substance in or added to an RTE product that has the effect of reducing or eliminating a microorganism, including a pathogen such as *L. monocytogenes*, or that has the effect of suppressing or limiting growth of *L. monocytogenes* in the product throughout the shelf life of the product. Examples of antimicrobial agents added to RTE products are potassium lactate and sodium diacetate.

Antimicrobial process. An operation, such as freezing, applied to an RTE product that has the effect of suppressing or limiting the growth of a microorganism, such as *L. monocytogenes*, in the product throughout the shelf life of the product.

Deli product. A ready-to-eat meat or poultry product that typically is sliced, either in an official establishment or after distribution from an official establishment, and typically is assembled in a sandwich for consumption.

Hot dog product. A ready-to-eat meat or poultry frank, frankfurter, or wiener, such as a product defined in 9 CFR 319.180 and 319.181.

Lethality treatment. A process, including the application of an antimicrobial agent, that eliminates or reduces the number of pathogenic microorganisms on or in a product to make the product safe for human consumption. Examples of lethality treatments are cooking or the application of an antimicrobial agent or process that eliminates or reduces pathogenic microorganisms.

Post-lethality exposed product. Ready-to-eat product that comes into direct contact with a food contact surface after the lethality treatment in a post-lethality processing environment.

Post-lethality processing environment. The area of an establishment into which product is routed after having been subjected to an initial lethality treatment. The product may be exposed to the environment in this area as a result of slicing, peeling, re-bagging, cooling semi-permeable encased product with a brine solution, or other procedures.

Post-lethality treatment. A lethality treatment that is applied or is effective after post-lethality exposure. It is applied to the final product or sealed package of product in order to reduce or eliminate the level of pathogens resulting from contamination from post-lethality exposure.

Prerequisite program. A procedure or set of procedures that is designed to provide basic environmental or operating conditions necessary for the production of safe, wholesome food. It is called “prerequisite" because it is considered by scientific experts to be prerequisite to a HACCP plan.

Ready-to-eat (RTE) product. A meat or poultry product that is in a form that is edible without additional preparation to achieve food safety and may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes. RTE product is not required to bear a safe-handling instruction (as required for non-RTE products by 9 CFR 317.2(l) and 381.125(b)) or other labeling that directs that the product must be cooked or otherwise treated for safety, and can include frozen meat and poultry products.

9 CFR 430.4, Control of *Listeria monocytogenes* in post-lethality exposed ready-to-eat products.

(a) *Listeria monocytogenes* can contaminate RTE products that are exposed to the environment after they have undergone a lethality treatment. *L. monocytogenes* is a hazard that an establishment producing post-lethality exposed RTE products must control through its HACCP plan or prevent in the processing environment through a Sanitation SOP or other prerequisite program. RTE product is adulterated if it contains *L. monocytogenes* or if it comes into direct contact with a food contact surface which is contaminated with *L. monocytogenes*.

(b) In order to maintain the sanitary conditions necessary to meet this requirement, an establishment producing post-lethality exposed RTE product must comply with the requirements included in one of the three following alternatives:

(1) Alternative 1. Use of a post-lethality treatment (which may be an antimicrobial agent) that reduces or eliminates microorganisms on the product and an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes*. If an establishment chooses this alternative:

(i) The post-lethality treatment must be included in the establishment's HACCP plan. The antimicrobial agent or process used to suppress or limit the growth of the pathogen must be included in either the establishment's HACCP plan or its Sanitation SOP or other prerequisite program.

(ii) The establishment must validate the effectiveness of the post-lethality treatment incorporated in its HACCP plan in accordance with Sec. 417.4. The establishment must document, either in its HACCP plan or in its Sanitation SOP or other prerequisite program, that the antimicrobial agent or process, as used, is effective in suppressing or limiting growth of *L. monocytogenes*.

(2) Alternative 2. Use of either a post-lethality treatment (which may be an antimicrobial agent) that reduces or eliminates microorganisms on the product or an antimicrobial agent or process that suppresses or limits growth of *L. monocytogenes*. If an establishment chooses this alternative:

(i) The post-lethality treatment must be included in the establishment's HACCP plan. The antimicrobial agent or process used to suppress or limit growth of the pathogen must be included in either the establishment's HACCP plan or its Sanitation SOP or other prerequisite program.

(ii) The establishment must validate the effectiveness of a post-lethality treatment incorporated in its HACCP plan in accordance with Sec. 417.4. The

establishment must document in its HACCP plan or in its Sanitation SOP or other prerequisite program that the antimicrobial agent or process, as used, is effective in suppressing or limiting growth of *L. monocytogenes*.

(iii) If an establishment chooses this alternative and chooses to use only an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes*, its sanitation program must:

(A) Provide for testing of food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *L. monocytogenes* or of an indicator organism;

(B) Identify the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food-contact surface for *L. monocytogenes* or an indicator organism;

(C) State the frequency with which testing will be done;

(D) Identify the size and location of the sites that will be sampled; and

(E) Include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes* or of indicator organisms is maintained.

(iv) An establishment that chooses this alternative and uses a post-lethality treatment of product will likely be subject to more frequent verification testing by FSIS than if it had chosen Alternative 1. An establishment that chooses this alternative and uses an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes* will likely be subject to more frequent FSIS verification testing than if it uses a post-lethality treatment.

(3) Alternative 3. Use of sanitation measures only.

(i) If an establishment chooses this alternative, its sanitation program must:

(A) Provide for testing of food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *L. monocytogenes* or of an indicator organism;

(B) Identify the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food-contact surface for *L. monocytogenes* or an indicator organism;

(C) State the frequency with which testing will be done;

(D) Identify the size and location of the sites that will be sampled; and

(E) Include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes* or of indicator organisms is maintained.

(ii) An establishment producing a deli product or a hot dog product, in addition to meeting the requirements of paragraph (b)(3)(i) of this section, must meet the following requirements:

(A) The establishment must verify that the corrective actions that it takes with respect to sanitation after an initial positive test for *L. monocytogenes* or an indicator organism on a food contact surface in the post-lethality processing environment are effective by conducting follow-up testing that includes a targeted test of the specific site on the food contact surface area that is the most likely source of contamination by the organism and such additional tests in the surrounding food contact surface area as are necessary to ensure the effectiveness of the corrective actions.

(B) During this follow-up testing, if the establishment obtains a second positive test for *L. monocytogenes* or an indicator organism, the establishment must hold lots of product that may have become contaminated by contact with the food contact surface until the establishment corrects the problem indicated by the test result.

(C) Further, in order to be able to release into commerce the lots of product that may have become contaminated with *L. monocytogenes*, the establishment must sample and test the lots for *L. monocytogenes* or an indicator organism using a sampling method and frequency that will provide a level of statistical confidence that ensures that each lot is not adulterated with *L. monocytogenes*. The establishment must document the results of this testing. Alternatively, the establishment may rework the held product using a process that is destructive of L. monocytogenes or the indicator organism.

(iii) An establishment that chooses Alternative 3 is likely to be subject to more frequent verification testing by FSIS than an establishment that has chosen Alternative 1 or 2. An establishment that chooses Alternative 3 and that produces deli meat or hot dog products is likely to be subject to more frequent verification testing than one that does not produce such products.

(c) For all three alternatives in paragraph (b):

(1) Establishments may use verification testing that includes tests for *L. monocytogenes* or an indicator organism, such as *Listeria* species, to verify the effectiveness of their sanitation procedures in the post-lethality processing environment.

(2) Sanitation measures for controlling *L. monocytogenes* and procedures for antimicrobial agents or processes that suppress or limit the growth of the pathogen may be incorporated either in the establishment's HACCP plan or in its Sanitation SOP or other prerequisite program. When these control procedures are incorporated into the Sanitation SOP or prerequisite program, and not as a CCP in the HACCP plan, the establishment must have documentation that supports the decision in its hazard analysis that *L. monocytogenes* is not a hazard that is reasonably likely to occur.

(3) The establishment must maintain sanitation in the post-lethality processing environment in accordance with part 416.

(4) If *L. monocytogenes* control measures are included in the HACCP plan, the establishment must validate and verify the effectiveness of measures for controlling *L. monocytogenes* included in its HACCP plan in accordance with Sec. 417.4.

(5) If *L. monocytogenes* control measures are included in the Sanitation SOP, the effectiveness of the measures must be evaluated in accordance with Sec. 416.14.

(6) If the measures for addressing *L. monocytogenes* are addressed in a prerequisite program other than the Sanitation SOP, the establishment must include the program and the results produced by the program in the documentation that the establishment is required to maintain under 9 CFR 417.5.

(7) The establishment must make the verification results that demonstrate the effectiveness of the measures it employs, whether under its HACCP plan or its Sanitation SOP or other prerequisite program, available upon request to FSIS inspection personnel.

(d) An establishment that produces post-lethality exposed RTE product shall provide FSIS, at least annually, or more often, as determined by the Administrator, with estimates of annual production volume and related information for the types of meat and poultry products processed under each of the alternatives in paragraph (b) of this section.

(e) An establishment that controls *L. monocytogenes* by using a post-lethality treatment or an antimicrobial agent or process that eliminates or reduces, or suppresses or limits the growth of the organism may declare this fact on the product label provided that the establishment has validated the claim.

PART 500--RULES OF PRACTICE

Sec. 500.1 Definitions.

(a) A ``regulatory control action'' is the retention of product, rejection of equipment or facilities, slowing or stopping of lines, or refusal to allow the processing of specifically identified product.

(b) A ``withholding action'' is the refusal to allow the marks of inspection to be applied to products. A withholding action may affect all product in the establishment or product produced by a particular process.

(c) A ``suspension'' is an interruption in the assignment of program employees to all or part of an establishment.

Sec. 500.2 Regulatory control action.

(a) FSIS may take a regulatory control action because of:

(1) Insanitary conditions or practices;

(2) Product adulteration or misbranding;

(3) Conditions that preclude FSIS from determining that product is not adulterated or misbranded; or

(4) Inhumane handling or slaughtering of livestock.

(b) If a regulatory control action is taken, the program employee will immediately notify the establishment orally or in writing of the action and the basis for the action.

(c) An establishment may appeal a regulatory control action, as provided in Secs. 306.5 and 381.35 of this chapter.

Sec. 500.3 Withholding action or suspension without prior notification.

(a) FSIS may take a withholding action or impose a suspension without providing the establishment prior notification because:

(1) The establishment produced and shipped adulterated or misbranded product as defined in 21 U.S.C. 453 or 21 U.S.C. 602;

(2) The establishment does not have a HACCP plan as specified in Sec. 417.2 of this chapter;

(3) The establishment does not have Sanitation Standard Operating Procedures as specified in Secs. 416.11-416.12 of this chapter;

(4) Sanitary conditions are such that products in the establishment are or would be rendered adulterated;

(5) The establishment violated the terms of a regulatory control action;

(6) An establishment operator, officer, employee, or agent assaulted, threatened to assault, intimidated, or interfered with an FSIS employee; or

(7) The establishment did not destroy a condemned meat or poultry carcass, or part or product thereof, in accordance with part 314 or part 381, subpart L, of this chapter within three days of notification.

(b) FSIS also may impose a suspension without providing the establishment prior notification because the establishment is handling or slaughtering animals inhumanely.

Sec. 500.4 Withholding action or suspension with prior notification.

FSIS may take a withholding action or impose a suspension after an establishment is provided prior notification and the opportunity to demonstrate or achieve compliance because:

(a) The HACCP system is inadequate, as specified in Sec. 417.6 of this chapter, due to multiple or recurring noncompliances;

(b) The Sanitation Standard Operating Procedures have not been properly

implemented or maintained as specified in Secs. 416.13 through 416.16 of this chapter;

(c) The establishment has not maintained sanitary conditions as prescribed in Secs. 416.2-416.8 of this chapter due to multiple or recurring noncompliances;

(d) The establishment did not collect and analyze samples for Escherichia coli Biotype I and record results in accordance with Sec. 310.25(a) or Sec. 381.94(a) of this chapter;

(e) The establishment did not meet the *Salmonella* performance standard requirements prescribed in Sec. 310.25(b) or Sec. 381.94(b) of this chapter.

Sec. 500.5 Notification, appeals, and actions held in abeyance.

(a) If FSIS takes a withholding action or imposes a suspension, the establishment will be notified orally and, as promptly as circumstances permit, in writing. The written notification will:

(1) State the effective date of the action(s),

(2) Describe the reasons for the action(s),

(3) Identify the products or processes affected by the action(s),

(4) Provide the establishment an opportunity to present immediate and corrective action and further planned preventive action; and

(5) Advise the establishment that it may appeal the action as provided in Secs. 306.5 and 381.35 of this chapter.

(b) The prior notification provided for in Sec. 500.4 of this part will:

(1) State the type of action that FSIS may take;

(2) Describe the reason for the proposed action;

(3) Identify the products or processes affected by the proposed action;

(4) Advise the establishment of its right to contact FSIS to contest the basis for the proposed action or to explain how compliance has been or will be achieved; and

(5) Advise the establishment that it will have three business days from receipt of the written notification to respond to FSIS unless the time period is extended by FSIS.

(c) An establishment may appeal the withholding action or suspension, as provided in Secs. 306.5 and 381.35 of this chapter.

(d) If FSIS suspends inspection and does not hold the suspension action in abeyance as provided in paragraph (e) of this section, the establishment may request a hearing pursuant to the Uniform Rules of Practice, 7 CFR Subtitle A, part 1, subpart H. Upon such request, the Administrator will file a complaint that will include a request for an expedited hearing.

(e) FSIS may hold a suspension in abeyance and allow the establishment to operate under the conditions agreed to by FSIS and the establishment.

Sec. 500.6 Withdrawal of inspection.

The FSIS Administrator may file a complaint to withdraw a grant of Federal inspection in accordance with the Uniform Rules of Practice, 7 CFR Subtitle A, part 1, subpart H because:

(a) An establishment produced and shipped adulterated product;

(b) An establishment did not have or maintain a HACCP plan in accordance with part 417 of this chapter;

(c) An establishment did not have or maintain Sanitation Standard Operating Procedures in accordance with part 416 of this chapter;

(d) An establishment did not maintain sanitary conditions;

(e) An establishment did not collect and analyze samples for Escherichia coli Biotype I and record results as prescribed in Sec. 310.25(a) or Sec. 381.94(a) of this chapter;

(f) An establishment did not comply with the *Salmonella* performance standard requirements as prescribed in Secs. 310.25(b) and 381.94(b) of this chapter;

(g) An establishment did not slaughter or handle livestock humanely;
(h) An establishment operator, officer, employee, or agent assaulted, threatened to assault, intimidated, or interfered with an FSIS program employee; or
(i) A recipient of inspection or anyone responsibly connected to the recipient is unfit to engage in any business requiring inspection as specified in section 401 of the FMIA or section 18(a) of the PPIA.

Sec. 500.7 Refusal to grant inspection.
(a) The FSIS Administrator may refuse to grant Federal inspection because an applicant:
(1) Does not have a HACCP plan as required by part 417 of this chapter;
(2) Does not have Sanitation Standard Operating Procedures as required by part 416 of this chapter;
(3) Has not demonstrated that adequate sanitary conditions exist in the establishment as required by part 308 or part 381, subpart H, and part 416 of this chapter;
(4) Has not demonstrated that livestock will be handled and slaughtered humanely; or
(5) Is unfit to engage in any business requiring inspection as specified in section 401 of the FMIA or section 18(a) of the PPIA.
(b) If the Administrator refuses to grant inspection, the applicant will be provided the opportunity for a hearing in accordance with the Uniform Rules of Practice, 7 CFR Subtitle A, part 1, subpart H.

Sec. 500.8 Procedures for rescinding or refusing approval of marks, labels, and containers.
(a) FSIS may rescind or refuse approval of false or misleading marks, labels, or sizes or forms of any container for use with any meat or poultry product under section 7 of the FMIA or under section 8 of the PPIA.
(b) FSIS will provide written notification that:
(1) Explains the reason for rescinding or refusing the approval;
(2) Provides an opportunity for the establishment to modify the marking, labeling, or container so that it will no longer be false or misleading; and
(3) Advises the establishment of its opportunity to submit a written statement to respond to the notification and to request a hearing.
(c) If FSIS rescinds or refuses approval of false or misleading marks, labels, or sizes or forms of any container for use with any meat or poultry product, an opportunity for a hearing will be provided in accordance with the Uniform Rules of Practice, 7 CFR Subtitle A, part 1, subpart H.

PART 416--SANITATION--Table of Contents

Sec. 416.1 General rules.
Each official establishment must be operated and maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product is not adulterated.

Sec. 416.2 Establishment grounds and facilities
(a) Grounds and pest control. The grounds about an establishment must be maintained to prevent conditions that could lead to insanitary conditions, adulteration of product, or interfere with inspection by FSIS program employees. Establishments must have in place a pest management program to prevent the harborage and breeding of pests on the grounds and within establishment facilities. Pest control substances used must be safe and effective under the conditions of use and not be applied or stored in a manner that will result in the adulteration of product or the creation of insanitary conditions.
(b) Construction. (1) Establishment buildings, including their structures, rooms, and compartments must be of sound construction, be kept in good repair, and be of sufficient size to allow for processing, handling, and storage of product in a manner that does not result in product adulteration or the creation of insanitary conditions. (2) Walls, floors, and ceilings within establishments must be built of durable materials impervious to moisture and be cleaned and sanitized as necessary to prevent adulteration of product or the creation of insanitary conditions. (3) Walls, floors, ceilings, doors, windows, and other outside openings must be constructed and maintained to prevent the entrance of vermin, such as flies, rats, and mice. (4) Rooms or compartments in which edible product is processed, handled, or stored must be separate and distinct from rooms or compartments in which inedible product is processed, handled, or stored, to the extent necessary to prevent product adulteration and the creation of insanitary conditions.
(c) Light. Lighting of good quality and sufficient intensity to ensure that sanitary conditions are maintained and that product is not adulterated must be provided in areas where food is processed, handled, stored, or examined; where equipment and utensils are cleaned; and in hand-washing areas, dressing and locker rooms, and toilets.
(d) Ventilation. Ventilation adequate to control odors, vapors, and condensation to the extent necessary to prevent adulteration of product and the creation of insanitary conditions must be provided.
(e) Plumbing. Plumbing systems must be installed and maintained to:
(1) Carry sufficient quantities of water to required locations throughout the establishment;
(2) Properly convey sewage and liquid disposable waste from the establishment;
(3) Prevent adulteration of product, water supplies, equipment, and utensils and prevent the creation of insanitary conditions throughout the establishment;
(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor;
(5) Prevent back-flow conditions in and cross-connection between piping systems that discharge waste water or sewage and piping systems that carry water for product manufacturing; and (6) Prevent the backup of sewer gases.

(f) Sewage disposal. Sewage must be disposed into a sewage system separate from all other drainage lines or disposed of through other means sufficient to prevent backup of sewage into areas where product is processed, andled, or stored. When the sewage disposal system is a private system requiring approval by a State or local health authority, the establishment must furnish FSIS with the letter of approval from that authority upon request.

(g) Water supply and water, ice, and solution reuse. (1) A supply of running water that complies with the National Primary Drinking Water regulations (40 CFR part 141), at a suitable temperature and under pressure as needed, must be provided in all areas where required (for processing product, for cleaning rooms and equipment, utensils, and packaging materials, for employee sanitary facilities, etc.). If an establishment uses a municipal water supply, it must make available to FSIS, upon request, a water report, issued under the authority of the State or local health agency, certifying or attesting to the potability of the water supply. If an establishment uses a private well for its water supply, it must make available to FSIS, upon request, documentation certifying the potability of the water supply that has been renewed at least semi-annually.

(2) Water, ice, and solutions (such as brine, liquid smoke, or propylene glycol) used to chill or cook ready-to-eat product may be reused for the same purpose, provided that they are maintained free of pathogenic organisms and fecal coliform organisms and that other physical, chemical, and microbiological contamination have been reduced to prevent adulteration of product.

(3) Water, ice, and solutions used to chill or wash raw product may be reused for the same purpose provided that measures are taken to reduce physical, chemical, and microbiological contamination so as to prevent contamination or adulteration of product. Reuse that which has come into contact with raw product may not be used on ready-to-eat product.

(4) Reconditioned water that has never contained human waste and that has been treated by an onsite advanced wastewater treatment facility may be used on raw product, except in product formulation, and throughout the facility in edible and inedible production areas, provided that measures are taken to ensure that this water meets the criteria prescribed in paragraph (g)(1) of this section. Product, facilities, equipment, and utensils coming in contact with this water must undergo a separate final rinse with non-reconditioned water that meets the criteria prescribed in paragraph (g)(1) of this section.

(5) Any water that has never contained human waste and that is free of pathogenic organisms may be used in edible and inedible product areas, provided it does not contact edible product. For example, such reuse water may be used to move heavy solids, to flush the bottom of open evisceration troughs, or to wash antemortem areas, livestock pens, trucks, poultry cages, picker aprons, picking room floors, and similar areas within the establishment.

(6) Water that does not meet the use conditions of paragraphs (g)(1) through (g)(5) of this section may not be used in areas where edible product is handled or prepared or in any manner that would allow it to adulterate edible product or create insanitary conditions.

(h) Dressing rooms, lavatories, and toilets. (1) Dressing rooms, toilet rooms, and urinals must be sufficient in number, ample in size, conveniently located, and maintained in a sanitary condition and in good repair at all times to ensure cleanliness of all persons handling any product. They must be separate from the rooms and compartments in which products are processed, stored, or handled.

(2) Lavatories with running hot and cold water, soap, and towels, must be placed in or near toilet and urinal rooms and at such other places in the establishment as necessary to ensure cleanliness of all persons handling any product.
(3) Refuse receptacles must be constructed and maintained in a manner that protects against the creation of insanitary conditions and the adulteration of product.

Sec. 416.3 Equipment and utensils.

(a) Equipment and utensils used for processing or otherwise handling edible product or ingredients must be of such material and construction to facilitate thorough cleaning and to ensure that their use will not cause the adulteration of product during processing, handling, or storage. Equipment and utensils must be maintained in sanitary condition so as not to adulterate product.
(b) Equipment and utensils must not be constructed, located, or operated in a manner that prevents FSIS inspection program employees from inspecting the equipment or utensils to determine whether they are in sanitary condition.
(c) Receptacles used for storing inedible material must be of such material and construction that their use will not result in the adulteration of any edible product or in the creation of insanitary conditions. Such receptacles must not be used for storing any edible product and must bear conspicuous and distinctive marking to identify permitted uses.

Sec. 416.4 Sanitary operations.

(a) All food-contact surfaces, including food-contact surfaces of utensils and equipment, must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.
(b) Non-food-contact surfaces of facilities, equipment, and utensils used in the operation of the establishment must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.
(c) Cleaning compounds, sanitizing agents, processing aids, and other chemicals used by an establishment must be safe and effective under the conditions of use. Such chemicals must be used, handled, and stored in a manner that will not adulterate product or create insanitary conditions. Documentation substantiating the safety of a chemical's use in a food processing environment must be available to FSIS inspection program employees for review.
(d) Product must be protected from adulteration during processing, handling, storage, loading, and unloading at and during transportation from official establishments.

Sec. 416.5 Employee hygiene.

(a) Cleanliness. All persons working in contact with product, food-contact surfaces, and product-packaging materials must adhere to hygienic practices while on duty to prevent adulteration of product and the creation of insanitary conditions.
(b) Clothing. Aprons, frocks, and other outer clothing worn by persons who handle product must be of material that is disposable or readily cleaned. Clean garments must be worn at the start of each working day and garments must be changed during the day as often as necessary to prevent adulteration of product and the creation of insanitary conditions.
(c) Disease control. Any person who has or appears to have an infectious disease, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, must be excluded from any operations which

could result in product adulteration and the creation of insanitary conditions until the condition is corrected.

Sec. 416.6 Tagging insanitary equipment, utensils, rooms or compartments.
When an FSIS program employee finds that any equipment, utensil, room, or compartment at an official establishment is insanitary or that its use could cause the adulteration of product, he will attach to it a ``U.S. Rejected'' tag. Equipment, utensils, rooms, or compartments so tagged cannot be used until made acceptable. Only an FSIS program employee may remove a ``U.S. Rejected'' tag.

PART 416--SANITATION

Sec. 416.11 General rules.
Each official establishment shall develop, implement, and maintain written standard operating procedures for sanitation (Sanitation SOP's) in accordance with the requirements of this part.

Sec. 416.12 Development of Sanitation SOP's.

(a) The Sanitation SOP's shall describe all procedures an official establishment will conduct daily, before and during operations, sufficient to prevent direct contamination or adulteration of product(s).
(b) The Sanitation SOP's shall be signed and dated by the individual with overall authority on-site or a higher level official of the establishment. This signature shall signify that the establishment will implement the Sanitation SOP's as specified and will maintain the Sanitation SOP's in accordance with the requirements of this part. The Sanitation SOP's shall be signed and dated upon initially implementing the Sanitation SOP's and upon any modification to the Sanitation SOP's.
(c) Procedures in the Sanitation SOP's that are to be conducted prior to operations shall be identified as such, and shall address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils.
(d) The Sanitation SOP's shall specify the frequency with which each procedure in the Sanitation SOP's is to be conducted and identify the establishment employee(s) responsible for the implementation and maintenance of such procedure(s).

Sec. 416.13 Implementation of SOP's.

(a) Each official establishment shall conduct the pre-operational procedures in the Sanitation SOP's before the start of operations.
(b) Each official establishment shall conduct all other procedures in the Sanitation SOP's at the frequencies specified.
(c) Each official establishment shall monitor daily the implementation of the procedures in the Sanitation SOP's.

Sec. 416.14 Maintenance of Sanitation SOP's.
Each official establishment shall routinely evaluate the effectiveness of the Sanitation SOP's and the procedures therein in preventing direct contamination or adulteration of product(s) and shall revise both as necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel.

Sec. 416.15 Corrective Actions.

(a) Each official establishment shall take appropriate corrective action(s) when either the establishment or FSIS determines that the establishment's Sanitation SOP's or the procedures specified therein, or the implementation or maintenance of the Sanitation SOP's, may have failed to prevent direct contamination or adulteration of product(s).

(b) Corrective actions include procedures to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product(s), including appropriate reevaluation and modification of the Sanitation SOP's and the procedures specified therein or appropriate improvements in the execution of the Sanitation SOP's or the procedures specified therein.

Sec. 416.16 Recordkeeping requirements.

(a) Each official establishment shall maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOP's and any corrective actions taken. The establishment employee(s) specified in the Sanitation SOP's as being responsible for the implementation and monitoring of the procedure(s) specified in the Sanitation SOP's shall authenticate these records with his or her initials and the date.

(b) Records required by this part may be maintained on computers provided the establishment implements appropriate controls to ensure the integrity of the electronic data.

(c) Records required by this part shall be maintained for at least 6 months and made available to FSIS. All such records shall be maintained at the official establishment for 48 hours following completion, after which they may be maintained off-site provided such records can be made available to FSIS within 24 hours of request.

Sec. 416.17 Agency verification.

FSIS shall verify the adequacy and effectiveness of the Sanitation SOP's and the procedures specified therein by determining that they meet the requirements of this part. Such verification may include:

(a) Reviewing the Sanitation SOP's;

(b) Reviewing the daily records documenting the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be taken;

(c) Direct observation of the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be taken; and

(d) Direct observation or testing to assess the sanitary conditions in the establishment.

Sec. 318.17 Requirements for the production of cooked beef, roast beef, and cooked corned beef products.

(a) Cooked beef, roast beef, and cooked corned beef products must be produced using processes ensuring that the products meet the following performance standards:

(1) Lethality. A 6.5-log10 reduction of *Salmonella* or an alternative lethality that achieves an equivalent probability that no viable *Salmonella* organisms remain in the finished product, as well as the reduction of other pathogens and their toxins or toxic metabolites necessary to prevent adulteration, must be demonstrated to be achieved throughout the product. The lethality process must include a cooking step. Controlled intermediate step(s) applied to raw product may form part of the basis for the equivalency.

(2) Stabilization. There can be no multiplication of toxigenic microorganisms such as Clostridium botulinum, and no more than 1-log10 multiplication of Clostridium perfringens within the product.

Sec. 318.23 Heat-processing and stabilization requirements for uncured meat patties.

(a) Definitions. For purposes of this section, the following definitions shall apply:

(1) Patty. A shaped and formed, comminuted, flattened cake of meat food product.

(2) Comminuted. A processing term describing the reduction in size of pieces of meat, including chopping, flaking, grinding, or mincing, but not including chunking or sectioning.

(3) Partially-cooked patties. Meat patties that have been heat processed for less time or using lower internal temperatures than are prescribed by paragraph (b)(1) of this section.

(4) Char-marked patties. Meat patties that have been marked by a heat source and that have been heat processed for less time or using lower internal temperatures than are prescribed by paragraph (b)(1) of this section.

(b) Heat-processing procedures for fully-cooked patties. (1) Official establishments which manufacture fully-cooked patties shall use one of the following heat-processing procedures:

Permitted Heat-Processing Temperature/Time Combinations for Fully-Cooked Patties

Minimum internal temperature at the center of each patty (Degrees)		Minimum holding time after required internal temperature is reached (Time)	
Fahrenheit	Or centigrade	Minutes	Or seconds
151	66.1	.68	41
152	66.7	.54	32
153	67.2	.43	26
154	67.8	.34	20
155	68.3	.27	16
156	68.9	.22	13
157 (and up)	69.4 (and up)	.17	10

(2) The official establishment shall measure the holding time and temperature of at least one fully-cooked patty from each production line each hour of production to assure control of the heat process. The temperature measuring device shall be accurate within 1 degree F.

(3) Requirements for handling heating deviations. (i) If for any reason a heating deviation has occurred, the official establishment shall investigate and identify the cause; take steps to assure that the deviation will not recur; and place on file in the official establishment, available to any duly authorized FSIS program employee, a report of the investigation, the cause of the deviation, and the steps taken to prevent recurrence.

(ii) In addition, in the case of a heating deviation, the official establishment may reprocess the affected product, using one of the methods in paragraph (b)(1) in this section; use the affected product as an ingredient in another product processed to one of the temperature and time combinations in paragraph (b)(1) in this section, provided this does not violate the final product's standard of composition, upset the order of predominance of ingredients, or perceptibly affect the normal product characteristics; or relabel the affected product as a partially-cooked patty product, if it meets the stabilization requirements in paragraph (c) of this section.

(c) Stabilization. (1) Fully cooked, partially cooked, and char-marked meat patties must be produced using processes ensuring no multiplication of toxigenic microorganisms such as Clostridium botulinum, and no more than a 1 log10 multiplication of Clostridium perfringens, within the product.

(2) For each meat patty product produced using a stabilization process other than one conducted in accordance with the Hazard Analysis and Critical Control Point (HACCP) system requirements in part 417 of this chapter, an establishment must develop and have on file, available to FSIS, a process schedule, as defined in Sec. 301.2 of this chapter. Each process schedule must be approved in writing by a process authority for safety and efficacy in meeting the performance standards established for the product in question. A process authority must have access to an establishment in order to evaluate and approve the safety and efficacy of each process schedule.

(3) Under the auspices of a processing authority, an establishment must validate new or altered process schedules by scientifically supportable means, such as information gleaned from the literature or by challenge studies conducted outside the plant.

(4) Partially cooked patties must bear the labeling statement ``Partially cooked: For Safety Cook Until Well Done (Internal Meat Temperature 160 degrees F.)." The labeling statement must be adjacent to the product name, and prominently placed with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(5) Char-marked patties must bear the labeling statement ``Uncooked, Char-marked: For Safety, Cook Until Well Done (Internal Meat Temperature 160 degrees F.)." The labeling statement shall be adjacent to the product name, at least one-half the size of the largest letter in the product name, and prominently placed with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

Sec. 381.150 Requirements for the production of fully cooked poultry products and partially cooked poultry breakfast strips.

(a) Fully cooked poultry products must be produced using processes ensuring that the products meet the following performance standards:

(1) Lethality. A 7-log10 reduction of *Salmonella* or an alternative lethality that achieves an equivalent probability that no viable *Salmonella* organisms remain in the finished product, as well as the reduction of other pathogens and their toxins or toxic metabolites necessary to prevent adulteration, must be demonstrated to be achieved throughout the product. The lethality process must include a cooking step. Controlled intermediate step(s) applied to raw product may form part of the basis for the equivalency.

(2) Stabilization. There can be no multiplication of toxigenic microorganisms such as Clostridium botulinum, and no more than a 1 log10 multiplication of Clostridium perfringens within the product.

(b) Partially cooked poultry breakfast strips must be produced using processes ensuring that the products meet the performance standard listed in paragraph (a)(2) of this section. Labeling for these products must comply with Sec. 381.125. In addition, the statement ``Partially Cooked: For Safety, Cook Until Well Done'' must appear on the principal display panel in letters no smaller than \1/2\ the size of the largest letter in the product name. Detailed cooking instructions shall be provided on the immediate container of the products.

(c) For each product produced using a process other than one conducted in accordance with the Hazard Analysis and Critical Control Point (HACCP) system requirements in part 417 of this chapter, an establishment must develop and have on file, available to FSIS, a process schedule, as defined in Sec. 381.1(b). Each process schedule must be approved in writing by a process authority for safety and efficacy in meeting the performance standards established for the product in question. A process authority must have access to an establishment in order to evaluate and approve the safety and efficacy of each process schedule.

(d) Under the auspices of a processing authority, an establishment must validate new or altered process schedules by scientifically supportable means, such as information gleaned from the literature or by challenge studies conducted outside the plant.

Part 417--Hazard Analysis and Critical Control Point (HACCP) Systems

Sec.
417.1 Definitions.
417.2 Hazard Analysis and HACCP plan.
417.3 Corrective actions.
417.4 Validation, Verification, Reassessment.
417.5 Records.
417.6 Inadequate HACCP Systems.
417.7 Training.
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Authority: 7 U.S.C. 450; 21 U.S.C. 451-470, 601-695; 7 U.S.C. 1901-1906; 7 CFR 2.18, 2.53. Source: 61 FR 38868, July 25, 1996, unless otherwise noted.

Sec. 417.1 Definitions.

For purposes of this part, the following definitions shall apply:

Corrective action - Procedures to be followed when a deviation occurs.

Critical control point - A point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

Critical limit- The maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

Food safety hazard- Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

HACCP System- The HACCP plan in operation, including the HACCP plan itself.

Hazard - SEE Food Safety Hazard.

Preventive measure - Physical, chemical, or other means that can be used to control an identified food safety hazard.

Process-monitoring instrument - An instrument or device used to indicate conditions during processing at a critical control point.

Responsible establishment official-The individual with overall authority on-site or a higher level official of the establishment.

Sec. 417.2 Hazard Analysis and HACCP Plan.

(a) Hazard analysis. (1) Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment. A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls. (2) A flow chart describing the steps of each process and product flow in the establishment shall be prepared, and the intended use or consumers of the finished product shall be identified. (3) Food safety hazards might be expected to arise from the following:

(i) Natural toxins;
(ii) Microbiological contamination;
(iii) Chemical contamination;
(iv) Pesticides;

(v) Drug residues;
(vi) Zoonotic diseases;
(vii) Decomposition;
(viii) Parasites;
(ix) Unapproved use of direct or indirect food or color additives; and
(x) Physical hazards.

(b) The HACCP plan. (1) Every establishment shall develop and implement a written HACCP plan covering each product produced by that establishment whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, based on the hazard analysis conducted in accordance with paragraph (a) of this section, including products in the following processing categories:
(i) Slaughter--all species.
(ii) Raw product--ground.
(iii) Raw product--not ground.
(iv) Thermally processed--commercially sterile.
(v) Not heat treated--shelf-stable.
(vi) Heat treated--shelf-stable.
(vii) Fully cooked--not shelf-stable.
(viii) Heat treated but not fully cooked--not shelf-stable.
(ix) Product with secondary inhibitors--not shelf-stable.

(2) A single HACCP plan may encompass multiple products within a single processing category identified in this paragraph, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in paragraph (c) of this section are essentially the same, provided that any required features of the plan that are unique to a specific product are clearly delineated in the plan and are observed in practice.
(3) HACCP plans for thermally processed/commercially sterile products do not have to address the food safety hazards associated with microbiological contamination if the product is produced in accordance with the requirements of part 318, subpart G, or part 381, subpart X, of this chapter.
(c) The contents of the HACCP plan. The HACCP plan shall, at a minimum:
(1) List the food safety hazards identified in accordance with paragraph (a) of this section, which must be controlled for each process.
(2) List the critical control points for each of the identified food safety hazards, including, as appropriate:
(i) Critical control points designed to control food safety hazards that could be introduced in the establishment, and
(ii) Critical control points designed to control food safety hazards introduced outside the establishment, including food safety hazards that occur before, during, and after entry into the establishment;
(3) List the critical limits that must be met at each of the critical control points. Critical limits shall, at a minimum, be designed to ensure that applicable targets or performance standards established by FSIS, and any other requirement set forth in this chapter pertaining to the specific process or product, are met;
(4) List the procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

(5) Include all corrective actions that have been developed in accordance with Sec. 417.3(a) of this part, to be followed in response to any deviation from a critical limit at a critical control point; and

(6) Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

(7) List the verification procedures, and the frequency with which those procedures will be performed, that the establishment will use in accordance with Sec. 417.4 of this part.

(d) Signing and dating the HACCP plan. (1) The HACCP plan shall be signed and dated by the responsible establishment individual. This signature shall signify that the establishment accepts and will implement the HACCP plan.

(2) The HACCP plan shall be dated and signed:

(i) Upon initial acceptance;

(ii) Upon any modification; and

(iii) At least annually, upon reassessment, as required under Sec. 417.4(a)(3) of this part.

(e) Pursuant to 21 U.S.C. 456, 463, 608, and 621, the failure of an establishment to develop and implement a HACCP plan that complies with this section, or to operate in accordance with the requirements of this part, may render the products produced under those conditions adulterated.

Sec. 417.3 Corrective actions.

(a) The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure:

(1) The cause of the deviation is identified and eliminated;

(2) The CCP will be under control after the corrective action is taken;

(3) Measures to prevent recurrence are established; and

(4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.

(b) If a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment shall:

(1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met;

(2) Perform a review to determine the acceptability of the affected product for distribution;

(3) Take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce;

(4) Perform or obtain reassessment by an individual trained in accordance with Sec. 417.7 of this part, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.

(c) All corrective actions taken in accordance with this section shall be documented in records that are subject to verification in accordance with Sec. 417.4(a)(2)(iii) and the recordkeeping requirements of Sec. 417.5 of this part.

Sec. 417.4 Validation, Verification, Reassessment.

(a) Every establishment shall validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis, and shall verify that the plan is being effectively implemented.

(1) Initial validation. Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCPs, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities.

(2) Ongoing verification activities. Ongoing verification activities include, but are not limited to:

(i) The calibration of process-monitoring instruments;

(ii) Direct observations of monitoring activities and corrective actions; and

(iii) The review of records generated and maintained in accordance with Sec. 417.5(a)(3) of this part.

(3) Reassessment of the HACCP plan. Every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging; finished product distribution systems; or, the intended use or consumers of the finished product. The reassessment shall be performed by an individual trained in accordance with Sec. 417.7 of this part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of Sec. 417.2(c) of this part.

(b) Reassessment of the hazard analysis. Any establishment that does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur shall reassess the adequacy of the hazard analysis whenever a change occurs that could reasonably affect whether a food safety hazard exists. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; packaging; finished product distribution systems; or, the intended use or consumers of the finished product.

Sec. 417.5 Records.

(a) The establishment shall maintain the following records documenting the establishment's HACCP plan:

(1) The written hazard analysis prescribed in Sec. 417.2(a) of this part, including all supporting documentation;

(2) The written HACCP plan, including decisionmaking documents associated with the selection and development of CCPs and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.

(3) Records documenting the monitoring of CCPs and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot. Each of these records shall include the date the record was made.

(b) Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the date and time recorded, and shall be signed or initialed by the establishment employee making the entry.

(c) Prior to shipping product, the establishment shall review the records associated with the production of that product, documented in accordance with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by someone trained in accordance with Sec. 417.7 of this part, or the responsible establishment official.

(d) Records maintained on computers. The use of records maintained on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

(e) Record retention. (1) Establishments shall retain all records required by paragraph (a)(3) of this section as follows: for slaughter activities for at least one year; for refrigerated product, for at least one year; for frozen, preserved, or shelf-stable products, for at least two years.

(2) Off-site storage of records required by paragraph (a)(3) of this section is permitted after six months, if such records can be retrieved and provided, on-site, within 24 hours of an FSIS employee's request.

(f) Official review. All records required by this part and all plans and procedures required by this part shall be available for official review and copying.

Sec. 417.6 Inadequate HACCP Systems.

A HACCP system may be found to be inadequate if:

(a) The HACCP plan in operation does not meet the requirements set forth in this part;

(b) Establishment personnel are not performing tasks specified in the HACCP plan;

(c) The establishment fails to take corrective actions, as required by Sec. 417.3 of this part;

(d) HACCP records are not being maintained as required in Sec. 417.5 of this part; or

(e) Adulterated product is produced or shipped.

Sec. 417.7 Training.

(a) Only an individual who has met the requirements of paragraph (b) of this section, but who need not be an employee of the establishment, shall be permitted to perform the following functions:

(1) Development of the HACCP plan, in accordance with Sec. 417.2(b) of this part, which could include adapting a generic model that is appropriate for the specific product; and

(2) Reassessment and modification of the HACCP plan, in accordance with Sec. 417.3 of this part.

(b) The individual performing the functions listed in paragraph (a) of this section shall have successfully completed a course of instruction in the application of the seven HACCP principles to meat or poultry product processing, including a segment on the development of a HACCP plan for a specific product and on record review.

Sec. 417.8 Agency verification.

FSIS will verify the adequacy of the HACCP plan(s) by determining that each HACCP plan meets the requirements of this part and all other applicable regulations. Such verification may include:

(a) Reviewing the HACCP plan;

(b) Reviewing the CCP records;
(c) Reviewing and determining the adequacy of corrective actions taken when a deviation occurs;
(d) Reviewing the critical limits;
(e) Reviewing other records pertaining to the HACCP plan or system;
(f) Direct observation or measurement at a CCP;
(g) Sample collection and analysis to determine the product meets all safety standards; and
(h) On-site observations and record review.