



**Food Safety and Inspection Service**  
U.S. DEPARTMENT OF AGRICULTURE

# **Inspection Methods Hybrid (IMH)**

## **Class Workbook Part 3 of 3**

**Revised January 2025**

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Only this provided printed IMH Workbook may be used during the test. Handwritten notes and highlights are allowed on the provided pages. No additional pages, sticky notes, paper clips, or anything else added to the workbook is allowed.

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## Module Workshops & Scenarios

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### E1 PROFESSIONALISM SCENARIOS

Please read the case study and answer the questions that pertain to your case study.

#### 1. Romantic Relationships

An FSIS employee has been seeing an establishment employee outside of work and this has evolved into a romantic relationship. USDA inspector says: "Hey it was great seeing you the other night! What are you up to on Friday?" Establishment employee says: "Nothing really." The USDA inspector says: "Would you like to get dinner and see a movie?" The Establishment employee says: "Sure that sounds great!" The USDA inspector says: "I'll pick you up at 7 pm. It's a date!"

- Is this professional behavior? Why or why not?
- How does this behavior compare to the definition of Professionalism?
- What is the potential impact for food safety/biosecurity?
- What impact does it have on the Agency's credibility?
- What might be the outcome of this situation?
- How could this behavior be prevented or avoided (by supervisor or employees)?
- How would you demonstrate your professionalism in this situation?

## **2. Attitude, Initiative, and Communications**

The FSIS Food Inspector is on the poultry line when the establishment evisceration Supervisor walks up. The establishment evisceration supervisor starts asking questions of the food inspector in a harsh manner. The Food Inspector slams the red button and stops the line as an argument ensues. At this point, the CSI comes upon the situation and approaches the two individuals. The CSI asks: "What's the problem?" The evisceration supervisor asks: "Why are you condemning so many birds?" The Food Inspector says: "Why are you questioning my judgement?" The CSI says: "I'll take care of the problem" and asks the Food Inspector to please go back to the line. Then the CSI tells the Evisceration Supervisor: "I will take the problem up with the IIC, please leave the immediate area." The CSI promptly reports the incident to the IIC.

- Which one of the FSIS inspectors exhibited professionalism? Why?
- How does this behavior compare to the definition of Professionalism?
- What is potential impact for food safety/biosecurity?
- What impact does it have on the Agency's credibility?
- What might be the outcome if the floor inspector had not taken action?
- How could this behavior be prevented or avoided?
- How would you demonstrate your professionalism in this situation if you were the Food Inspector in this scenario?

## **E2A SPS REGULATIONS WORKSHOP #1**

1. The SPS requirements are found in 9 CFR Part:
  - a. 301
  - b. 319
  - c. 416
  - d. 417
  
2. Which statement best describes SPS regulations?
  - a. They contain highly prescriptive sanitation requirements.
  - b. They prescribe the step-by-step methods or means of achieving defined sanitation requirements.
  - c. They provide the establishment with minimum flexibility to be innovative in sanitary facility design, construction, and operations.
  - d. They define the expected sanitation results, but do not prescribe the methods or means to achieve those sanitation results.
  
3. The SPS regulations:
  - a. Require establishments to develop, implement, and maintain written procedures it conducts daily, before, and during operations, to prevent product from direct contamination and adulteration.
  - b. Address conditions in and around the establishment that may result in insanitary conditions that could lead to the adulteration of product.
  - c. Cover the scheduled, daily pre-operational and operational cleaning and sanitation of equipment and surfaces that directly contact product.
  
4. The grounds and pest control performance standard requires the establishment to:
  - a. Store useful materials and equipment in an orderly manner on elevated racks at least 12 inches high outside the establishment.
  - b. Have a pest management program in place to prevent the harborage and breeding of pests on the grounds and within the establishment.
  - c. Provide concrete paving extending at least 20 feet from the building, at loading docks, livestock chutes, or other areas where vehicles or loaded and unloaded.

5. Which of the following statements regarding the grounds and pest control performance standard is true?
- a. The establishment does not have to prevent potential sources of product contamination or adulteration if the source originates from conditions outside the official premises of the establishment.
  - b. The establishment's pest management program must be a written document.
  - c. Documents supporting the safe and effective use of a pest control substance must be available for FSIS review.
  - d. Pest control substances used on the official premises must be approved by FSIS prior to use.
6. Which of the following statements is not found in the performance standard for construction?
- a. Doors and doorjambs that may contact product must be clad with a rust-resistant metal, e.g., stainless steel, with tightly soldered or welded seams, and the juncture of the doorjamb sealed with an effective sealing compound.
  - b. Establishment buildings, including their structures, rooms, and compartments, must be of sound construction and in good repair.
  - c. Walls, floors, ceilings, doors, windows, and other outside openings must be constructed and maintained to prevent the entrance of vermin.
  - d. Walls, floors, and ceilings within establishments must be built of durable materials impervious to moisture.
7. The lighting performance standard requires the establishment to:
- a. Provide a minimum of 50 foot-candles of shadow-free light in areas where food is processed, handled, stored, and examined.
  - b. Cover light bulbs, fixtures, skylights, or other glass suspended over exposed food in any stage of preparation with a non-shattering protective shield or provide safety-type light bulbs.
  - c. Provide lighting intense enough to allow both establishment and inspection personnel to determine if sanitary conditions are maintained and that product is not adulterated in areas where food is processed, handled, stored, and examined.
  - d. Provide a minimum of 30 foot-candles of shadow-free light in areas where food is processed, handled, stored, and examined so that both establishment and inspection personnel can determine if sanitary conditions are maintained, and that product is not adulterated.



## **E2B SPS REGULATIONS WORKSHOP #2**

1. The ventilation performance standard requires the establishment to:
  - a. Prevent all odors and vapors in production areas.
  - b. Control odors, vapors, and condensation to prevent product adulteration.
  - c. Prevent the formation of any condensation inside the establishment.
  
2. Which statement is not found in the performance standard for plumbing?
  - a. The establishment's plumbing system must provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning.
  - b. The establishment's plumbing system must prevent sewer gases from entering the establishment.
  - c. Hot and cold water outlets must be equipped with functioning mechanical anti-backflow devices.
  - d. The establishment's plumbing system must properly convey sewage and liquid disposable waste from the establishment.
  
3. According to the performance standard for dressing rooms, lavatories, and toilets, lavatories (handwash sinks) must be:
  - a. Equipped with hot and cold running water, a supply of soap and towels, and located near toilet and urinal rooms and other places in the establishment as needed to ensure cleanliness of employees handling product.
  - b. Conveniently located and equipped with hot and cold running water delivered through a mixing faucet with an outlet 12 inches from the rim of the bowl, to ensure employees wash their arms as well as hands.
  - c. Equipped with hot and cold running water, a supply of soap and towels, and operated by a means other than with the hand, e.g., the knee or foot.
  
4. How often must an establishment using a municipal water supply renew the water potability certificate?
  - a. There is no mandatory renewal period.
  - b. Every year.
  - c. Twice a year.

5. How often must an establishment using a private well as its water supply renew the water potability certificate?
  - a. At least semi-annually.
  - b. Every year.
  - c. Twice a year.
  
6. Establishments can reuse water or solutions if:
  - a. The establishment has a written water and solution reuse program on file.
  - b. The establishment's water and solution reuse program is approved by FSIS.
  - c. The pipes carrying the reuse water or solution are clearly identified by name, colored tape, or other method acceptable to the IPP.
  - d. The reuse of the water or solution does not adulterate product or create insanitary conditions.
  
7. Equipment and utensils used for processing or otherwise handling edible product or ingredients must:
  - a. Be made of stainless steel (series 300).
  - b. Have their design and construction approved by FSIS or a third (outside) party before being used in the establishment.
  - c. Be made of materials and constructed in a manner that facilitates thorough cleaning.
  
8. Which of the following statements regarding the sanitation performance standards is true?
  - a. All chemicals used in the food-processing environment must be approved by a Federal Agency.
  - b. Documentation substantiating the safety of a chemical's use in a food-processing environment must be available to FSIS for review.
  - c. Extended cleanup procedures must have prior approval by FSIS.

9. According to the sanitary operations performance standard, food-contact surfaces of equipment and utensils must be cleaned and sanitized:
  - a. At a frequency that prevents the creation of insanitary conditions and the adulteration of product.
  - b. Every four hours to prevent the creation of insanitary conditions and the adulteration of product.
  - c. Daily to prevent the creation of insanitary conditions and the adulteration of product.
  - d. Before operations begin and at mid-shift to prevent the creation of insanitary conditions and the adulteration of product.
10. Food-contact surfaces of equipment and utensils must be:
  - a. Periodically cleaned and sanitized with 180°F water.
  - b. Maintained in a sanitary condition using any effective cleaning and sanitizing method.
  - c. Maintained in a sanitary condition using cleanup water that is at least 140°F and FSIS-approved disinfectants.
11. Outer clothing (e.g., aprons, frocks, smocks, and garments) worn by employees who handle product must be:
  - a. Changed every four hours to prevent insanitary conditions.
  - b. Made of disposable materials or readily cleaned.
  - c. White in color so soilage can be easily detected.
12. All persons working in contact with product, food-contact surfaces, and product packaging materials must:
  - a. Wear disposable plastic or rubber gloves to prevent their hands from directly contaminating product.
  - b. Wear cleanable caps or hats to prevent dislodged hair from falling into the product or ending up in product.
  - c. Adhere to hygienic practices while on duty to prevent adulteration of product.

13. Which of the following statements is not listed in the regulations for employee hygiene?

- a. Employees working in contact with product must clean their hands and exposed forearms with a cleaning compound by vigorously rubbing the surfaces of their lathered hands and arms for at least 20 seconds.
- b. Clean garments must be worn at the start of each working day.
- c. Any person who has an open lesion such as a boil must be excluded from any operations that could result in product adulteration (if the lesion is uncovered).
- d. Garments must be changed during the day as often as necessary to prevent adulteration.

### E2C SPS REGULATIONS WORKSHOP #3

Match the noncompliance in the left column with the appropriate sanitation performance standard in the right column. The SPS can be used more than once.

\_\_\_\_\_ The establishment is applying a pesticide in a manner that is different than the documented uses.

\_\_\_\_\_ Odor coming from the condemned/inedible product rendering area is spreading to the slaughter floor.

\_\_\_\_\_ The establishment is reusing a brine solution to chill ready-to-eat products but has no documentation or other evidence that the reused brine is free of pathogens.

\_\_\_\_\_ A chute connecting an edible product department to an inedible product department does not have an access point or opening for sanitary inspection.

\_\_\_\_\_ There are round holes in several drop ceiling panels where pipes and electrical conduits have been removed.

\_\_\_\_\_ A commode in the men's restroom is backed up and has overflowed onto the floor.

\_\_\_\_\_ An employee working with exposed product scratched his head with his fingers and did not clean them before continuing his work duties.

\_\_\_\_\_ A U.S. condemned barrel is leaking fluids from the bottom and there is an accumulation of poultry parts and whole birds on the floor.

\_\_\_\_\_ There is beaded condensation forming on the vent hood above the wiener casing peeler.

- A. Sanitary Operations
- B. Employee Hygiene
- C. Sewage Disposal
- D. Construction
- E. Grounds and Pest Control
- F. Plumbing
- G. Ventilation
- H. Dressing Rooms, Lavatories, and Toilets
- I. Equipment and Utensils
- J. Water Supply and Reuse
- K. Lighting

## **E2D SPS REGULATIONS WORKSHOP #4**

1. The verification task for verifying compliance with the SPS regulations has two parts. Which of the following is not one of those parts?
  - a. Interviewing establishment production line employees.
  - b. Reviewing specific establishment documentation.
  - c. Directly observing conditions in the establishment.
  
2. The establishment must generate and maintain daily records sufficient to document compliance with the SPS regulations.
  - a. True.
  - b. False.
  
3. When IPP perform the routine SPS verification task, he or she should verify:
  - a. That all the requirements in the SPS regulations are met in the establishment.
  - b. That the requirements in at least five of SPS regulations are met in the establishment.
  - c. That the requirements for the selected SPS regulations are met in one or more areas of the establishment.

### **E3A SSOP WORKSHOP #1: IDENTIFYING THE BASIC ELEMENTS**

Objective: Carefully read the sample Sanitation SOP below. Evaluate the Sanitation SOP for compliance with 9 CFR 416.11 and 9 CFR 416.12. After you have evaluated the Sanitation SOP, answer the questions listed on the next page.

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#### ***BEEF SLAUGHTER ESTABLISHMENT M41777—Sanitation SOP***

Owner – Joe Green

*This Sanitation SOP is for Beef Slaughter Establishment M41777 and becomes effective on January 28, 2021*

##### ***Pre-operational***

*All food contact surfaces of the facility, equipment, and utensils on the kill floor will be cleaned daily after production by rinsing, soaping, and sanitizing.*

*All cleaning will be monitored daily by Joe Green before production begins the next day. Records will be kept on Form Pre-Op I by Joe Green.*

##### ***Operational***

*Every day all equipment and surfaces on the kill floor will be kept as sanitary as necessary by cleaning and sanitizing, if necessary, to prevent contamination or adulteration of the carcasses.*

*Every day all employees will follow hygienic practices to keep themselves from contaminating or adulterating carcasses. These actions will be monitored by Joe Green once each day. Records of this monitoring will be kept on Form Ops I by Joe Green.*

*Corrective actions taken during pre-operational sanitation inspection or during operations will be written on the back of the Form Pre-Op I or Form Ops I as necessary.*

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*(Signature and date of 1/25/21) Joe Green*

##### **Modification Log**

1. (signature and date of Joe Green, 12/11/2021)
2. (signature and date of Joe Green, 6/17/2022)

Verification of compliance with the basic development of SSOPs (For Training Purposes Only)

PHIS Task: Pre-Operational & Operational SSOP Record Review task			
Relevant Regulatory Question	Yes	No	Comments
Does the establishment have written Sanitation SOP's that describe the procedures the establishment conducts daily to prevent direct contamination or adulteration of product(s)? [§416.12 (a)]			
Do the establishment's SSOPs identify which of the procedures are pre-operational procedures? [§416.12 (c)]			
Do the establishment's pre-operational SSOP procedures address (at a minimum) the cleaning of food contact surfaces of facilities, equipment, and utensils? [§416.12 (c)]			
Do the establishment's SSOPs specify the frequency with which the establishment will conduct each procedure? [§416.12(d)]			
Do the establishment's SSOPs identify the establishment employee or employees responsible for implementing and maintaining specified procedures? [§416.12 (d)]			
Does the establishment have records that identify the documentation and the implementation and monitoring of the SSOPs on a daily basis and any corrective actions taken? [§416.16 (a)]			
Did the individual with overall authority on- site or a higher-level official of the establishment sign and date the Sanitation SOP's  (1) Upon initial implementation, or (2) Upon modification [§416.12 (b)]			
Are there any failures to comply?			



## **E3B SSOP WORKSHOP #2: IMPLEMENTATION AND MONITORING**

A CSI is performing a Pre-Operational SSOP Review and Observation task. The CSI observes the monitor, Ms. Jones (Sanitation Manager), performing her pre-operational inspection. Ms. Jones walks down the aisle between lines 1 and 2 and down the aisle between lines 3 and 4. Ms. Jones inspects the visible portion of the band saw blade. The CSI notices that Ms. Jones does not open the door to the band saw cabinet. After she releases the area for operation, the CSI performs the review portion of the SSOP task by going back to the band saw and opening the door to the cabinet. The CSI observes meat, fat particles, and bone dust adhering to the direct and indirect food contact surfaces.

1. Based on the CSI's observations, what should the CSI do?
  - a. Take a regulatory control action
  - b. Not sure, currently
  - c. Do not take a regulatory control action
2. What actions should the CSI take? More than one could apply.
  - a. Take a regulatory control action, using a U.S. Rejected tag
  - b. Ensure that Ms. Jones observes the CSI's findings
  - c. Document noncompliance on a noncompliance record
  - d. Notify Ms. Jones of the CSI's actions
3. What regulations should the CSI cite on the Noncompliance Record?
  - a. 416.13(c)
  - b. 416.13(a)
  - c. 416.13(b)
  - d. 416.17

### **E3C SSOP WORKSHOP #3: CORRECTIVE ACTIONS**

In the processing department, the CSI observed two employees pick up five poultry carcasses off the floor and place them onto the moving sizing belt which is a food contact surface. The contaminated carcasses were placed on top of other poultry carcasses that were placed on the sizing belt. The CSI initiated an RCA due to the cross contamination of the poultry carcasses on the sizing belt. The employee stopped the sizing belt and removed the affected product. The sizing belt was cleaned and sanitized. The QC manager retrained and certified all sizing belt personnel on product handling procedures. Three additional Sanitation SOP monitoring checks will be performed for the next two months to assure that the training for sizing belt personnel is effective.

1. Did the establishment put measures in place to Prevent the recurrence of direct contamination or adulteration of product?
  - a. Yes
  - b. No
  
2. Did the establishment Restore sanitary conditions?
  1. Yes
  2. No
  
3. Did the establishment ensure appropriate Disposition of product?
  - a. Yes
  - b. No

## **E4 SANITATION SCENARIOS WORKSHOP**

Objective: To provide practice applying the SPS and SSOP regulatory thought process to inspection scenarios.

1. You observe an open gap of approximately one-half inch around a window that opens to the outside. Upon a close further examination, you do not observe any dirt or debris on the equipment ready for use, and no product is in the area.

Is there an insanitary condition?

If so, is it affecting product or food contact surfaces?

Is this a noncompliance?

If so, which regulation(s)?

Should you take a regulatory control action?

Under which task should you document this?

Would the establishment have to take any corrective actions? If so, which?

2. While passing through the fabrication department, you observe about 5 specks of a black substance on a piece of meat on the cutting table and about 20 more specks on the table surface. Further inspection reveals a heavy accumulation of grease and rust on an overhead rail.

Is there an insanitary condition?

If so, is it affecting product or food contact surfaces?

Is this a noncompliance?

If so, which regulation(s)?

Should you take a regulatory control action?

Under which task should you document this?

Would the establishment have to take any corrective actions? If so, which?

## **E5 NONCOMPLIANCE RECORD ASSOCIATION WORKSHOP**

Review the following 5 NRs and then answer the following questions:

1. Should any or all of the NRs be associated? If Yes, please list the NR #s and why.
  
  
  
  
  
  
  
  
  
  
2. If any of these NRs should not be included in the association, identify the NR(s) and state why the NR(s) should not be associated.
  
  
  
  
  
  
  
  
  
  
3. Is there additional language that should be included in the NR block #10?

## 10 Noncompliance – NR #1

U.S. Department of Agriculture FOOD SAFETY AND INSPECTION SERVICE NONCOMPLIANCE RECORD		TYPE OF NONCOMPLIANCE <input checked="" type="checkbox"/> Food Safety <input type="checkbox"/> Other Consumer Protection
1. DATE <b>3/01/2015</b>	2. RECORD NO. <b>LIC9487568734N</b>	3. ESTABLISHMENT NO. <b>M38574+P38574</b>
4. TO (Name and Title) <b>Joe Smith                      Plant Manager</b>		5. PERSONNEL NOTIFIED <b>So Klean</b>
6. RELEVANT REGULATIONS 416.13(a) Implementation of SSOP's		6a. ASSOCIATED NR(s)
7. TITLE(S) OF HACCP OR SSOP PLAN or OTHER SUPPORTING PROGRAM DOCUMENTATION		7a. NAME OF CCP(S) or PREREQUISITE
8. INSPECTION TASK <b>SSOP Pre Operational</b>		9. VERIFICATION ACTIVITY <input checked="" type="checkbox"/> Review & Observation <input type="checkbox"/> Recordkeeping <input type="checkbox"/> Both 9a. AFFECTED PRODUCT INFORMATION <b>No product affected.</b> 9b. RETAIN/REJECT TAGS # <b>B1468923 and B1468924</b>

### 10. DESCRIPTION OF NONCOMPLIANCE

At approximately 0400 hours while performing the preoperational SSOP review & observation task, I observed the following: rust and meat particles on three band saw blades stored on the boning table; rust, meat particles, and a white residue on the food contact surfaces of the cuber. These surfaces are all food contact surfaces and rust and product residue on these surfaces would cause product to become contaminated at the start of operations I applied US Reject tags # B1468923 and B1468924 to the blades and cuber parts, respectively. I notified Mr. S.K., Sanitation Supervisor of the noncompliance, and he initiated action to restore sanitary conditions. The regulatory control actions were relinquished once sanitary conditions were restored.

The three band saw blades were disposed of. The sanitation crew soaked the cuber parts in acid solution to remove rust, meat specs, and white residue.

The SSOP will be modified to include a procedure for cleaning the saw blades in a manner that will prevent rust formation. A procedure will also be included for soaking the cuber in an acid solution.

## 10 Noncompliance – NR #2

U.S. Department of Agriculture FOOD SAFETY AND INSPECTION SERVICE NONCOMPLIANCE RECORD		TYPE OF NONCOMPLIANCE <input checked="" type="checkbox"/> Food Safety <input type="checkbox"/> Other Consumer Protection
1. DATE <b>03/14/2015</b>	2. RECORD NO. <b>LIC3408124976N</b>	3. ESTABLISHMENT NO. <b>M38574+P38574</b>
4. TO (Name and Title) <b>Joe Smith                      Plant Manager</b>	5. PERSONNEL NOTIFIED <b>Tiana Lee</b>	
6. RELEVANT REGULATIONS 416.13(a) Implementation of SSOP's 416.4(b) Sanitary Operations		6a. ASSOCIATED NR(s)
7. TITLES OF HACCP OR SSOP PLAN or OTHER SUPPORTING PREREQUISITE PROGRAM DOCUMENTATION		7a. NAME OF CCP(S) or
8. INSPECTION TASK <b>SSOP Pre Operational</b>	9. VERIFICATION ACTIVITY <input checked="" type="checkbox"/> Review & Observation <input type="checkbox"/> Recordkeeping <input type="checkbox"/> Both 9a. AFFECTED PRODUCT INFORMATION <b>No product affected.</b> 9b. RETAIN/REJECT TAGS # <b>B1469277, B1469278, B1469279, B1469280, and B1469281</b>	

### 10. DESCRIPTION OF NONCOMPLIANCE

At approximately 0410 hours while performing the preoperational SSOP review & observation task, I observed the following: rust on the auger and auger throat of the #2 grinder, rust on the auger and blender arms of the small Hobart grinder; rust on the crossbar on top of the hopper to the stuffer, and dried residue on the blade guides and the bottom of the pulley on both band saws. These surfaces are all food contact surfaces and rust and product residue in these areas would cause product to become contaminated at the start of operations. I applied US Reject tags # B1469277, B1469278, B1469279, B1469280, and B1469281 to the #2 grinder, the small Hobart grinder, the stuffer, and both band saws, respectively.

I notified Ms. Tiana Lee, QC Supervisor, of my findings, and she initiated corrective action to restore sanitary conditions. After I verified that the establishment's corrective actions restored sanitary condition, I removed the US Reject tags and released the equipment.

Ms. Lee stated that she would instruct the pre-op crew to start pre-op monitoring 30 minutes earlier each day to provide more time for inspection and that she would also instruct the sanitation supervisor to work more closely with the sanitation crew to ensure procedures are being appropriately implemented.

## 10 Noncompliance – NR #3

U.S. Department of Agriculture FOOD SAFETY AND INSPECTION SERVICE NONCOMPLIANCE RECORD		TYPE OF NONCOMPLIANCE <input checked="" type="checkbox"/> Food Safety <input type="checkbox"/> Other Consumer Protection
1. DATE <b>3/20/2015</b>	2. RECORD NO. <b>LIC4307125717N</b>	3. ESTABLISHMENT NO. <b>M38574+P38574</b>
4. TO (Name and Title) <b>Joe Smith                      Plant Manager</b>		5. PERSONNEL NOTIFIED <b>So Klean</b>
6. RELEVANT REGULATIONS 416.4(b) Sanitary Operations		6a. ASSOCIATED NR(s)
7. TITLES OF HACCP OR SSOP PLAN or OTHER SUPPORTING PREREQUISITE PROGRAM DOCUMENTATION		7a. NAME OF CCP(S) or
8. INSPECTION TASK <b>Preoperational SSOP</b>	9. VERIFICATION ACTIVITY <input checked="" type="checkbox"/> Review & Observation <input type="checkbox"/> Recordkeeping <input type="checkbox"/> Both 9a. AFFECTED PRODUCT INFORMATION <b>No product affected.</b> 9b. RETAIN/REJECT TAGS # <b>B14688765, B12674657, and B14686473</b>	

### 10. DESCRIPTION OF NONCOMPLIANCE

At approximately 0415 hours while performing the Pre-Operational SSOP Review & Observation task, I observed the following: rust on the outer surfaces of the product brine tank; dried meat particles on the outer surface of the band saw cabinet; and dried fat and meat particles on one of the legs of the boning table. I applied US Reject tags # B14688765, B12674657, and B14686473 on the brine tank, band saw cabinet, and boning table, respectively. I notified Mr. So Klean, Sanitation Supervisor, of my observations. He instructed the sanitation crew to initiate immediate corrective actions.

The boning table, brine tank, and band saw were re-cleaned and sanitized immediately. All deficiencies were documented on the pre-op sanitation report. Mr. Klean stated that he will instruct the sanitation crew to check all pieces of equipment for rust and meat particles after cleaning. And he will assess the cleaning process for the equipment more closely.



## 10 Noncompliance – NR #4

U.S. Department of Agriculture FOOD SAFETY AND INSPECTION SERVICE NONCOMPLIANCE RECORD		TYPE OF NONCOMPLIANCE <input checked="" type="checkbox"/> Food Safety <input type="checkbox"/> Other Consumer Protection	
1. DATE <b>3/22/2015</b>	2. RECORD NO. <b>LIC5606123921N</b>	3. ESTABLISHMENT NO. <b>M38574+P38574</b>	
4. TO (Name and Title) <b>Joe Smith Plant Manager</b>		5. PERSONNEL NOTIFIED <b>So Klean</b>	
6. RELEVANT REGULATIONS 416.13(a), Implementation of SSOP's 416.4(b), Sanitary Operations 416.3(a) Equipment and utensils		6a. ASSOCIATED NR(s)	
7. TITLES OF HACCP OR SSOP PLAN or OTHER SUPPORTING PREREQUISITE PROGRAM DOCUMENTATION		7a. NAME OF CCP(S) or	
8. INSPECTION TASK <b>Preoperational SSOP</b>	9. VERIFICATION ACTIVITY <input checked="" type="checkbox"/> Review & Observation <input type="checkbox"/> Recordkeeping <input type="checkbox"/> Both 9a. AFFECTED PRODUCT INFORMATION <b>No product affected</b> 9b. RETAIN/REJECT TAGS <b>B1472001, B1472002, B1472003, and B1472004</b>		

### 10. DESCRIPTION OF NONCOMPLIANCE

At approximately 0425 hours after while performing the preoperational SSOP review & observation task, I observed the following: frayed plastic edges on four bone dust scrapers, rust on the blender arm and in the bottom of the hopper of the small Hobart grinder, rust on the tenderizer needles, and rust on the hand contact surface of the edible product shovel. I placed US Rejected tags # B1472001, B1472002, B1472003, and B1472004 respectively. I notified Mr. So Klean, Sanitation Supervisor, of my findings and he initiated corrective actions. Sanitary conditions were restored at approximately 0502 hours, and I removed the US reject tags. No product was adulterated due to the deficiency.

The operations manager stated that he will address the importance of following procedures appropriately and completing the sanitation checklist each day in their weekly staff meeting. The production manager will check the room before the pre- op sheet is signed.

## 10 Noncompliance – NR #5

U.S. Department of Agriculture FOOD SAFETY AND INSPECTION SERVICE NONCOMPLIANCE RECORD		TYPE OF NONCOMPLIANCE <input checked="" type="checkbox"/> X Food Safety <input type="checkbox"/> Other Consumer Protection
1. DATE <b>3/28/2015</b>	2. RECORD NO. <b>LIC5706123321N</b>	3. ESTABLISHMENT NO. <b>M38574+P38574</b>
4. TO (Name and Title) <b>Joe Smith                      Plant Manager</b>		5. PERSONNEL NOTIFIED <b>So Klean</b>
6. RELEVANT REGULATIONS 416.13(a) Implementation of SSOP's		6a. ASSOCIATED NR(s)
7. TITLES OF HACCP OR SSOP PLAN or OTHER SUPPORTING PREREQUISITE PROGRAM DOCUMENTATION		7a. NAME OF CCP(S) or
8. INSPECTION TASK Preoperational SSOP	9. VERIFICATION ACTIVITY <input checked="" type="checkbox"/> Review & Observation <input type="checkbox"/> Recordkeeping <input type="checkbox"/> Both 9a. AFFECTED PRODUCT INFORMATION <b>No product affected.</b> 9b. RETAIN/REJECT TAGS <b>B1472103 and B14721204</b>	
10. DESCRIPTION OF NONCOMPLIANCE		

At approximately 0400 hours, I performed the preoperational review & observation task in the processing area. I observed the following: meat particles from the previous day's operation were scattered on the metal wire guard of the packing machine; an accumulation of raw meat in the seams of the paddles and paddle cogs of the Hobart mixer. These surfaces are all food contact surfaces and product residue in these areas would cause product to become contaminated at the start of operations. I applied US Reject tag #s B1472103 and B14721204, respectively and notified Mr. So Klean, Sanitation Supervisor. The areas were re-cleaned and sanitized. Sanitary conditions were restored at approximately 0425 hours. No product was adulterated due to the deficiency.

To prevent recurrence, the establishment trained the sanitation crew on how to properly clean the areas in question and instructed the night manager to inspect these and other areas more thoroughly each night. They were also instructed to check those areas specifically for the next 2 weeks.

## E6 COMMON HAZARDS FOR RAW PRODUCT WORKSHOP

1. For each of the following biological hazards, list the temperature growth range from the information in the module. Looking over the list, what conclusion can you make about the value of refrigeration in the control of these hazards?

Organism	Temperature Growth Range
<i>Salmonella</i>	
<i>E. coli</i> O157:H7, other STEC	
<i>Campylobacter</i>	

Conclusion:

2. Which biological hazard is regularly present in cattle, and therefore is often considered a food safety hazard in beef processes?
3. Which biological hazard is associated with all food animal species?
4. What are the sources of biological hazards in the slaughter process?
5. What are some examples of potential chemical hazards in the slaughter process and what type of animals are most often found to have violative chemical levels?
6. What are some examples of potential physical hazards in the slaughter process?

## E7 HACCP 7 PRINCIPLES WORKSHOP

1. What does HACCP stand for?
2. Name the three categories of food safety hazards?
3. What must be developed as a “prerequisite” for performing a hazard analysis?

### Fill In the Blank

4. For each hazard that is reasonably likely to occur, the establishment must develop a \_\_\_\_\_.
5. For each hazard that is *not* reasonably likely to occur, the establishment must provide \_\_\_\_\_ for their decision.
6. Corrective actions must be planned for all \_\_\_\_\_ and must be implemented any time there is a \_\_\_\_\_.
7. Every HACCP system must include an effective system of \_\_\_\_\_.
8. Critical limits are best described as:
  - a. Maximum temperatures for cooking products
  - b. Time limits for production of certain products
  - c. Parameters indicating a CCP is under control
  - d. Minimum temperatures for cooking products
9. Which of the following best describe the purpose of monitoring? (Choose all that apply)
  - a. Determine when a process has deviated from a critical limit
  - b. Provide a written record for use during verification
  - c. Provide a basis for why a hazard is not reasonably likely to occur
  - d. Identify trends to allow for correction before a critical limit deviation occurs

## E8 HACCP REGULATORY PROCESS WORKSHOP

Refer to the workbook to complete the following questions. Then use the answers from questions 2 – 5 to complete the Word Search on the next page.

1. According to 9 CFR 417.1 the HACCP System is defined as:
2. The HACCP plan in operation includes the:
3. List the 4 components of the HACCP regulatory process and give a short explanation of each component.
4. What are the two tasks that may be used to verify the HACCP regulatory requirements?
5. What are the two components that may be used to verify the HACCP regulatory requirements when IPP perform HACCP verification tasks?

# Word Search

I	D	O	B	N	I	N	P	A	I	N	G	M	E	N	N	I	N	G	O	U	V	N	D	Z
A	N	B	N	E	D	O	C	A	N	S	U	M	S	I	S	A	C	C	P	P	F	C	N	E
I	N	S	U	P	P	O	R	T	I	N	G	D	O	C	U	M	E	N	T	A	T	I	O	N
H	A	C	P	D	I	N	C	E	C	P	S	I	S	H	A	M	T	A	R	A	H	H	I	F
B	E	N	S	E	F	R	I	E	S	B	A	V	O	S	I	M	E	O	L	G	Y	E	T	O
H	A	N	L	C	C	Y	S	I	C	S	D	R	O	C	E	R	P	C	C	A	H	B	A	R
C	C	P	I	I	T	T	S	A	Z	I	S	Y	S	L	O	G	I	S	Y	N	A	C	V	C
A	P	C	S	S	A	M	I	I	D	O	L	Z	I	M	P	L	A	S	R	S	V	A	R	E
T	A	M	E	I	A	N	D	O	B	J	E	R	E	M	Y	D	A	M	E	M	T	B	E	M
S	A	M	E	O	O	N	E	S	N	T	A	S	C	K	E	C	T	S	C	M	A	M	S	E
T	O	M	B	N	U	C	B	V	F	M	A	S	H	M	N	A	S	I	O	I	S	S	B	N
B	I	M	E	M	S	A	M	I	S	I	E	E	M	T	H	O	H	L	R	L	K	G	O	T
Y	C	E	N	A	M	A	T	H	O	L	O	T	G	I	A	N	A	L	D	Y	S	S	D	I
W	A	R	S	K	S	E	A	S	R	E	C	D	H	S	A	C	C	C	K	K	I	A	N	N
U	C	D	C	I	I	O	N	M	A	T	I	O	N	O	O	N	C	S	E	S	A	N	A	M
W	A	S	H	N	I	N	G	M	A	S	T	E	R	S	D	I	P	N	E	N	G	H	W	C
H	E	L	N	G	P	O	N	U	Y	O	U	R	A	L	L	O	P	R	P	I	G	H	E	T
C	O	M	P	E	R	T	A	S	M	I	N	G	D	O	C	N	L	A	I	L	S	S	I	S
F	E	E	R	E	P	C	E	O	D	O	C	V	E	N	T	A	A	O	N	A	N	I	V	U
U	N	D	E	R	D	O	C	U	M	E	N	T	A	T	I	O	N	I	G	N	G	F	E	R
A	S	E	E	P	T	H	E	M	S	W	F	G	H	J	K	L	M	N	D	Y	S	A	R	M
T	I	N	G	O	O	D	L	U	C	K	O	N	Y	O	U	R	T	E	S	T	X	Y	Z	A
A	H	A	C	C	P	V	E	R	I	F	I	C	A	T	I	O	N	T	A	S	K	N	I	S
A	H	A	Z	E	D	N	H	M	N	S	I	S	I	N	C	A	M	E	O	R	E	S	T	A
O	P	E	H	A	Z	A	R	D	A	N	A	L	Y	S	I	S	A	N	L	Y	S	I	S	A

## **E9A WORKSHOP: HACCP VERIFICATION TASK METHODOLOGY**

1. IPP are to verify that the establishment implements its HACCP system in accordance with the regulations in \_\_\_\_\_ by performing the HACCP verification task.
2. IPP must be familiar with the establishment's \_\_\_\_\_, \_\_\_\_\_, and any \_\_\_\_\_ or other programs that the establishment uses to support the decision(s) that specific food safety hazards are not reasonably likely to occur.
3. IPP use the \_\_\_\_\_ and/or the \_\_\_\_\_ components to verify that an establishment is effectively implementing the procedures set out in its HACCP plan.
4. IPP are to verify that establishments are meeting \_\_\_\_\_ the HACCP regulatory requirements.
5. IPP will document their findings in \_\_\_\_\_, including any noncompliance they find when performing their verification activities.

## E9B MONITORING

1. Review the record below and answer the questions.

Goat Slaughter HACCP Plan				
Process Step	CCP Number	CCP Description	Critical Limits	Monitoring Procedures
Carcass Trim zero tolerance	1B	No visible contamination	No visible feces, milk, or ingesta	Every carcass will be visually examined by the carcass trimmer for visible feces, ingesta, or milk

### Goat Slaughter HACCP record

Slaughter Number	Feces, ingesta, milk present? (Y or N) *	Performed by	Date: 2-8-23 Time	Corrective Actions and/or Comments
1	N	TDM	0840	
2	N	TDM	0915	
3	N	TDM	0955	
4	N	TDM	1035	
5	N	TDM	1140	
6	N	TDM	1229	
7	N	TDM	1320	
8	N	TDM	1405	
9	N	TDM	1455	

\* N indicates no feces, ingesta or milk present. Y indicates feces, ingesta or milk was observed. If so, described in comments.

- a. Are the monitoring procedures being performed at the frequency described in the HACCP plan?
- b. Is the CL met?
- c. Where would he perform the recordkeeping component?
- d. If he decides to perform the review and observation component, how would he proceed?



2. At Est. P42, the Fully Cooked-Not Shelf Stable HACCP verification task is scheduled on the PHIS task calendar. The IPP verifies the monitoring requirement while performing the review and observation component of the Fully Cooked-Not Shelf Stable HACCP verification task. The IPP reviews the HACCP plan and sees that the monitoring procedure for CCP-3 is to check the cooked internal temperature of turkey bologna. The plan states that the smokehouse operator will check the internal temperature using a hand-held digital thermometer of 1 piece of product from 3 locations on each rack of product (top, middle, and bottom) in every smokehouse of product. The critical limit is 160°F or higher. The smokehouse operator will document all 3 readings on the Smokehouse Record.

a. The IPP goes to the smokehouse area and discovers that the smokehouse operator is ready to conduct a monitoring check on the product the IPP planned to check. What does the IPP expect to see?

b. The IPP decides to take a product temperature. What does the IPP do?

3. An IPP is performing the Heat Treated – Shelf Stable HACCP verification task and verifying 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

a. Is this portion of the HACCP plan in compliance? Why or why not?

## **E9C VERIFICATION**

1. Answer the following questions:
  - a. What are the 3 verification activities that the HACCP regulations specify?
  - b. Must all three occur at each CCP in the HACCP plan? Please explain your answer.
  - c. Would an establishment be in compliance if the same establishment employee performed all three of the verification activities at one CCP?

2. An IPP is performing the Raw-Intact HACCP verification task in a poultry-boning operation and verifying the establishment verification requirements for the chilling CCP. While performing the task, she reviews the establishment's HACCP plan:

HACCP plan: raw boneless skinless chicken breasts					
CCP #	Critical Limits	Monitoring Procedures & Frequencies	HACCP Records	Verification Procedures & Frequencies	Corrective Actions
2 Chilling	Product temperature not to exceed 40 degrees F	QC personnel will record temperature every 4 hours  Check internal temperature of the product, using a handheld calibrated thermometer inserted into the thickest portion of the breast muscle	Product Temperature Log  Corrective Action Log  Thermometer Calibration Log	HACCP Coordinator will review the Product Temperature Log and observe QC personnel performing monitoring once per shift  Daily, the QC will check the accuracy of all thermometers used for monitoring devices for accuracy by immersion in slush ice, and will verify to within 2° F.  All thermometers found to be inaccurate will be calibrated using immersion in slush ice and re-evaluated  HACCP Coordinator will review the Corrective Action Log (if applicable) and the Thermometer Calibration Log once per week.	Corrective actions shall meet all requirements of Part 417.3(a)

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

If yes, what is the procedure?

If yes, what is the frequency?

- b. Does the HACCP plan contain procedures and frequencies for direct observation of monitoring activities?

If yes, what is the procedure?

If yes, what is the frequency?

- c. 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)?

If yes, what is the procedure?

If yes, what is the frequency?

## E9D RECORDKEEPING

1. An inspector is verifying the recordkeeping requirement at the pre-evisceration antimicrobial rinse CCP as part of the Slaughter HACCP verification task. He reviews the monitoring record for the CCP, which follows.

<b>Pathogen Reduction Log</b>							
<i>Date</i>	<i>Lot No.</i>	<i>Time</i>	<i>Solution Conc. (%)</i>	<i>Pressure (psi)</i>	<i>Corrective Actions</i>	<i>Monitored by</i>	<i>Verified by *</i>
2-1-2024	1	0730	OK	OK	-	TDM	PP
<i>*direct observation verification-results as per HACCP plan</i>							

- a. Are there any noncompliances in this record? Please explain and cite the relevant regulation.
- 
2. 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?
- 
3. Evaluate the record below.

<b>Thermometer Calibration Log</b>							
<b>Calibrate to 32° F while in slush ice water</b>							
Date	Time	Dept.	Thermometer ID	Personal Thermometer Reading	Adjustment Required? (Yes or No)	Initials	Comments
2/15/24	PM	Carcass Cooler	2B	32°F	No	TDM	

- a. Is there any noncompliance with recordkeeping requirements here?
- 
- b. If so, what is the regulatory reference?

4. While performing the recordkeeping component of the Heated Treated-Not Fully Cooked-Not Shelf Stable HACCP verification task at a smoked pork chop establishment, the IPP is verifying the record retention requirement. The establishment has been producing this product for two years. The QC Manager gives the IPP a thick file and says that it contains all the HACCP records that the establishment has for these products. The IPP looks at yesterday's record (January 29, 2024), which is on top. The IPP looks through the records in the folder and notes that the oldest date is for June 30, 2023. Is there noncompliance?

## **E9E SUPPORTING DOCUMENTATION- PREREQUISITE PROGRAMS AND OTHER SUPPORTING PROGRAMS**

1. An IPP is performing the Raw Intact HACCP verification task, she reviews the hazard analysis and finds that the establishment implements a prerequisite program for product temperature control to support the decision they made in the hazard analysis that the growth of pathogens is not reasonably likely to occur. The temperature control program indicates that 2 internal product temperatures are taken daily. She asks the establishment manager to provide her with the prerequisite program record for the day the specific production was produced. She sees that only one measurement is documented on the record instead of two results.
  - a. Is there any noncompliance with the support documentation recordkeeping requirements at this point?
  - b. What should she do next?

## **E9F CORRECTIVE ACTION**

1. An IPP is reviewing a HACCP record and observes that a result of 3% is recorded as a monitoring check. The critical limit at this CCP is "at least 6%."
  - a. At this point in the 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 performed met the requirements of 417.3(a), is there a HACCP noncompliance?
2. The HACCP plan specifies that the CCP for product temperature will be monitored by checking product at three locations in the cooler each hour and recording all results. An IPP reviews the temperature log and observes that at each monitoring check there are only two temperatures recorded. All 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 the IPP expect to see all corrective actions in section 417.3(a) taken for this situation? Please explain.
3. An IPP has recently rotated assignments and his new patrol includes a pork fabrication operation. Today's schedule includes the Raw Non- Intact HACCP verification task. He observes that there is a metal detector in use on the pork cuts. He reviews the HACCP plan and hazard analysis, and he sees that the hazard analysis identifies metal, but finds it is not likely to occur because of the metal detection program so the HACCP plan does not have a CCP for metal detection.

Later that day, he learns that the metal detector has rejected product. He reviews the corrective action log.



HACCP CORRECTIVE ACTION OR UNFORESEEN HAZARD REPORT

IJK Corporation

Date: 3-2-24

Product and amount affected: *25 lb. boneless pork loin*

Describe the unforeseen hazard, including cause:

*At 9:00 am the metal detector rejected product, which was carefully examined by QC, what looks like a syringe needle was found EF 10:05 am.*

Describe how the affected product was segregated and held:

*We disposed of the piece as inedible EF 10:05 am*

Describe how the product was reviewed to determine acceptability for distribution:

*All product from that same load was run back through the metal detector but nothing else was found EF 1:00 pm.*

Describe measures taken to prevent a reoccurrence and/or to eliminate the cause:

*We have contacted the supplying establishment XYZ and notified them that if it happens again, we will no longer purchase from that supplier GH 11:00 am.*

State whether HACCP plan reassessed, conclusions, and any changes:

*Yes. Established a new CCP for metal detection. See new version of HACCP plan, dated 3-2-24 GH 1:00 pm.*

Eric Fazoli      3-2-24

Plant Management, date

Gerry Harroldson 3-2-24

QA Manager, date

- a. What regulation applies to this situation?
- b. Did the establishment meet corrective action requirements?
- c. Is there a HACCP noncompliance?
- d. What else should the IPP do?

### **E9G PRE-SHIPMENT REVIEW**

1. The establishment must accomplish the pre-shipment review prior to the specific production leaving the physical premises. True or False?
2. An IPP is assigned to a very small beef slaughter establishment that stores a wide variety of finished products (raw and cooked) for several months in the freezer. The HACCP plan includes a CCP for cold storage of finished products after processing. The establishment monitors the CCP daily and documents the results. The pre-shipment review form is then completed, signed, and dated, and any product in the freezer is clear to be shipped that day.

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

## **E10 HAZARD ANALYSIS VERIFICATION (HAV) TASK WORKSHOP**

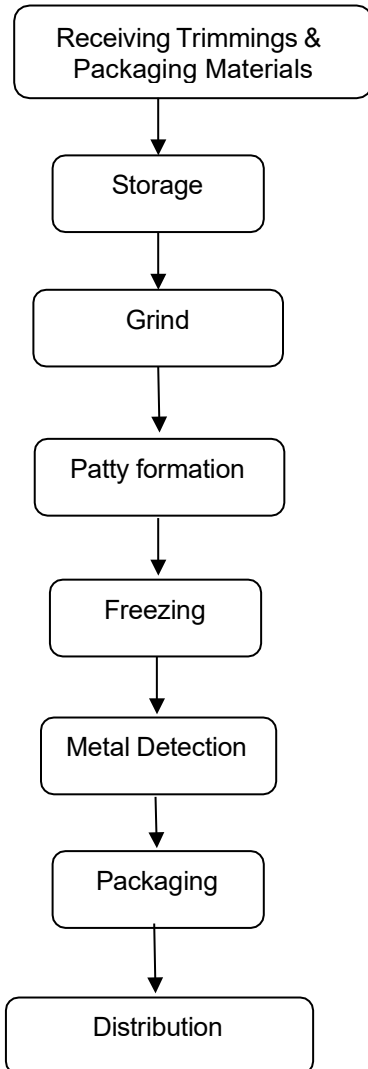
Refer to the handout and the HAV Task Summary Table to complete the following questions.

1. When should IPP perform the HAV task?
2. Review the flow diagram, product description, hazard analysis, and HACCP plan on the following pages, and answer the following questions:
  - a. How did the establishment address biological hazards at receiving?
  - b. How did the establishment address physical hazards at receiving?
  - c. How did the establishment address biological hazards at storage?
3. What decisions in the hazard analysis would the IPP request supporting documentation for, if any? Please explain your answer.

4. Are all steps in the flow diagram addressed in the hazard analysis? If not, please explain.
5. Are all hazards identified as reasonably likely to occur addressed by a CCP somewhere in the process? If not, please explain.
6. Is the use of terms like “microbial growth” or “growth of pathogens” sufficient to identify microbiological hazards?
7. What decision in the HACCP Plan would the IPP request supporting documentation for, if any?

## Raw ground beef patties

### Process flow diagram



### Product Description:

Process category: Raw ground

Product: Frozen ground beef patties

Name: Ground beef patties 6 per pound

Type of package: 10 pounds per box, in plastic bag with paper liners separating layers

Length of shelf life: 3-6 months if maintained frozen as recommended on label; 5 days if thawed and held refrigerated

Intended use: Fast food restaurant

Labeling instructions: Keep frozen, safe food handling label

Distribution: Frozen

Note: No rework used in this process

Example: for training use only



Hazard Analysis: Raw ground beef patties (Continued)					
Process Step	Food Safety Hazards	Is hazard likely to occur?	Justification for decision	What control measures can be applied to prevent the significant hazards?	Is step a critical control point?
Receiving trimmings & Packing materials	<b>Chemical:</b> non-food grade	No	Letters of guarantee		
	<b>Physical:</b> foreign material	No	Establishment records show that there has been no incidence of foreign material in products in past several years		
Storage	<b>Biological:</b> Growth of pathogens  <b>Chemical:</b> none  <b>Physical:</b> none	No	Cooler temperature at <44°F to prevent outgrowth (Tompkin, R.B. 1996). Cooler Temperature monitored twice daily.		

Example: for training use only

Hazard Analysis: Raw ground beef patties (Continued)					
Process Step	Food Safety Hazards	Is hazard likely to occur?	Justification for decision	What control measures can be applied to prevent the significant hazards?	Is step a critical control point?
Grind	<b>Biological:</b> Pathogen Growth	Yes	Processing could result in product temperatures above 45°F, permitting pathogen growth.	CCP-1 Patty Temp at later step  Room Temperature SOP	No
	<b>Chemical:</b> none  <b>Physical:</b> metal Contamination	Yes	Past history indicates that metal contamination has occurred during grinding	Proper maintenance of equipment, routine examination during cleaning, metal detector later in process	No
Patty formation	<b>Biological:</b> Pathogen Growth	Yes	Processing could result in product temperatures above 45°F, permitting pathogen growth.	CCP-1 Patty Temp  Room Temperature SOP	Yes
	<b>Chemical:</b> none  <b>Physical:</b> metal contamination	Yes	Past history indicates that metal contamination has occurred during patty formation	Proper maintenance of equipment, routine examination during cleaning, metal detector later in process-CCP2	No

Example: for training use only



Hazard Analysis: Raw ground beef patties (Continued)					
Process Step	Food Safety Hazards	Is hazard likely to occur?	Justification for decision	What control measures can be applied to prevent the significant hazards?	Is step a critical control point?
Freezing	<b>Biological:</b> none <b>Chemical:</b> none <b>Physical:</b> none				
Metal Detection	<b>Biological:</b> none <b>Chemical:</b> none <b>Physical:</b> Metal Contamination	Yes	Past history indicates that metal contamination has occurred in previous process steps	Functioning metal detection equipment to identify and reject contaminated product- CCP 2	Yes
Packaging	<b>Biological:</b> none <b>Chemical:</b> none <b>Physical:</b> none				

Example: for training use only

<b>HACCP Plan: Raw ground beef patties</b>					
<b>CCP</b>	<b>Critical Limits</b>	<b>Monitoring Procedures and Frequencies</b>	<b>HACCP Records</b>	<b>Verification Procedures &amp; Frequencies</b>	<b>Corrective Actions</b>
# 1 Patty Temp	Product internal temperature ≤44 ° F	<p>QC personnel will record the internal temperature of 3 patties at the exit to of the patty machine prior to freezing every hour.</p> <p>Internal temperature measure by inserting a calibrated thermometer into the center most part of the patty.</p>	<p>Product Temperature Log</p> <p>Corrective Action Log</p> <p>Thermometer Calibration Log</p>	<p>HACCP Coordinator will verify accuracy of the Product Temperature Log once per shift and observe QC personnel performing monitoring.</p> <p>QC will calibrate thermometer once per week (per manufacturer's instructions)</p> <p>QC will directly observe corrective actions at each occurrence</p>	Corrective actions shall meet all requirements of Part 417.3 (a)

**Example: for training use only**

HACCP Plan: Raw ground beef patties				(Continued)	
CCP	Critical Limits	Monitoring Procedures and Frequencies	HACC P Records	Verification Procedures & Frequencies	Corrective Actions
# 2 Metal Detector	Ferrous detection 1 mm & larger Nonferrous detection 1.5 mm & larger	QC personnel will verify that the metal detector is functioning as intended by running a 1mm Ferrous seeded sample and a 1.5mm nonferrous seeded sample through the metal detector every 2 hours. The seeded sample will be placed between 2 patties. Functioning metal detector must identify and remove the seeded sample- reject the patties.	Metal Detection Log  Corrective Action Log	HACCP Coordinator will verify accuracy of the Metal Detection Log and observe packaging line supervisor performing monitoring once per shift.  Maintenance personnel will perform calibration procedure once per shift.	Corrective actions shall meet all requirements of Part 417.3 (a)

Example: for training use only

## E11 HACCP SYSTEM AND RECALL WORKSHOP

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

1. You are the IIC at a small establishment that produces frozen spaghetti and tomato sauce with meat entrees and frozen non-amenable spaghetti entrees made with a lobster cheese sauce. You are performing Pre-Operational Sanitation Review and Observation Task.
  - a. What are the regulation sections that you are verifying regulatory compliance with?

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 spaghetti in the morning and tomato sauce with meat spaghetti in the afternoon. The label of the spaghetti containing meat does not list any lobster (crustacean) or milk ingredients.

- b. Are the conditions you observed creating an insanitary condition?
    - c. Can the conditions you observed lead to contaminated product?
    - d. Is there a food safety hazard associated with the contamination you observed?
    - 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 a Directed Fully Cooked but Not Shelf Stable HACCP Verification Task, you 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 regulations would you use?
- k. What actions would you take next?

2. While performing a Fully Cooked Not Shelf Stable HACCP verification task in a ready- to-eat product operation to verify the HACCP regulatory requirements, you review the establishment's HACCP plan. During this review, you notice that the establishment has documented a reassessment of its HACCP plan. You go to establishment management and ask what event triggered the reassessment. The establishment manager indicates that the reassessment was performed in response to a positive *Listeria monocytogenes* result from its microbiological testing of the finished ready-to-eat ham lunchmeat. This microbiological testing program is not referenced in the establishment's HACCP plan. *Listeria monocytogenes* testing is performed as a verification requirement for their customer. You request the establishment to provide the results of their microbiological testing of the finished ham lunchmeat. The establishment provides this data to you.

You observe that the last sample analyzed was found to be positive for *Listeria monocytogenes*. You request information about corrective actions taken and are shown an unforeseen hazard log that documents that the establishment segregated and held affected product. The establishment also has records to show that it performed a review to determine the acceptability of affected product and took action to ensure that no product injurious to health entered commerce by denaturing and disposing of the adulterated product. Documentation that the product was denatured and disposed of in a landfill is provided. The log further shows that a reassessment was performed, and the establishment determined that this was not a hazard reasonably likely to occur in its process. It made no alterations to the hazard analysis or the HACCP plan. The basis for this decision is documented as: "It is the only positive ever received. We apply a full lethality treatment and apply our Sanitation Standard Operating Procedures daily. The application of our Sanitation Standard Operating Procedures daily should continue to be sufficient in the future. This result is a fluke. No changes to the HACCP plan are necessary at this point." When you ask for support for the decision that the hazard is still not reasonably likely to occur, the establishment manager says, "the result was a fluke" and we documented that on the corrective action log. As part of the Fully Cooked Not Shelf Stable HACCP Verification Task on this specific production, you verify that all HACCP requirements, including pre-shipment review, were met for all CCPs, other than what is described above.

- a. Has the establishment supported its decision about the results of the reassessment?
- b. What are the 4 questions you would seek answers to as you gather information to determine whether or not to document this as a noncompliance, and what conclusion would you make? Remember the 4 questions from the HACCP Regulatory Process presentation. If the system is working, you may not document some noncompliances.
- c. What regulations need to be considered?

- d. Is there a noncompliance? Please explain your answer.
  
  
  
  
  
  
  
  
  
  
- e. If you determine that a noncompliance should be documented, what regulation would you cite?
  
  
  
  
  
  
  
  
  
  
- f. What are the questions you would seek answers to as you gather information to determine whether or not there is an inadequate system, and what conclusion would you make?

Is there an indication of an inadequate system?

- g. If you determine that you would document an NR, please complete blocks 6, 8, 9, and 10 only on the next page.

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 <input checked="" type="checkbox"/> Food Safety <input type="checkbox"/> Other Consumer Protection
1. DATE	2. RECORD NO.	3. ESTABLISHMENT NO.
4. TO (Name and Title)		5. PERSONNEL NOTIFIED
6. RELEVANT REGULATIONS		6a. ASSOCIATED NR(s)
7. TITLES OF HACCP OR SSOP PLAN or OTHER SUPPORTING PROGRAM DOCUMENTATION		7a. NAME OF CCP(S) or PREREQUISITE
8. INSPECTION TASK	9. VERIFICATION ACTIVITY <input type="checkbox"/> Review & Observation <input type="checkbox"/> Recordkeeping <input type="checkbox"/> Both	
	9a. AFFECTED PRODUCT INFORMATION	
	9b. RETAIN/REJECT TAGS #	
10. DESCRIPTION OF NONCOMPLIANCE		
11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE		



## E12 HAZARD ANALYSIS VERIFICATION (HAV) AND RAW BEEF SAMPLING SCENARIO

**Objective:** To review performance of certain steps of the HAV task.

**Scenario:** You recently submitted a sample of raw ground beef which was confirmed positive result for *E. coli* O157:H7. You decide to perform a directed HAV task as one follow-up. Excerpt of establishment documents provided.

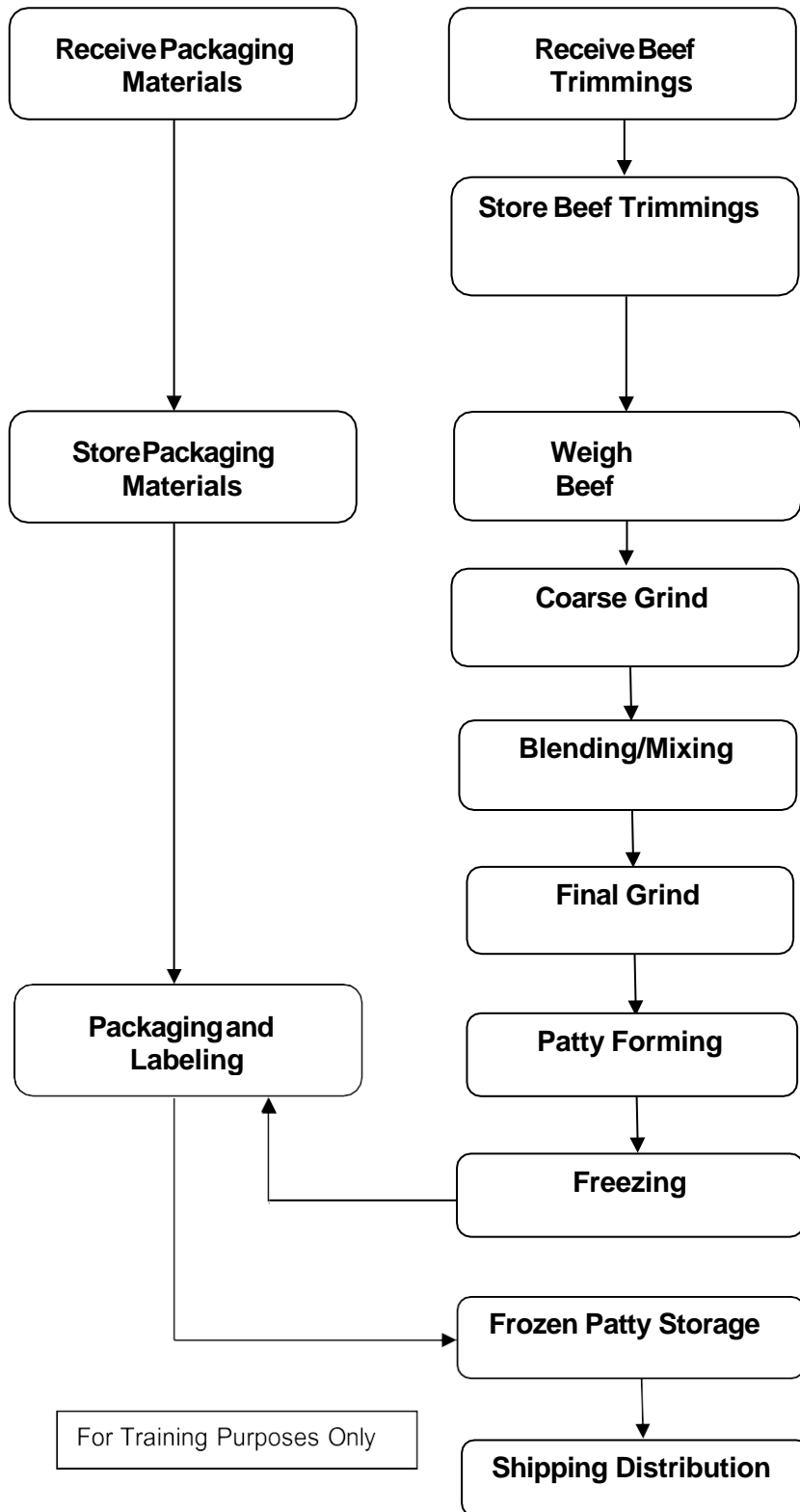
Consider:

- What documents and records should you review?
- What will you look for when reviewing these documents and records?
- What findings would be evidence of noncompliance?

Product Description	
Common Name:	Ground Beef Patties
Formulation:	Fresh beef trimmings from Open Beef
Packaging:	Bulk (frozen patties) in 20 lb. box
Shelf Life:	3-6 months if frozen
Intended Use:	Restaurants

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## Process Flow Diagram



## Raw Non-Intact Product Hazard Analysis (Ground Beef Patties) ...EXCERPT...

Process Step	Food Safety Hazard	Reasonably Likely to Occur	Basis	Measures Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level
Receiving-Raw Beef Trimmings	Biological: Pathogens:  <i>E. coli</i> O157:H7 <i>Salmonella</i>	No	<i>E.coli</i> O157:H7 is a known pathogen in raw beef products  (Interventions for <i>E. coli</i> should also reduce <i>Salmonella</i> )	Receiving Inspection Program
	BSE / SRMs	No	SRMs may be found in incoming product from beef animals	Supplier will provide documentation that product is derived from animals less than 30 months of age and the SRMs are removed
	Chemical: None			
	Physical: Foreign Materials	No	Damaged containers can result in product exposure to foreign material or cross contamination.	Visual inspection for damaged containers at receiving – (Receiving log)
...	...	...	...	...

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## **RECEIVING INSPECTION PROGRAM**

### **Required Documents**

Before unloading beef trimmings from truck trailer, the receiving manager will verify there is documentation accompanying the shipment stating that:

1. Intervention(s) were applied to the source materials of the beef trimmings in compliance with the supplier's HACCP program.
2. The beef trimmings are derived from cattle that are less than 30 months of age and SRMs have been removed.
3. Each lot of beef trimmings has been tested and found to be negative for *E. coli* O157:H7, each lot has an associated letter of guaranty.

### **Measuring Receiving Temperature**

The surface temperature of the beef trimmings must be  $\leq 40^{\circ}\text{F}$ . Temperature is monitored in at least 2 containers per trailer by receiving foreman at the receiving dock for each delivery of beef trimmings.

### **Inspection of Containers**

100% visual inspection of shipping container condition by the receiving foreman.

### **Corrective Actions**

If the required documentation does not accompany the shipment of beef trimmings, placed on "hold" until the required documentation is received.

If the temperature of beef trimmings is above  $40^{\circ}\text{F}$ , the supplier may provide evidence which demonstrates the temperature of the beef trimmings from time of shipping to receipt was above  $40^{\circ}\text{F}$  for no more than 2 hours but never above  $50^{\circ}\text{F}$ .

Beef trimmings with damaged containers are segregated and placed in "Product Reinspection" area for further evaluation.

### **Records**

1. Receiving Log
2. Bills of Lading
3. Letters of Guaranty

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### **Receiving Log**

Date	Supplier	Product	Lot Codes	Temperature (trimmings)	Condition (Acc. or UnAcc.)	Receiving Initials
1-25-2019	Open Beef	5combos beef trim	Lot 012416AC	38, 40	Acc	EP
...	...	...	...	...	...	...

Corrective Actions:

# STRAIGHT BILL OF LADING

**Open Beef  
Co, Inc.**

**8305 Hawthorne Way  
Petaluma, CA 94954**

Date	B/L #
1-24-19	25744

CONSIGNED TO:
Groveton Meats, Inc. 1200 Presley Drive Los Angeles, CA 94852

SPECIAL INSTRUCTIONS	
Trailer Temp:	34 degrees F

Pallets Used	S.O. Number	Seal Numbers	Ship Date	Delivery Date
	799	23012/931	1-24-19	1-25-19
Piece Count	Description		Weight	
5	Combos – Beef Trimmings Lot 012416AC		2476 lbs.	

Total Pc Cnt:	5	Driver Initials: <i>JT</i>	Total Wt.:	2476 lbs.
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*Note: This shipment contains beef products derived only from animal determined to be less than 30 months of age and contains no SRM's such as tonsils or distal ileum.*

SHIPPER: Open Beef Co. PER: <u><i>JT</i></u>	CARRIER: Open Beef Co. PER: <u><i>JT</i></u> DATE: <u>1-25-19</u>
---	---

# Open Beef Company, Inc.

Petaluma, CA  
700-777-7000

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*"Where Good Beef Is Found"™*

Dear Customer,

As part the Food Safety System at Open Beef, we apply a validated antimicrobial organic acid rinse to all of our carcasses and variety meats. This letter is to convey the results of Open Beef Co, Inc. *E. coli* O157:H7 "Verification" testing. We perform verification testing of trimmings that will be used as raw ground beef components to provide ongoing validation of our Food Safety system. We use the N-60 sampling method to collect our samples and the contract lab utilizes test methods which are equivalent in sensitivity to FSIS methods.

**Current Results:**

Lot Number: 012416AC

Production Date: 01/23/19

Sample Date: 01/23/19

Shipment Number: 25744

Trailer Number: T43

N60 Sample Result: NEGATIVE for *E.coli* O157:H7

Result Received: 01/24/19

Contract Lab: JDL Laboratories, Inc.

Please contact me if you have any further questions.

---

*Bert Earnest*

Bert Earnest  
Director of Quality Assurance

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## E13 LETHALITY, STABILIZATION, AND MULTIPLE HURDLES WORKSHOP

1. State the regulatory lethality performance standard for cooked beef, including the log reduction and the target organism. Include the regulation that covers this.
2. Why must high relative humidity be applied during the first part of the heating process (lethality treatment) for jerky products, and certain fully cooked RTE meat and poultry products?
3. Could an establishment use the FSIS Appendix A lethality compliance guideline to support its critical limits for meeting the lethality performance standard, if the establishment cooks cured beef briskets in a sealed, moisture impermeable bag to an internal temperature of 145°F for 4 minutes?

## **E14 LISTERIA MONOCYTOGENES REGULATIONS: WORKSHOP**

1. Establishments are required to comply with section 9 CFR 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:

- a. Alternative 1
- b. Alternative 2, Choice 1
- c. Alternative 2, Choice 2
- d. Alternative 3

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

\_\_\_\_\_ 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*.

\_\_\_\_\_ 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.

\_\_\_\_\_ 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 the establishment is producing:

- a. RTE products exposed to the environment after the lethality treatment using Alternative 1, 2, or 3.
- b. Non-deli and hot dog type RTE products exposed to the environment after the lethality treatment using Alternative 3.
- c. Deli and hot dog type RTE products exposed to the environment after the lethality treatment using Alternative 3.
- d. 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 the establishment is producing:
  - a. 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. Deli and hot dog type RTE products exposed to the environment after the lethality treatment using either Alternatives 1, 2, or 3.
  - c. Deli and hot dog type RTE products exposed to the environment after the lethality treatment using Alternative 1 or Alternative 2, Choice 1.
  - d. Non-deli and hot dog type RTE products exposed to the environment after the lethality treatment using Alternative 2, Choice 1
5. Case Study. (Please note: This is a simplified training example only.) You are assigned to an establishment that makes smoked turkey for slicing at delis. The establishment has chosen to produce this product under Alternative 2, Choice 2. In order to comply with Part 430.4(b)(2), the establishment's sanitation program must provide for testing of food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Listeria monocytogenes*. The establishment includes sanitation measures to prevent *Listeria monocytogenes* in processing environment in the Sanitation SOP. The sanitation program targets the packaging room, where product is taken off of smokehouse racks, cut into halves, and vacuum packaged. The establishment conducts routine, random food contact surface testing as follows:
  - It has identified 20 food contact surface sites, such as tabletops, packaging equipment, and knife blades. These represent all possible sites.
  - Each month 5 sites are randomly selected and tested for *Listeria* spp. The sites are tested twice weekly, at the end of production before cleaning. Testing frequency is based on past data. For 6 months testing was done weekly, and data showed that the process ensured control of *Lm*. Additionally, they are testing more frequently than recommended by FSIS in the Compliance Guidelines to Control *Listeria monocytogenes* in Post-lethality Exposed Ready to Eat Meat and Poultry Products.
  - Sample size is 1 square foot for each surface.
  - Sample sites are recorded, along with visual observation of each site. Test results are recorded on the same form.
  - If a positive food contact surface sample result is detected that site is given intensified cleaning and sanitizing during the next sanitation and re-swabbed daily for 5 days.
  - If the site is again positive for *Listeria* spp. during this 5-day period, the food contact surface is taken out of production and subjected to intensive cleaning and sanitizing, holding product, and retesting, as follows.

- ☐ Equipment is completely disassembled.
- ☐ The food contact surface and surrounding areas receive intensified cleaning and sanitizing, and the item is re-assembled and placed back into production.
- ☐ Corrective actions are recorded.
- ☐ Food contact surface swabs are then taken every two hours during production.
- ☐ All product is placed on hold until results are received.
- ☐ If all food contact surface swabs are negative, product is released.
- ☐ If any swab tests positive for *Listeria* spp., product from that 2-hour time period and from each period on either side of the positive result is tested for *Listeria monocytogenes*.
  - Testing will be done following a statistically derived sampling plan.
  - Product that tests negative for Lm is released.
  - Product that tests positive for Lm is destroyed.
- ☐ The process of intensified sanitation, holding product, and testing food contact surfaces is repeated daily until test results are negative for *Listeria* spp.

a. At what point during production are the random food contact surface samples taken?

b. Does this program identify conditions under which the establishment will implement hold-and-test procedures following a positive test of a food contact surface? If so, what are those conditions?

c. Does this program identify the frequency with which testing will be done? If so, what is that frequency?

- d. Does this program identify the size and location of the sites that will be sampled? If so, what is the size and location?
  
  
  
  
  
  
  
  
  
  
- e. When are product samples for *Listeria monocytogenes* taken?
  
  
  
  
  
  
  
  
  
  
- f. Would you review records associated with this program? If so, when? Please explain your answer.
  
  
  
  
  
  
  
  
  
  
- g. Would you observe employees performing the sampling procedures? If so, when? Please explain your answer.

6. You are a CSI assigned in August 2023 to an RTE establishment that produces post-lethality exposed deli meats under the Fully Cooked-Not Shelf Stable HACCP processing category. The establishment follows Alternative 3 (i.e. sanitation only to control *Lm*) for these products. In addition to testing food contact surfaces as required by regulation, the establishment incorporated environmental (non-food contact) sampling into its prerequisite *Listeria* Control Program. It also regards a presumptive positive *Listeria* spp. sample the same as a positive *Lm* result.

The establishment completed construction of a smokehouse in the RTE area three months earlier. Over the past few weeks, multiple environmental presumptive positive *Listeria* spp. results were received by the establishment. After determining corrective actions were implemented and documented, you review the establishment profile in PHIS. You verify that 30 noncompliances, seven of which were associated, were documented over the previous three months for SPS, Operational, and Pre-Operational SSOP deficiencies.

Review the following examples of establishment records and answer Exercise #6 questions.

#### **ESTABLISHMENT RECORDS:**

##### **May 23, 2023**, Establishment Record - Presumptive Positive *Listeria* spp. Findings

- Large floor drain in RTE room
- Floor at NW corner of entry from raw area into RTE room
- Corrective actions cited the following possible causes: Product roller rack moved from raw side to RTE room through smokehouses without first being cleaned and sanitized.
- All follow-up samples were negative for *Listeria* spp. after cleaning and sanitizing.

##### **June 3, 2023**, Establishment Record - Presumptive Positive *Listeria* spp. Findings

- Southeast floor drain in RTE room
- Line 3 splitter control box housing
- RTE room west wall seam
- Corrective actions cited the following possible causes: Raw side pallet jack in RTE room; product roller racks from raw area moved into RTE room without first being cleaned and sanitized; raw inedible barrel in RTE room.
- All follow-up samples were negative for *Listeria* spp. after cleaning and sanitizing.

##### **June 23, 2023**, Establishment Record - Presumptive Positive *Listeria* spp. Findings

- Vinyl curtain strips from RTE room entry door on product roller rack wash
- All follow-up samples were negative for *Listeria* spp. after cleaning and sanitizing.

##### **June 24, 2023**, Establishment Record -Presumptive Positive *Listeria* spp. Findings

- Floor in front of the entrance to blast freezer 6
- Cement floor at the entrance to blast freezer 6 broken and in pieces
- As of 7/23/23, the cement floor was not yet repaired. Establishment should schedule this with a contractor.
- All follow-up samples were negative for *Listeria* spp. after cleaning and sanitizing.

**July 1, 2023, Establishment Record - Presumptive Positive *Listeria* spp. Findings**

- Northwest floor drain in RTE room
- Corrective actions cited the following possible causes: Inedible barrel from raw area found sitting in RTE room hallway.
- All follow-up samples were negative for *Listeria* spp. after cleaning and sanitizing.

**KNOWLEDGE CHECKS**

1. Based on what you have reviewed in this scenario and your knowledge of FSIS Directive 10,240.4, what risk factors for *Listeria monocytogenes* can you identify (more than one answer may apply)?
  - a. There are no risk factors.
  - b. Increase in and repetitive presumptive positives for *Listeria* spp.
  - c. Sanitation noncompliance related to equipment, SPS, and traffic flow as noted in corrective action information.
  - d. Construction in the smokehouse.
2. What information in this scenario would cause a CSI to escalate this up the supervisory chain of command (FLS and/or DO)?
  - a. Repetitive presumptive positive *Listeria* spp. and ineffective corrective actions that indicate an inadequate HACCP system.
  - b. Repetitive sanitation noncompliance, including cross contamination between raw side and RTE area.
  - c. Noncompliance trends related to sanitation and HACCP.
  - d. All the above.

## **WORKSHOP #1 – POULTRY SLAUGHTER/PROCESSING ESTABLISHMENT, SPS, SSOP, AND HACCP**

Please read the following scenario and answer the questions at the end within the table boxes. Please review the HACCP plan and the records that are associated with this scenario.

**Background:** K. Nugget, a Consumer Safety Inspector (CSI), is assigned to a poultry establishment that slaughters and further processes young chickens during a single operating shift, Monday through Friday, from 0700 to 1530 hours. The establishment has 2 evisceration lines, produces raw intact and raw non-intact products, and occasionally exports poultry products.

**Scenario:** At 1000 hours, on March 1, 2023, CSI Nugget was leaving the shipping dock after completing export certifications and noticed a foul odor in the hallway outside the processing department. The CSI determined the odor originated from empty, damaged, inedible containers that were being stored in the hallway to be discarded due to their unacceptable condition. CSI Nugget performed an Operational SSOP Review and Observation verification task as she walked through the further processing department on her way to the slaughter department. In the processing department, she observed the establishment monitoring operational sanitation activities. Quality Assurance (QA) personnel were applying yellow caution tape around an area below a leak in the processing room ceiling. The leak was located between two processing lines in a potential product zone.

CSI Nugget proceeded to the slaughter floor to continue to observe operational sanitation throughout the establishment.

At 1230 hours, CSI Nugget decided to review the establishment's SSOP program and records for the leak that was observed earlier in the further processing department. (Note that these SSOP records are not required to be available until the start of the same shift on the following day). The establishment's SSOP records had two entries related to the leaking ceiling. An entry at 0900 hours which stated that an employee observed a leak and notified QA and maintenance personnel. The area was roped off by QA. There was another entry on the SSOP record at 1030 hours that the area was released because maintenance fixed the leak, and the ceiling was no longer leaking.

Before CSI Nugget headed back to the processing room, she asked the establishment QA Supervisor for the CCP 1 records for the current day since she had not noticed any establishment personnel performing the Zero Tolerance CCP monitoring. CSI Nugget was told that due to short staffing, the designated monitor had been working on the ceiling leak in the further processing department, but the record is usually kept on the clipboard on the wall. CSI Nugget found the clipboard with the CCP monitoring record, but it was blank. CSI Nugget asked the QA Supervisor about the monitoring checks, she stated that the checks were performed by the QA Tech, but the checks were not documented. The establishment's HACCP program specified that the slaughter Zero Tolerance CCP will be monitored each production hour on each line.

CSI Nugget decided to follow-up on the conditions in the processing room. When she arrived, she noticed that the caution tape had been removed from the area that was previously segregated. Now, there were five metal combo bins with poultry thighs and wings in that area. The CSI observed that there was a large blue plastic tarp partially covering three of the five

bins. The other two combo bins were completely uncovered. There was an accumulation of clear liquid on the plastic tarp that was slowly running into one of the three combo bins that were partially covered. The CSI investigated further and noticed that the ceiling above the metal combo bins was slowly leaking liquid into the uncovered combo bins.

*HACCP Plan (excerpt) CCP 1*

Poultry Slaughter HACCP Plan					
Process Step	CCP Number	CCP Description	Critical Limits	Monitoring Procedures	Verification Procedures
Zero tolerance Examination (carcass)	1 – Biological (Pathogens in fecal material)	No visible contamination	No visible fecal material  If a deviation from the critical limit occurs, corrective actions shall meet all requirements of 9 CFR 417.3 and be documented on the Zero Tolerance Monitoring form.	Designee will examine 10 randomly selected carcasses each production hour per shift per line.  Document findings on Zero Tolerance Monitoring Form.	Once per week a supervisor observes the designee performing the monitoring.  A supervisor will conduct records review daily.

*Establishment's Zero Tolerance Monitoring Record for March 1, 2023*

Zero Tolerance Monitoring Form (CCP1)					
Date	No fecal material identified on 10 carcasses sample = 0	Performed by	Time	Corrective Actions and/or Comments	Verification Procedures
3/1/2023					

*Establishment's SSOP Monitoring Record for March 1, 2023*

SSOP Monitoring Record – Further Processing (Monitor Implementation 4 times daily)				
Date	Time	Performed by	Processing Room	Corrective Actions and Preventive Measures
3/1/23	0800	MJ	Acceptable	
3/1/23	0900	MJ	Unacceptable - employee observed leak and notified QA and maintenance personnel.	No product was involved. Maintenance is working on the leak and area is sectioned off.
3/1/23	1030	MJ	Acceptable	Maintenance fixed the leak. The ceiling is no longer leaking. Area released.  Blue plastic tarps will be placed over the product combo bins until the corrective actions are complete.  A QA Tech will monitor the area twice per shift, per day for the next three days.



**Questions:**

<b>Q1</b> - Please explain why the establishment is not in compliance with FSIS regulations. Include the regulatory citation.		<b>Q2</b> - If you were the CSI in this establishment, what are the actions you would take? (i.e., List the actions you should take as a CSI in relation to each noncompliance you identify in this scenario).
<b>Noncompliance Description</b>	<b>Regulation(s) not met</b>	<b>Your Actions for This Noncompliance</b>
HACCP Noncompliance	HACCP Regulation	
SSOP Noncompliance	SSOP Regulation	
SPS Noncompliance	SPS Regulation	

## WORKSHOP #2 – LIVESTOCK ESTABLISHMENT NR

After completing the workshop, the participants will be able to:

1. Determine the required data that needs to be included in an NR.
2. Determine the situations that require associating NRs.

Please read the scenario, review the NR, and answer the questions at the end. Livestock Establishment Scenario

**Background:** CSI Naomi Thompson is assigned to Veal on Wheels, a small veal slaughter and processing facility. The establishment slaughters approximately fifty veal calves a day on one shift, five days a week. They use a bed dress system (cradle) during slaughter operations. Incorporated into the HACCP system to address E. coli O157:H7 and non-O157:H7 STEC are two critical control points including zero tolerance and a lactic acid intervention.

**Scenario:** On June 1, 2022, at approximately 0910 hours CSI Thompson performed a scheduled Slaughter HACCP verification task on the slaughter floor. While verifying the lactic acid CCP, CSI Thompson observed the establishment employee perform a titration to verify the appropriate concentration prior to starting operations. Note: Titration is a standard method of chemical analysis which can be used to determine the concentration of a known reactant. CSI Thompson also noted that the establishment used a small garden type sprayer to apply the lactic acid. She determined that solution was mixed to the correct concentration and the garden sprayer was an acceptable means of applying the solution.

CSI Thompson then went to the slaughter floor to observe the application of the lactic acid to the carcasses. She noticed that the establishment was hanging both hindquarters of carcasses together on one rail trolley hook prior to the final wash and antimicrobial intervention steps. This caused the inner surface of the hindquarters of each carcass to be in contact (no separation between the legs). The establishment does not split the veal carcasses and usually uses a gambrel to separate the hindquarters for adequate washing and antimicrobial coverage. When she observed the establishment employee apply the lactic acid intervention to three carcasses, CSI Thompson noted that the inside of the hindquarters did not receive any lactic acid coverage due to the way the carcasses were hung.

The employee pushed the carcasses into the chill cooler. CSI Thompson went into the chill cooler and observed ten veal carcasses already hanging in the cooler. These carcasses were hanging from one hook in the same manner. She asked the employee if he had applied the intervention to these ten carcasses in the same manner as the three carcasses that she had observed him applying the intervention. The employee stated that he had applied the intervention to all carcasses in the same way.

CSI Thompson told Mr. Drayer she is taking a regulatory control action by applying U.S. Retained tag B19042869 to the carcass cooler door. She notified Mr. Drayer that the one tag encompassed all thirteen carcasses. It included the carcasses she observed on the slaughter floor and the ones slaughtered earlier that morning because of the deviation from a critical limit. CSI Thompson reviewed PHIS and determined NR KIH4527923981N was documented May 10, 2022, for failing to detect a deviation from the critical limit at the zero tolerance CCP. She associates the two NRs because they indicate a problem with establishment employees assigned to monitor CCPs.

# CSI Thompson's Noncompliance Record

U.S. Department of Agriculture FOOD SAFETY AND INSPECTION SERVICE NONCOMPLIANCE RECORD		TYPE OF NONCOMPLIANCE <input checked="" type="checkbox"/> Food Safety <input type="checkbox"/> Other Consumer Protection	
1. DATE 06/01/2022	2. RECORD NO. KNL1612111329N	3. ESTABLISHMENT NO. M8383	
4. TO (Name and Title) Mr. Scott Snook, Plant Manager		5. PERSONNEL NOTIFIED Mr. James Drayer, Slaughter Forman	
6. RELEVANT REGULATIONS 9 CFR 417.2(c)(4)		6a. ASSOCIATED NR(s) KIH4527923981N	
7. TITLES OF HACCP OR SSOP PLAN or OTHER or SUPPORTING DOCUMENTATION PROGRAM Veal Slaughter		7a. NAME OF CCP(S) PREREQUISITE Lactic Acid	
8. INSPECTION TASK Slaughter HACCP	9. VERIFICATION ACTIVITY <input type="checkbox"/> Review & Observation <input type="checkbox"/> Recordkeeping <input checked="" type="checkbox"/> Both 9a. AFFECTED PRODUCT INFORMATION: Thirteen Whole Veal Carcasses 9b. RETAIN/REJECT TAGS: B19042869		
10. DESCRIPTION OF NONCOMPLIANCE  On June 1, 2022, at approximately 0910 hours, while performing the Slaughter HACCP verification task, I noticed that the establishment was hanging both hindquarters of each veal carcass on one hook prior to the final wash and antimicrobial intervention steps. The critical limit for the antimicrobial intervention CCP includes a 2% lactic acid concentration applied to the entire carcass so that complete coverage is achieved. I observed the establishment perform a titration to verify the concentration prior to starting operations. Upon observing the inside of the hindquarters of each carcass were not receiving any lactic acid coverage, I notified the slaughter foreman, Mr. James Drayer, of the noncompliance. A review of PHIS showed a similar NR documented on May 10, 2022, in NR KIH4527923981N, for a different CCP. The preventative measures and further planned actions of retraining employees on correct HACCP monitoring procedures have been ineffective in preventing noncompliance recurrence.			
11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE  <i>You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR</i>			
12. PLANT MANAGEMENT RESPONSE:  <b>This document serves as written notification that your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.</b>			
13. SIGNATURE OF PLANT MANAGEMENT		14. DATE	
15. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE		16. DATE	

**Questions:**

1. What errors can you detect in the written NR?
2. Rewrite the NR Block 10 the way you would write it if you were the CSI.

### WORKSHOP #3 – POULTRY ESTABLISHMENT: SAMPLING AND PROCESS CONTROL

Please read the following scenario and answer the questions at the end.

**Background:** Establishment Ink, LLC is a large poultry slaughter and processing establishment (P-0000) located in Salt, Alabama. Their slaughter and processing operations are conducted by way of a first shift (0530 to 1400 hours) and second shift (1400 to 2030 hours), with a cleanup operation after both shifts have been completed. Establishment Ink has two Meyn Maestro slaughter lines that run at a maximum speed of 140 birds per minute. Establishment Ink slaughters and processes approximately 268,000 young chickens a day. The further processing operations consist of a Cut-up Department, Debone Department, and Mechanically Deboned Meat (MDM) Department. The MDM Department produces NRTE ground chicken that is shipped to their sister plant where it is used to produce raw chicken patties. This product is eligible for Salmonella/Campylobacter testing. Both shifts have a staffing level of 8 Food Inspectors (4 inspectors per line), 2 Consumer Safety Inspectors, 1 Supervisory Consumer Safety Inspector, and a Public Health Veterinarian.

**Scenario:** It's Tuesday, April 5, 2022. CSI Red opens PHIS and observes in the establishment task list that he needs to verify the establishment's generic *E. coli* testing procedures and results to see if they are maintaining process control for microbial contamination. He knows that Establishment P-IK has chosen generic *E. coli* as their indicator organism to demonstrate whether or not they are maintaining process control and that this program is addressed in their SSOP plan, so he schedules a routine Operational SSOP Review and Observation task in PHIS.

He goes to the QA office and reviews the SSOP program which contains the procedures for collecting and testing for generic *E. coli*. The program states that the establishment will perform testing via a carcass rinse using an approved AOAC method. The procedures state that the establishment will aseptically collect 1 carcass rinse sample per 22,000 carcasses, but a minimum of one sample during each week of operation. The sample will then be maintained under refrigerated conditions and analyzed the same day in the establishment's onsite laboratory.

He next inquires about the next time a sample would be taken for *E. coli* sampling. The QA supervisor informs him that one of his technicians was about to take a sample in the next few minutes. He goes along with the QA technician to the post chill location where the sample will be taken. He observes her prepping the sampling table and using aseptic technique by washing her hands, etc. The technician decides to do a swab sample using a carcass from the chiller belt.

CSI Red was confused, because the program read that the sampling was supposed to entail a whole bird rinse. He saw nothing about a swab sampling nor support for it.

He observes the technician follow through on procedures of a swab sampling but not a bird rinse as per the establishment's written program. Once completed, he follows the QA technician to the lab and watches her place the sample in the freezer. She states that it is the end of the day, and she needs to make an appointment and will analyze it in the morning. In the meantime, CSI Red asks to review the Statistical Process Control chart for data that has been plotted for the last 10 days. When he reviews the chart, he notices that 4 of those 10 days had results that were markedly below the normal (average) control line in the chart. This was very odd to CSI

Red, because he knows that 2 sanitation NRs and 3 fecal zero tolerance NRs were written during this ten day period.

**Resources:**

- 9 CFR 381.65(g) & (h)
- 9 CFR 416.15(b)
- 9 CFR 417.3(b)
- FSIS Directive 5000.1 - Verifying an Establishment's Food Safety System
- FSIS Directive 6420.5 - Verifying Poultry Slaughter Establishments Maintain Adequate Procedures for Preventing Contamination with feces and Enteric Pathogens

**Question:**

Please list the issues that you noticed in the above scenario that you have concerns about (critique the actions, results, or the procedure that was performed by the establishment employee).

# Public Health Information System (PHIS)

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## PHIS - INTRODUCTION TO THE PUBLIC HEALTH INFORMATION SYSTEM

### **Objective:**

Understand how PHIS enhances inspection and protects public health The Food Safety and Inspection Service (FSIS) is the public health regulatory agency responsible for ensuring that domestic and imported meat, poultry, and processed egg products are safe, wholesome, and properly labeled.

FSIS has made significant advances in the inspection process and is constantly evolving to enhance our ability to protect public health. Looking back, certain milestones may come to mind. In 1906, Congress passed the Federal Meat Inspection Act. In 1996, FSIS finalized the “Pathogen Reduction: Hazard Analysis Critical Control Point (HACCP) Systems” rule. In 2011, FSIS implemented the Public Health Information System (PHIS) to support a data-driven approach to FSIS inspection, auditing, and scheduling.

### **PHIS Introduction**

PHIS is a user-friendly, web-based application that replaces several legacy systems and automates many processes. It allows FSIS to obtain and quickly analyze more data about domestic and international food safety systems producing FSIS regulated products. It also enables the Agency to better identify food safety risks before they result in outbreaks or recalls. The Predictive Analytics component supports a data driven approach to inspection and sampling by automatically searching data to identify trends and notifying FSIS personnel about potential public health threats.

PHIS generates specific tasks and adjusts task frequencies based on public health risk factors. IPP, supervisors, and analysts access real time data for early recognition of food safety system deficiencies and trends. Data is used to quickly, and effectively respond to prevent product adulteration, recalls, and outbreaks. The quality of the analysis and the response however depends on the quality of the data in the system. It is critical that IPP enter data that is complete and accurate.

PHIS was developed in response to an Office of the Inspector General (OIG) recommendation that FSIS develop an integrated data infrastructure to support a comprehensive, timely and reliable data driven inspection system. PHIS enables FSIS to utilize real time data to inform all aspects of its business process (e.g., domestic inspection, import inspection, and export activities).

PHIS replaced several legacy systems, facilitating maintenance and analysis of the composited data. Work efficiency and effectiveness continues to improve since FSIS personnel with different roles (e.g., inspectors, managers, analysts, policy developers) can readily access and utilize inspection and sampling data. Agency resources are better utilized since tasks are prioritized.

There are four functional areas within PHIS:

- **Domestic Inspection**
- **Exports Certification**
- **Imports**
- **Predictive Analytics**

This course covers Domestic Inspection and Export Certification. Imports are covered in a separate training course.

PHIS is role-based. There are many different roles and permissions based on duties, job description and job series. Each user role sees a unique navigation menu. For example, CSIs can access the establishment profile, task calendar, inspection verification data, animal disposition, and export certification menus for their assignments.

Establishment profile data drives many important PHIS functions. Therefore, IPP must routinely update and ensure the accuracy of the profile data. The profile includes critical information about the establishments' operations, product types, product volumes, and HACCP system.

This information allows FSIS to tailor inspection, sampling, or other activities based on establishment factors. Sample requests are electronically routed to inspectors based on establishment profile information. If profile data is inaccurate or missing, IPP could receive sample requests for products that the establishment no longer produces.

A "task list" is generated for each establishment based on profile data. The Task List identifies task priorities and frequencies. IPP consider the task priorities, time constraints, and their knowledge of establishment operations to schedule tasks on their task calendar.

In addition to routine tasks, "directed" tasks may be added to the task list. PHIS generates some directed tasks in response to sample results. Sampling tasks specify a time frame during which IPP are to schedule and collect the requested sample. IPP can add directed tasks to document a noncompliance found when not performing a routine task. PHIS also allows directed tasks to be initiated at various Agency levels and targeted to subsets of establishments in response to public health findings or other information. The system tracks completion of tasks and can alert supervisors when tasks are performed.

PHIS contains links to applicable guidance material (e.g., Directives, Notices). The guidance is based on the establishment profile and the specific inspection task. Linking to only the applicable guidance reduces time spent searching for and reviewing information that may not be helpful or pertinent.

In PHIS, IPP document the specific regulations verified and the findings of compliance or noncompliance for each regulation. If a noncompliance is found, it is documented on an NR along with other applicable information such as product type, lot number, retain or reject tags used, and/or the applicable CCP verified for some tasks. The system also facilitates documenting meeting minutes in a memorandum of interview (MOI). Inspectors can create notes in PHIS that can be used to communicate with other inspectors or included as agenda topics for meetings.



## **Predictive Analytics**

Predictive analytics integrates data from various sources such as Centers for Disease Control and Prevention (CDC), PulseNet, the Agricultural Research Service VetNet, and the National Antimicrobial Resistance Monitoring System (NARMS) and stores the collected data in the FSIS Data Warehouse.

Algorithms perform real time data analysis. When anomalies are identified, PHIS sends alerts to the appropriate user homepages or email addresses. Users may subscribe to alerts that are of interest.

Predictive analytics also uses algorithms to automate scheduling in response to certain events. The system generates appropriate follow-up tasks in response to sampling results. For performing and scheduling directed tasks, IPP should follow guidance in FSIS Directive 13,000.1.

Predictive analytics incorporates decision criteria to schedule Food Safety Assessments and identifies when an establishment should reassess their hazard analysis. Analysts can also conduct spontaneous data analyses from multiple data sources to identify trends and anomalies.

## **PHIS 1 – ESTABLISHMENT PROFILE**

### **Objectives**

1. Describe the Establishment Profile in PHIS and why it is important to maintain the accuracy of information.
2. Describe when and how to perform the Update Establishment Profile task in PHIS.
3. Describe what to discuss and do at the weekly meeting related to the profile.

### **Background**

The Establishment Profile (EP) is a series of web pages in PHIS that Inspection Program Personnel (IPP) use to enter data about official establishments and other facilities where FSIS provides inspection services. The profile includes information on the products produced, the processes performed, the equipment employed, the HACCP systems that the establishment has put in place, and other general information.

PHIS uses the establishment profile information to assign routine inspection tasks, to create tailored inspection tasks, to generate FSIS sample requests, and to manage inspection assignments. Therefore, it is critical to make sure that the profile is accurate and reflects what the establishment is actually producing and the food safety system it is using to ensure that its products are safe.

For new establishments, the District Office enters information in PHIS to populate parts of the profile and IPP complete the remainder and verify the accuracy of information on an ongoing basis. For existing establishments, IPP maintain and verify accuracy of information on an ongoing basis. During the process of granting inspection, the Grant Curator (GC) is to assign an establishment number and enter information regarding the application for grant of inspection or inspection services. A Frontline Supervisor (FLS), EIAO, or other designated personnel will visit the applicant's establishment and report the information gathered at the establishment which will be used to complete parts of the establishment profile. After the grant process is complete, the assigned inspector-in-charge (IIC) is responsible for keeping the information in the establishment profile up-to-date and accurate as part of their in-plant duties.

The EP information is essential to the Agency's goal of protecting public health because FSIS uses the establishment profile information for generating inspection tasks, determining eligibility for sampling programs, for automated reporting and for ad hoc data analysis. When an establishment begins production of a new product, there is a significant change in product volume, an establishment address changes or there is a jurisdiction change, IPP are to update the establishment profile as soon as the change occurs to ensure the appropriate inspection tasks are being generated. Other changes, not directly related to task scheduling and sampling eligibility, can be completed during the next routine monthly Update Establishment Profile task.

**The following profile features aid in the determination of task scheduling and sampling eligibility and are critical to keep updated and accurate:**

1. **HACCP Processing Category**
2. **Product Volume Information**
3. **Jurisdiction**
4. **Sampling Supplies Address**

Other Establishment Profile information of critical importance includes:

- Grants and Approvals
- Operating Status
- Inspection Activities
- Production Shifts
- Slaughter
- Products produced.

**Grants** include all information related to the Application for Federal Inspection (AFI) and Application for Voluntary Reimbursable Services (AVRS). **Operating Status** is the overall status of the establishment (not just of a particular grant) and is “active” or “inactive”. When Operating Status is “inactive”, no inspection tasks are allocated to the establishment, so it is critical to recognize and correct an “inactive” status as soon as possible. An **Inspection Activity** is one of the following: meat slaughter, meat processing, poultry slaughter, poultry processing, egg product, or imported product. Inaccurate inspection activities indicate that EP information needs changing and as a result the proper tasks may not show up in the establishment task list. **Shift** information is critical to ensure that all shifts receive the appropriate inspection tasks and coverage. Operating Status, Inspection Activities, Grants and Shifts cannot be modified by IPP as it is “Read Only.” However, it is very important that this information is corrected as soon as possible, so IPP should examine it right away. Contact the DO through supervisory channels if it is incorrect.

**Slaughter** includes the slaughter system, inspection system, number of slaughter lines, number of slaughter lines operating simultaneously, maximum line speed, and staffing. **HACCP Processing Categories** are critical because the tasks for each category will only be assigned if reflected in the profile. It is important that **Inspection Tasks** assigned to the establishment’s inspection task list are applicable and no tasks are missing. The **Products** and **Production Volume Information** has an impact on sampling projects and sampling frequencies. The **Jurisdiction** information identifies the government organization that performs inspection of food products at the establishment. The **Sampling Supplies Address** is critical since lab sampling supplies cannot be delivered to the establishment if this information is missing or not accurate. This information can be entered or edited by IPP.

### Performing the Update Profile Task

PHIS will display the routine update profile task on the establishment task list monthly.

- IPP are to perform the routine Update Establishment Profile inspection task monthly by updating the information in the establishment profile with any new information and reviewing the establishment task list. IPP are also to focus on verifying the accuracy of a specific area of the establishment profile each month according to the following schedule:

Table: Establishment Profile Update Schedule	
Month	Profile Information Focus Area
January	<b>Establishment Contacts</b>
February	<b>HACCP Systems Information</b> for Raw-Intact product categories
March	<b>HACCP Systems Information</b> for Raw-Non-Intact product categories
April	<b>HACCP Systems Information</b> for Thermally Processed-Commercially Sterile, Not Heat Treated-Shelf Stable, and Heat Treated Shelf Stable product categories
May	<b>HACCP Systems Information</b> for Fully Cooked–Not Shelf Stable, Product with Secondary Inhibitors–Not Shelf Stable, and Heat Treated but Not Fully Cooked–Not Shelf Stable product categories
June	<b>General Profile Information</b>
July	<b>Product Information</b> for Raw-Intact product categories
August	<b>Product Information</b> for Raw-Non-Intact product categories
September	<b>Product Information</b> for Thermally Processed-Commercially Sterile, Not Heat Treated-Shelf Stable, and Heat Treated Shelf Stable product categories
October	<b>Product Information</b> for Fully Cooked–Not Shelf Stable, Product with Secondary Inhibitors–Not Shelf Stable, and Heat Treated but Not Fully Cooked– Not Shelf Stable product categories
November	<b>Slaughter Information</b>
December	<b>General Profile Information</b>

- IPP are to also perform the Update Establishment Profile task if they become aware while performing other inspection tasks, or through communication with a management official, that the establishment is producing a **new product**. A directed task may be used for this purpose if the routine task has already been performed for that month. IPP perform the update profile task by reviewing and updating the information in the establishment profile. The EP link on the left navigation menu contains the sub-links needed to access the various establishment profile pages. IPP can only edit profile information for establishments in their inspection assignments.
- IPP provide a copy of the EP report to establishment management during the next weekly meeting upon entering a new assignment or following a change to an existing assignment. Management will have an opportunity to affirm or correct any of the profile information in PHIS. When management responds with a correction, IPP are to change their response only after seeing establishment records or other data that is needed to support the basis for the correction. IPP are to resolve any issues or discrepancies regarding profile information before they document the task as completed in PHIS.

To generate the Establishment Profile Report, IPP are to:

- Select the establishment under the **Establishment Profile** tab on the left navigation menu;
- Scroll down to the bottom of the page and find the **Reports** tab; and
- Click on **Reports**, then select **Establishment Profile Report**. This will generate the report that can then be saved or printed.

**Note:** Refer to the PHIS user guide or the PHIS Help Button for step-by-step information.

When performing the **Update Establishment Profile** task, IPP are to gather information from a management official at the establishment or facility and complete or update information as needed. The following parts of the EP will be accessed in making updates:

- Establishment Contacts
- General
- Establishment Task List
- HACCP Systems Information (meat and poultry establishments only)
- Slaughter Information (meat and poultry establishments only)
- Product Information (meat and poultry establishments only)
- Production Volume Information (meat and poultry establishments only)
- Profile Questionnaires

Note: Information concerning Grants and Approvals (Read only), Profile Summary, Operating Schedule, Facilities, Equipment (Thermal Processing), and Training can also be accessed.

## **References**

FSIS Directive 5300.1, Managing the Establishment Profile in the Public Health Information System (PHIS)

PHIS Quick Reference Guide

## PHIS 2 – TASK LIST / TASK CALENDAR

### Objectives

1. Identify the FSIS directive that provides instructions to IPP for scheduling inspection task in PHIS.
2. Define the following terms: Task Library, Establishment Task List, Task Calendar, Routine Task, and Directed Task.
3. Describe how the task list is created for an establishment and how to navigate the features of the task list.
4. Identify situations that require IPP to schedule and perform directed tasks and how to schedule a directed task.
5. Identify the two sections of the PHIS tasks calendar page and how to navigate the features of the page and filter for the inspector and the establishment.
6. Describe the principles that IPP follow when scheduling and performing inspection tasks.
7. Describe the steps that IPP need to perform the first time they log in to PHIS each day.

PHIS, which stands for Public Health Information System, is a web-based application used by FSIS to generate specific tasks for inspection personnel to schedule tasks to perform based on public health risk factors.

The PHIS Task Library is a component of PHIS that lists **all** the different kinds of routine inspection tasks that may be performed by IPP. It also provides a description of each task. The Office of Policy and Program Development staff members maintain the tasks in the task library. Each task is given a priority level and an expected frequency to be performed in a one-month period. The Task Library will also display inspector guidance, mandatory regulations cited, other regulatory concerns, and the specific data to be recorded each time IPP perform the task.

The Task Calendar page is divided into two sections, the Establishment Task List, and the Establishment Task Calendar. The Establishment Task List displays all the tasks which are assigned to the establishment based on the information in the establishment profile. In other words, the establishment task list is the source of routine inspection tasks added on the Task Calendar and performed by IPP assigned to that establishment. The Establishment Task Calendar displays all the scheduled, in-process, completed, and not performed task for the establishment. It provides IPP with the flexibility to schedule tasks on days that work best for their assignments.

### Routine tasks and Directed tasks

- **Routine** tasks are inspection verification activities conducted on a routine, on-going or planned basis under normal conditions. Routine tasks are allocated based on the information in the establishment's profile, e.g., HACCP processing category and products.

- **Directed** tasks are those that do not occur on a routine basis under normal circumstances. These tasks are performed on an as needed basis. Sampling tasks and export certification tasks are considered to be directed tasks because they do not occur on a routine basis. Directed tasks may be initiated in several ways: Positive pathogen result, FSIS headquarters personnel, supervision, and conditions observed in the establishment.

When scheduling tasks, inspection personnel should use the frequency and priority level of each task. They should also utilize their knowledge of the establishment, travel times between inspection assignments, allocate the tasks over the entire month, avoid predictable patterns, and do not schedule too many tasks. If IPP determine that they will not be able to complete all high priority tasks or all directed tasks by the applicable end dates, they are to discuss the situation with their immediate supervisor as soon as possible. The supervisor will be able to advise IPP on how to best arrange the necessary tasks or may be able to spread the necessary work to other IPP.

At the beginning of each work week, IPP should ask establishment management what operations will be conducted and what products will be produced during the week. Based on the information provided by the establishment, IPP may need move, or remove and reschedule inspection tasks. If all of the work cannot be performed on a given day due to the addition of directed tasks, sampling tasks or export certification requests, IPP should adjust the Task Calendar by moving tasks to another day. IPP assigned to the same establishment are expected to coordinate work efforts. This may require reassigning and completing tasks on the Task Calendar that **have not been started** and tasks that have been started (in-progress) but **not completed** from each another. **Note:** An inspector cannot assign a task (work) to another inspector, but an inspector can claim a task (work) assigned to or originally scheduled by another inspector. The ideal situation or overall goal is that IPP complete all routine tasks for the month. In this case, the number of completed tasks would equal the number of planned tasks by the end of the month.

The ideal situation or overall goal is that IPP complete all the routine tasks for the month (**i.e., the number of completed tasks matches the number of expected or planned tasks at the end of the month**). Even though IPP have scheduled all of the expected tasks, there are going to be times when they cannot perform all of them by the end of the month. Those tasks that are still on the Task Calendar that have not been started by the end of the month are marked as “not performed”. IPP must select the appropriate “justification” for not performing the task from a dropdown list in PHIS. Thus, at the end of the month, IPP account for all the expected instances of a task that were on the establishment’s Task List in one way or another.

PHIS maintain information about IPP in-plant assignments. The information available to the IPP is limited to his/her work assignments. However, IPP often cover assignments other than their permanent assignment. The most obvious example is relief inspectors, but other IPP will temporarily cover an assignment that is not their assignment. To access and interact with PHIS while temporarily covering another employee’s inspection duties, IPP must be designated as covering that assignment in PHIS. The temporary coverage does not disrupt the permanent assignment structure but allows IPP to enter information into the system for the coverage assignment. A coverage assignment can be set up within PHIS on a long-term basis and only used when needed, or it can be set up only when the coverage occurs.

**PHIS Daily Activities to Ensure Tasks are Scheduled and Performed when Logging into PHIS for the First Time during the Workday, IPP should (in this order):**

1. Review any new alerts on the dashboard of the homepage. The alerts:
  - Are generated automatically based on data entered into the system and events that occur in the establishment
  - Provide IPP with urgent or critical information
  - May direct IPP to perform additional inspection tasks or take other action
2. Review each establishment's Task List to find any new directed tasks. Directed inspection tasks:
  - Are generated automatically based on data entered into the system
  - May be generated by supervision, the District Office, or Headquarters
3. Review each establishment's task list to find any new sampling tasks.
4. If the establishment exports product, determine if there are any new export requests.
5. Review the task calendar to see what inspection tasks are already scheduled for the week or month.
6. Add any new directed inspection tasks/sampling tasks/export requests to the Task Calendar.

IPP are to consider the priorities of the new tasks relative to the tasks already scheduled on the calendar to ensure that they still complete the most important tasks by the end of the month. For sampling tasks, they need to plan to ensure they can collect the sample during the designated time period.

7. Adjust the Task Calendar, if the work cannot all be performed on a given day due the addition of directed inspection tasks/sampling tasks/export requests.
8. Review any open NRs to determine if they can verify that the establishment has brought itself back into compliance while performing inspection tasks.



	Status in PHIS	Definition
Inspection Task	<b>Not Open</b> Task Color Blue on the calendar	Task has been added to inspector's task calendar. Verification component option has NOT been selected in PHIS
	<b>Open</b> (in-progress) Task Color Yellow on the calendar	Verification component option has been selected in PHIS IPP have begun to enter results

	Status in PHIS	Definition
Inspection Task	<b>Completed</b> Task Color Green on the calendar	<b>All</b> verification has been performed and <b>all</b> results have been entered for the task. If an NR was issued, the NR's status has been updated to "completed." "Inspection completed" box has been marked on "the inspection results" page for the task
	<b>Not Performed</b> Task Color Red on the calendar "if scheduled"	IPP has NOT started the task before its end date (usually the last workday of the month)

## PHIS 3 - INSPECTION DOCUMENTATION, NRS, MOIS, INSPECTOR NOTES, MEETING AGENDA

### Objectives:

Understand how to:

1. Navigate the Inspection Results page
2. Record the result of an inspection task
3. Document the regulations verified
4. Create an inspection note
5. Document an NR
6. Document an MOI
7. Create a meeting agenda

### Documenting Inspection Task Results in PHIS

FSIS uses the results of inspection tasks and information about establishment operations to guide policy development and target Agency resources to those activities that will best protect public health. To assist with these types of decisions, the **Public Health Information System** (PHIS) is designed to capture information about inspection tasks such as:

1. Which regulatory requirements IPP verified, and whether they observed compliance or noncompliance;
2. How IPP verified the regulatory requirements (i.e., recordkeeping, review, and observation, or both).

IPP use PHIS to document the results of their inspection tasks. After IPP perform an inspection task, they are to open the “**Inspection Results**” page for the specific inspection task, select applicable “tabs”, and record their results in PHIS. They are to make the appropriate entries regarding the task and their findings of regulatory compliance or noncompliance by checking appropriate boxes, making appropriate selections from lists, or typing in text. PHIS will allow inspection tasks to extend over more than one day. Thus, IPP may enter partial results on one day and then continue/finish performing the task by entering the remaining results on another day.

The primary method of accessing the Inspection Results page is through the Task Calendar. Other pathways are also available in PHIS for accessing the Inspection Results page. For example, IPP can also access the Inspection Results page using the Inspection Verification left navigation menu. The results of all inspection tasks are documented on the **Inspection Results** page.

## Completing the Noncompliance Record (NR, FSIS Form 5400-4) in PHIS

When IPP determine that the establishment has not met one or more regulatory requirements, they check the “**Regulatory Noncompliance**” box at the bottom of the “Regulations” tab of the Inspection Results page, and then click “Save” in PHIS. Checking the “Regulatory Noncompliance” box enables the “Create/Edit NR button” on the bottom of the Inspection Results page. Much of the information that appears in the sections/blocks on the printed NR is automatically added by PHIS. Some blocks on the printed NR are completed with information entered by the IPP. For instance, the IPP must provide a complete, clear, and concise description of each noncompliance.

## The Role of Inspection Notes

The “Notes” tool enables IPP to document observations, trends, and other issues that relate to establishment operations that should be brought to the attention the establishment. Notes can also be used as memory joggers for IPP to follow-up on a particular observation or issue. For example, IPP should document and discuss less-than-perfect sanitary conditions or execution of establishment procedures and programs with establishment management that at the time do not represent noncompliance but could lead to noncompliance. Inspection notes are maintained within the system in 10 categories: facilities, equipment, sanitation, processing, safety, FSA, food defense, export, support, and records.

There are **several advantages** to entering specific observations into PHIS using the Inspection Notes feature. For instance, entering notes into PHIS can facilitate communication between:

1. IPP in the same assignment;
2. Relief IPP and the assigned IPP;
3. IPP and their supervisors, and
4. IPP and other parts of the FSIS chain of command.

The Inspection Notes tool allows IPP in the same assignment and relief IPP to review findings, issues, or concerns previously observed. By having access to such information, they are better equipped to identify developing problems. They can act to prevent issues that could affect public health. For example, while performing inspection verification tasks, assigned IPP can continue to focus attention on a particular finding, trend, or issue and if necessary, continue to document the establishment’s inability or unwillingness to address or correct the issue before it leads to noncompliance.

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**Note:** The use of inspection notes is not intended to replace documentation of noncompliance on NRs. All regulatory noncompliance should be documented on an NR.  
\*\*\*\*\*

## PHIS Features IPP Use to Document Meetings between IPP and Establishment Management

PHIS has several timesaving features that IPP use to document the mandatory meetings that they have with establishment management. These features enable IPP to work efficiently. First, there is a Meeting Agenda tool for recording the topics to be discussed at the meeting.

Secondly, there is an inspection notes tool to record IPP concerns that do not rise to the level of noncompliance but still need to be discussed with establishment management. The Inspection Notes can be easily transferred to the Meeting Agenda. Lastly, the Memorandum of Interview (MOI) tool creates the official record of the discussion between IPP and establishment management at each meeting.

### **Entrance Meetings**

Upon rotation into an assignment, or when IPP are newly assigned to an establishment, they are to review the establishment's history, which is reflected in the **establishment's homepage in PHIS**. They are to consult with their immediate supervisor if they have questions or concerns about the establishment's history.

After IPP familiarize themselves with establishment's history, HACCP plans, and programs, they are to conduct an **entrance meeting (e.g., the first weekly meeting)** with the establishment management. At this meeting, IPP should inquire about the specific operations of the establishment and seek to answer any questions that came up during their review of the establishment's history or programs. IPP are to ask establishment management about the location of the applicable records and the protocol for FSIS personnel to access and review the records. Establishments are required to provide access to records needed by IPP to perform their duties. However, IPP must review the necessary records in the location specified by establishment management. IPP are not to maintain any copies of the establishment's written programs or data from such programs in the inspection office.

Likewise, IPP are to ask about any previously agreed upon notification (e.g., when IPP need to inform the establishment, they will be collecting a sample) when Agency sampling is performed at the establishment. IPP need to know this information so that an establishment can properly control sampled product pending FSIS test results.

**IPP take notes at the entrance meeting and document the notes in a MOI in PHIS and provide a copy of the MOI to the establishment.**

### **Awareness Meetings**

When new regulations, policies, performance standards, compliance guidelines, or product sampling protocols are published in a Federal Register Notice, FSIS provides information, guidance, and instructions to IPP for verifying the new policy or implementing the new performance standards or implementing the new sampling protocol through either a FSIS Directive or FSIS Notice. The Directive or Notice often directs IPP to conduct an awareness meeting with establishment management upon receipt of notice or directive. The Notice or Directive identifies specific information that IPP are to share with establishment management at the meeting. **IPP take notes at the awareness meeting and document the notes in a MOI in PHIS and provide a copy of the MOI to the establishment.**

### **Weekly Meetings and Agenda Items**

As set out in FSIS Directive 5000.1, IPP are to have weekly meetings with establishment management. IPP are to use the tools in PHIS to record inspection notes, create meeting agendas, document MOIs, and record the performance of weekly meeting tasks. The performance of the weekly meeting **AND** other meetings is documented in PHIS under the "Meeting with Establishment Management" task.

The purpose of the weekly meeting is to provide an opportunity for IPP to address matters that affect the establishment's on-going compliance with FSIS requirements. The discussion of issues during the weekly meeting is not intended to replace documentation of noncompliance on an NR. Moreover, the fact that an issue is not discussed at the weekly meeting does not mean that the issue could not become the subject of an NR.

Meetings should benefit both IPP and the establishment. For instance, it is important that IPP discuss topics pertinent to the establishment's food safety system that could affect public health. IPP are not precluded from asking establishments about any subject of regulatory concern, e.g., recalls, allergen control, etc. Establishment management may wish to share information regarding their operations, such as facility improvements and changes to their food safety systems, or express concerns at the meetings.

A wide variety of topics can be discussed at the meetings, including individual noncompliances, developing trends of noncompliance, and findings by IPP that do not represent regulatory noncompliance but that need to be brought to the attention of the establishment. For example, discussion of information from external sources, such as customer or consumer complaints, can provide information to alert establishment management about a safety risk or about other information that is relevant to the establishment's food safety system.

**Note:** FSIS Directive 5000.1 **requires** IPP to discuss developing trends in noncompliance at the weekly meetings and document the discussion of noncompliance trends and the associated NRs in an MOI. IPP are to discuss any identified associations between current and past noncompliances and describe to establishment management why the associated NRs indicate a trend of noncompliance. It is recommended that IPP explain that continued noncompliance may result in further enforcement actions, to help the establishment understand the consequences of continued noncompliance.

FSIS Directive 5010.1 provides a **general list** of food safety related topics that IPP **may** consider discussing with the establishment during weekly meetings. Given the range of the issues confronting FSIS-regulated establishments, it may be difficult to discuss all of the topics that either FSIS or the establishment wishes to address during any one weekly meeting.

Similarly, IPP should not use the list of topics in FSIS Directive 5010.1 like check list nor should they attempt to discuss all topics listed during a given period of time. The topics in the directive should be discussed as they arise. The list below is not all-inclusive. Possible topics for discussion listed in FSIS Directive 5010.1 include:

1. In-plant observations, e.g., individual NRs, less than perfect conditions that may, if not addressed, become noncompliances, and humane handling/poultry good commercial practices issues;
2. Issues and information that the establishment wishes to share;
3. Agency issuances, e.g., FSIS Notices and Directives and askFSIS questions;
4. Information regarding FSIS sampling;
5. Information related to the establishment's food safety system, e.g., changes to prerequisite programs used to support food safety decisions;
6. Information from external sources, e.g., consumer complaints and recalls; and
7. Any inspection related activities occurring outside of approved hours of operation.

On a periodic basis, about once a month as scheduled using the PHIS “Update Establishment Profile” task, IPP are to ask establishment management at the weekly meeting whether it has made any changes in the production process or other changes that could affect the safety of the product. If IPP learn that establishment management has made a change in its process, based on the nature of the change, IPP are to perform the appropriate verification activities outlined in FSIS Directives 5000.1 and 5000.6. If IPP are unsure how to proceed, they are to contact their supervisor for guidance.

Before the weekly meeting with the establishment, IPP may use the **Meeting Agenda tool** in PHIS to create an outline of the topics to be discussed. The topics discussed at the weekly meeting are dependent upon the events or conditions that occur in the establishment each week. The meeting agenda may be printed and distributed to IPP who will attend the meeting. IPP are to share a copy of the meeting agenda with establishment management when requested. PHIS will enable IPP to link the meeting agenda to an MOI to create an establishment meeting MOI.

When an establishment has multiple inspection shifts and/or multiple assigned IPP, it is the Inspector-in-Charge’s (IIC) duty and responsibility to conduct and document weekly meetings. The IIC:

- Ensures that regulatory concerns that arise on all shifts are discussed at the weekly meetings;
- May delegate conducting the meeting to IPP;
- May include IPP (CSIs or FIs) in the meeting with establishment management;
- Signs all documentation, and
- Ensures that all IPP on all establishment shifts are made aware of regulatory concerns that are discussed at weekly meetings.

When the IIC designates an FSIS employee to conduct the weekly meeting, it **does not** mean that IIC never conducts the weekly meeting or attends the weekly meeting. Depending upon the events occurring (e.g., a product recall, positive pathogen result, humane handling issues or an inadequate HACCP system) or conditions observed (e.g., trends in noncompliance) in the establishment, it may be appropriate for the IIC, or even the FLS, to conduct the weekly meeting or at least be in attendance to assist and support IPP.

**As set out in FSIS Directive 5000.1, IPP are to take notes at the weekly meetings and are to document the notes in a MOI in PHIS. IPP are to provide establishment management with a copy of the MOI.**

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**Note:** If IPP do not conduct a weekly meeting, they are to document this fact and the reason why in an MOI. For example, if establishment management chooses not to attend the weekly meeting, IPP are to document this in an MOI. If IPP cannot conduct the meeting due to the performance of higher priority tasks, such as sampling, IPP are to document this in an MOI.

## For Cause Meetings

As needed, IPP can schedule a meeting with establishment management to discuss urgent issues such as a positive pathogen result, recall, outbreak, or inhumane handling incident.

**IPP take notes at the meeting, document in a MOI in PHIS, and provide a copy of the MOI to the establishment.**

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## Memorandum of Interview (MOIs)

FSIS Directives 5000.1 and 5010.1 and several notices instruct IPP to meet with establishment management and document the outcome of the meeting in an MOI. **An MOI is used to record and convey discussions with establishment or facility management.** The MOI is the written summary of an interview. It should not be a verbatim recitation of the interview, nor does it necessarily have to be written in the same order as the interview was conducted. Instead, it includes the date of the meeting, who was at the meeting, and captures and summarizes critical, relevant information including the specific topics discussed and answers to any questions asked during the meeting.

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**Note:** IPP are not to use the MOI as a means to document daily conversations with establishment employees.

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IPP can create and document the following MOIs in PHIS:

- Establishment Meeting
- Standard
- Domestic Food Defense
- Import Food Defense

An MOI is a very important inspection tool for IPP because it documents the fact that IPP maintain open lines of communication with official establishments. For instance, after the weekly meeting, IPP are to prepare either an establishment meeting MOI or a standard MOI in PHIS to document the agenda items covered in the meeting and document any establishment responses. IPP are to document any discussion of noncompliance trends and NR associations at the weekly meeting in the MOI. Open NRs and NRs under appeal may be linked to an establishment meeting MOI or a standard MOI in PHIS.

An MOI can **also** document a variety of other issues including, but not limited to the:

- Discussion of a new inspection policy transmitted through a FSIS notice (e.g., a directed awareness meeting);
- Performance of records review in accordance with FSIS Directive 5000.2, and
- Performance of specific verification activities (e.g., supplier tracking information and humane handling) as deemed necessary by FSIS.

If establishment management provides no response to issues/concerns, this fact should be recorded in the MOI.

IPP are to maintain a copy of the MOI in the official government file and must provide a copy of the MOI to the establishment. When the MOI is provided to the establishment or facility, it is designated as “finalized” in PHIS.

MOIs can be used to track the establishment’s history of responding to issues/conditions in the establishment that are not noncompliance but can lead to noncompliance if conditions worsen or if the establishment doesn’t act upon the information the IPP has given the establishment, e.g., less than perfect execution of prerequisite program. If the situation has been documented in a MOI on numerous occasions, it would be hard for the establishment to say it didn’t know the issue/condition could lead to noncompliance when it finally results in noncompliance documented on an NR.

If an establishment objects to any part of the MOI, IPP are to document the objection at the end of, or as an attachment to, the MOI. If the establishment’s objection is in writing, IPP are to attach the written objection to the MOI. When the establishment’s written objection is transmitted electronically, e.g., e- mail or other file format, IPP can upload the file in PHIS and save the document as an attachment to the MOI record. IPP provide a copy of the amended MOI to the establishment. MOIs can be reviewed by the Frontline Supervisor.

### ***Tips for Writing MOIs***

- Write the MOI as soon as possible after conducting the meeting. “Cold notes” are difficult to understand.
- Document who attended the meeting, the topics that were discussed, and what was said at the meeting. Document only the facts and not any opinions.
- Use quotations only when directly quoting a person. *Example: Mr. Adams said, “I told Ms. Popadoupolis, the Food Safety Manager, that the SSOP and HACCP records need to be available to the second shift inspector. “Ms. Popadoupolis said she would take care of it.”*
- Paraphrasing is generally a safer way of relating what someone said since it is difficult to capture the verbatim account when a person is speaking quickly.
- When paraphrasing, use words like “said” and “stated” to maintain a neutral tone. *Example: “Mr. Adams stated that Mr. Wallace, the Maintenance Manager, is waiting for a quote to repair a large section of epoxy flooring outside the smokehouses and rack wash area.”*
- Do not use “claimed” as a synonym for “said” because this verb has an undertone of blame and mistrust. *Example: “Mr. Wilson claimed he was not present during pre-operational sanitation inspection.” (This sounds as though we do not believe him.)*
- When discussing several people of the same sex, restate the name to prevent confusion. *Example: “Mr. Irvine said that he told his Quality Assurance Manager that not making the SSOP and HACCP records available to the second shift inspector was a violation of the USDA regulations and that he will develop a method of making them available.” (Who will develop a method of making the records available? Mr. Irvine or the Quality Assurance Manager?)*
- Use the first person for your observations. *Example: “I asked Mr. Irvine to tell me which office he contacted within the FSIS.”*



- Use the third person to relate information about the interviewee. *Example: “Ms. Jones said she was the acting HACCP Coordinator of the establishment during the Food Safety Assessment.”*

### **Creating Inspection Notes**

The PHIS inspection notes feature is designed to be helpful to IPP in several ways: First, inspection notes help foster communication between IPP assigned to the establishment across days and shifts. Secondly, they provide a way to capture inspection findings that do not rise to the level of noncompliance but still need to be discussed with establishment management.

Lastly, PHIS provides a mechanism for easily transferring these notes into a meeting agenda for the weekly meeting and MOIs.

### **Creating a Meeting Agenda**

FSIS Directive 5000.1 requires IPP to conduct entrance meeting and weekly meetings with establishment management. Some FSIS Notices require IPP to conduct an awareness meeting with establishment. Conditions in the establishment and some inspection findings may require IPP to have non-routine meeting with establishment management, e.g., a positive pathogen or positive residue sample result, humane handling issues, or a recall. These are often referred to as for cause meetings. A wide variety of topics can be discussed at the meetings, including individual noncompliances, developing trends of noncompliance, and findings by IPP that do not represent regulatory noncompliance but need to be brought to the attention of the establishment. IPP can use the meeting agenda tool in PHIS to create an agenda for the meeting.

The PHIS agenda feature lets IPP select inspector notes and import those notes into a meeting agenda. This allows IPP to include appropriate entries from the PHIS inspector notes feature into a draft agenda in preparation for the weekly meeting. Some inspector notes may be memory joggers for the IPP or just to convey information to IPP assigned to the same establishment that may not need to be a discussion item at the weekly meeting with the establishment. When there are no inspection notes that need to be discussed at the weekly meeting, IPP will use the Agenda tab to add discussion topics to the meeting agenda.

Inspection notes are placed in the agenda “as is” and may need some editing and additions such as introduction and conclusion text before completing the meeting agenda.

IPP may add additional topics to the agenda that they did not enter in as inspector notes that they feel need to be discussed at the weekly meeting. If the IPP feels that a particular noncompliance on an open NR needs to be discussed with establishment management at the weekly meeting, IPP should associate the open NR with the Meeting Agenda.

### **Conduct the Meeting**

Now that the IPP has created the establishment meeting Agenda, he or she would log off PHIS and conduct the meeting. IPP use the Agenda to assist in the organization and focus of the meeting. IPP are required to take notes and document the outcome of the meetings they have with establishment management. An MOI is used to record and convey IPP discussions with establishment or facility management.

**Creating an Establishment Meeting MOI from the Agenda**

After the meeting, IPP document the outcome of the meeting on the MOI. IPP should include the establishment's response to regulatory and non-regulatory concerns discussed at the meeting.

## 34 FOOD SAFETY SYSTEMS THINKING

### Objectives:

1. Define “System” as it applies to FSIS.
2. Name the components of a Food Safety System.
  - a. How they are interconnected
  - b. What influences the system
3. Describe the process of:
  - a. Gathering information from verification activities
  - b. Assessing the findings and any associations or trends
  - c. Determining compliance and system effectiveness
4. Describe how to respond to systemic problems in establishments.
5. Given examples or scenarios, be able to apply the Systems Thinking approach to reach a conclusion about the overall Food Safety System.

### System Definition

(FSIS Definition) – A coordinated body of methods or a scheme or plan of procedures.

### Food Safety System

Purpose: produce safe, wholesome, unadulterated food

#### Components:

- HACCP Plan in Operation including the Hazard Analysis, HACCP Plan, HACCP Records, Supporting Documentation (i.e., Prerequisite Programs, SOPs)
- SPS
- SSOP
- GMPs

All of the parts/components are connected and must work together to achieve the overall goal. Facilities, employees, and equipment are also parts of the system along with the components discussed.

### Influences on the System

- External disturbances
  - Example-environmental factors (e.g., extreme cold, extreme heat, power outages)
  - Establishments may take actions to minimize the effects on their system (e.g., continuous monitoring devices, additional cooling/heating units, generators)

- Internal disturbances (non-static)
  - Example-equipment wear
  - Establishments will often have maintenance programs (i.e., preventative and ongoing) and monitoring of the equipment for wear
- Faults or variations
  - Non-common-usually large variations (e.g., boiler malfunction) that require immediate reaction
  - Common or Normal Variation-usually small in nature, performance variations that often do not require immediate reaction to remain steady

### **Systems Approach**

IPP will implement the GAD thought process while performing verification tasks and evaluating the overall system.

- **Gather** all relevant information needed to determine compliance
- **Assess** the information gathered
  - Answer the question, “What does the information gathered say about the Food Safety System and how it is functioning?”
  - Also consider: Is it improving or declining over time, is the issue occurring repeatedly and consistently, and is the establishment responding appropriately.
- **Determine** if the findings support compliance with the regulatory requirements
  - Consider the findings in the context of the whole Food Safety System (systems approach)

Each finding is to be evaluated regarding the effectiveness of the system and any potential for product adulteration as a result. IPP will document their findings in PHIS.

**Example:** *IPP may identify many minor concerns with the Hazard Analysis, which by themselves may not be noncompliance. When each concern is considered in context of the whole system together, they may indicate a systemic problem.*

IPP should consider:

- Is the piece of information part of a pattern?
- Is there other information to indicate the system is working or not?
- Does the information agree with the other available information about the Food Safety System?

- Do these results support each other, or is there an apparent contradiction?

When IPP determine there is noncompliance they are to consider if the current finding is associated with past noncompliance for similar issues or if associated with other past findings that did not result in a noncompliance.

Examples of past findings not documented in an NR that may be associated:

- Establishment positive sample results
- Corrective actions in response to a deviation
- Recent HACCP reassessments
- Changes in source material, supporting documentation/programs, facilities and/or equipment, or sanitation procedures
- Remember that when determining associations between noncompliances this may also include NRs documented during an FSA performed by an EIAO
- While determining if associations exist, IPP are to be looking for a pattern or trend that may be developing. This may include repetitive noncompliances or a pattern of repetitive findings not documented as noncompliance

**Example:** *If there are repetitive positive results from either FSIS or Establishment testing these results collectively may indicate ineffective prevention of insanitary conditions, direct product contamination, or product adulteration*

### **Assessing Trends**

When IPP determine that an NR is associated with previous findings they are to:

- Assess the significance of the findings in context with the Food Safety System
- Document how the noncompliance is related to previous NRs or other findings using the Inspection Notes feature in PHIS, describing the reason for the association
- Work with FLS to determine how the findings affect the overall Food Safety System
  - If potential systemic problems found—FLS will contact the DO

### **Notification of Supervisory Chain**

Supervisor: IPP will reach out to the supervisor when:

- Questions regarding findings/observations
- Concerns with hazard analysis
- Concerns there are systemic problems with the Food Safety System

- Reason to believe product have become adulterated
- Findings suggestive of a pattern or trend
- Questions/concerns about establishment testing results
- Repetitive noncompliances are documented

FLS: The FLS is to be notified when IPP:

- Identify associations between current and past noncompliances
- Identify associations between current noncompliances and other related past findings not in an NR

**\*Note:** There should be open communication between IPP and the FLS regarding findings and developing trends. The FLS may provide support in assessing the significance of findings and associations.

### **Weekly Meetings**

IPP are to hold weekly meetings with the establishment management and discuss any identified associations and describe the reasons these associations indicate a trend of noncompliance or systemic problems with the Food Safety System. IPP are to discuss these findings with the FLS, either before or after the meeting.

IPP may use the tools in PHIS to develop the agenda for the weekly meeting. After the conclusion of the meeting, IPP need to document the weekly meeting in an MOI capturing:

- What was discussed in the meeting
- Any outcomes and establishment responses

### **Systems Approach Examples**

#### Scenario 1:

IPP documented noncompliance with **9 CFR 417.5(a)(3)** this week at Establishment D when they observed during the Records Review component of the Fully Cooked-Not Shelf Stable HACCP verification task that the establishment did not monitor their cooking CCP at the frequency specified in the RTE HACCP plan during one day of production. IPP also noted that the records showed the establishment identified a HACCP deviation at their cooking CCP on the following day where the same product did not meet the critical limit for the minimum cooking temperature. The establishment documented corrective actions in response to the deviation to ensure product was not overlapping on the cooking conveyor belt. IPP reviewed additional records and determined that the establishment had also not performed thermometer calibration verification procedures at the frequencies specified in their HACCP plan. Even though the establishment identified the CCP deviation and took corrective actions as required, IPP documented the association in an inspection note. **IPP specifically documented the association between the missed CCP checks identified by IPP, missed thermometer calibration procedures identified by IPP, and the CCP deviation identified by the**

**establishment because this association may indicate a problem with the establishment's monitoring procedures to ensure the critical limits are met and products are cooked to lethality. IPP notified the FLS** of their observations and the concern that there may be a systemic problem with the establishment's ability to support their food safety programs. The FLS notified the DO of the findings by IPP and the DO took an enforcement action against the establishment in accordance with Rules of Practice 9 CFR 500.4(a) due to the establishment's inadequate HACCP system.

**Scenario 2:**

IPP documented noncompliance with 9 **CFR 416.13(a)** this week at Establishment B after performing the Pre-Operational SSOP Review and Observation task and identified residue from the previous day's production on an RTE food contact surface that was released by the establishment for production. IPP is aware that the establishment has a history of associated pre-operational sanitation noncompliances for similar findings in the RTE area. IPP reviewed additional noncompliance history and identified SPS NRs, including noncompliances for employees who did not change their garments when moving from the raw production area to the RTE room, chipping floor tiles in the RTE room that could harbor pathogen growth, and use of high-pressure hoses that led to contamination of RTE food contact surfaces (FCS) in production. IPP also reviewed the establishment's recent test results for aerobic plate count (APC) testing that the establishment included in their Sanitation SOPs and identified an increasing trend in APC findings. IPP reviewed the documented corrective actions for the test results and noted that the establishment re-cleaned and sanitized the affected FCS, collected follow-up APC samples, and retrained employees. IPP identified that the establishment documented the same corrective actions for every APC sampling result collected in accordance with the establishment's written Sanitation SOPs. **IPP notified the FLS** of their observations and the concern that there may be a systemic problem with the establishment's ability to support their sanitation procedures and corrective actions. The FLS notified the DO of the findings by IPP and the DO scheduled an EIAO to perform a Food Safety Assessment to evaluate if the Sanitation SOPs are adequate.

## **PHIS 4 - SAMPLE MANAGEMENT**

### **Objectives**

1. Describe the difference between directed samples and collector generated samples.
2. Schedule a directed sampling task.
3. State the purpose of the laboratory capacity reservation system.
4. Document a directed sampling task.
5. Cancel a scheduled sampling task from the Task Calendar.
6. Check laboratory results.
7. Print laboratory forms.
8. Describe the method of collecting a sample for establishments with no internet access.

### **General Instructions:**

- IPP review relevant FSIS Directives and Notices applicable to the sampling program before collecting the sample.
- IPP utilize the PHIS Quick Reference and Users Guides for detailed instructions on the sample management feature of PHIS.
- IPP answer the sample questionnaire, submit it, then print the lab sample form, sign it, and place it in sample box.
- IPP follow the instructions in FSIS Directive 7355.1 for packaging, sealing sample boxes, and maintaining the integrity of samples submitted to the lab.

The Sample Management feature of PHIS streamlines scheduling, assigning, documentation, and tracking of FSIS's sampling tasks. IPP have the flexibility to schedule sample collection within the constraints of their particular assignment and the availability laboratory resources.

### **Sampling Verification Programs and Sampling Tasks**

FSIS administers three sampling verification programs:

- Microbiological sampling for food borne pathogens such as for *E. coli* O157:H7 on raw beef products, Salmonella sampling for raw products, and Listeria monocytogenes and Salmonella on ready-to-eat (RTE) products.
- Carcass/tissue (kidney, liver, heart, or spleen) sampling for drug and chemical residues (antibiotics, pesticides, and heavy metals) to ensure that residue tolerance or action level established by FDA and EPA are not violated.



- Carcass/tissue sampling for pathology determinations (e.g., disease conditions, wholesomeness, etc.) to determine if there is a risk to humans handling or consuming the meat or poultry products.

Lab sampling tasks fall into two collection types:

1. Directed Sampling task
2. Collector Generated sample

**Directed Sampling Tasks** displayed on the **Establishment Task List** are based on the sampling verification programs for which the establishment is eligible. Eligibility for a specific sampling program is determined by information entered in the establishment's profile in PHIS such as the slaughter class, type of product produced or processed, and production volumes. One or more directed lab sampling tasks may be created by an authorized user (typically at the Headquarters or District level) and directed to specified establishments. IPP must use the Establishment Task List and Task Calendar when scheduling or collecting **a directed sample**. For each lab sampling project, IPP will add the sampling tasks on their Task Calendar.

Scheduling the task, reserving lab capacity, and documenting the collection of all directed sample requests is done through the Task Calendar and not the sample management left navigation menu in PHIS.

**Collector Generated Samples** are **not** displayed on the Establishment Task List.

For *all* collector generated samples, the IPP will need to create a sampling task in PHIS by determining laboratory capacity, scheduling the collection date, and documenting the collection of the sample. The mechanism for scheduling a sampling task and documenting collector generated samples varies in PHIS.

### **PHIS Laboratory Capacity Reservation System**

PHIS allows IPP to schedule sample collection tasks using the **PHIS Laboratory Capacity Reservation System**. The laboratory reservation system alerts the laboratory to expect the sample and ensures that FSIS laboratory resources will be available on the day the sample arrives. The requested collection date will be checked against the laboratory capacity and reservation module of PHIS. Confirmation will be provided indicating that there is available laboratory capacity on the requested collection date for the type of sample being collected. If capacity is not available, IPP are to select an alternate date. Once sample scheduling is completed, PHIS will display the address of the FSIS Laboratory that is scheduled to receive and analyze the sample.

Remember:

- Sampling tasks should be scheduled to the task calendar using a realistic collection date based on the plant's production schedule. This should be done as early as possible to ensure a capacity slot is available for the desired collection date. Once the sampling task has been moved from the task list to the calendar, a capacity slot is reserved to accommodate the scheduled sample (see FSIS Directive 13,000.2).

- Scheduled sampling tasks should be canceled or rescheduled as soon as IPP are aware they will not collect on a scheduled date so capacity slots can be released for others to use.
- Waiting to schedule sampling tasks in the last few days of the collection window may result in no capacity being available.
- Sampling for low and infrequent producers should be scheduled as far in advance as possible.

### **General Instructions for Performing Sampling Tasks in PHIS**

The FSIS laboratory is completely dependent on IPP to properly collect, prepare, and ship the sample. The FSIS Sampling Form that accompanies each sample must be completely and accurately filled out. The IPP role in the sampling process is vital. The information entered on the form becomes part of a legal document. If mistakes are made during the collection of the sample or on the form, the lab will discard the sample.

### **References:**

- FSIS Directive 13,000.2, Performing Sampling Tasks in Official Establishments using the Public Health Information System
- FSIS Directive 10,800.1, Residue Sampling, Testing and Other Verification Procedures under the National Residue Program for Meat and Poultry Products
- FSIS Directive 10,800.2, Residue Sampling and Testing under the National Residue Program
- PHIS Users Guide

## PHIS 5 - ANIMAL DISPOSITION REPORTING (ADR)

### Objective:

Perform the following functions in PHIS:

1. Specify weight reporting frequencies
2. Record No Kill periods
3. Enter livestock inspection results
4. Record custom slaughter data
5. Enter poultry inspection results
6. Print condemnation certificates

### Animal Disposition Reporting

Inspection findings by Inspection Program Personnel (IPP) during ante-mortem and post-mortem inspection that identify diseased animals or carcasses, must be reported in PHIS in Animal Disposition Reporting. The IPP is responsible for collecting, storing, and reporting information on the disposition of livestock and poultry presented for slaughter at all official Federal and Talmadge-Aiken establishments. Within PHIS, IPP are authorized to create and edit several types of animal disposition data within the system.

Daily dispositions for livestock slaughter establishments are entered on a **per shift** basis. If there are two slaughter shifts, then data will be entered for both shifts. Daily dispositions for poultry slaughter establishments are entered on a **per lot** basis. The establishment is responsible for designating the lots.

Disposition data is associated with the actual day of slaughter, not the date that the information is entered into PHIS. Whenever possible, ADR data should be entered at the end of shift.

In PHIS, only the post-mortem carcass dispositions made by the PHV (carcasses railed out to the PHV) are entered into PHIS. The individual entries will have the retain tag number, and there is a free text narrative box to record additional information.

Condemnation certificates can be automatically generated by PHIS for both AM and PM condemnations. These certificates can be printed out and signed.

Animal Disposition will be the portal for collecting data on in-plant residue screening test results (KIS™) and for requesting laboratory confirmation of presumptive positive test results. Each residue screening test result will be individually associated with the AM or PM disposition decision for that carcass.

Additionally, ADR will be the portal for collecting the number of Brucellosis and Tuberculosis samples taken, along with BSE sample information.

## **References**

PHIS Users Guide – USDA Intranet

FSIS Directive 6100.1, Ante-Mortem Livestock Inspection

FSIS Directive 6100.2, Post-Mortem Livestock Inspection

FSIS Directive 6100.3, Ante-Mortem and Post-Mortem Poultry Inspection

FSIS Directive 6170.1, Ratite Ante-Mortem and Post-Mortem Inspection

FSIS Directive 10,800.1, Residue Sampling, Testing and Other Verification Procedures under the National Residue Program for Meat and Poultry Products

## PHIS SIMULATIONS

There are 16 training simulations that will familiarize you with navigating and using the Public Health Information System (PHIS) to document various inspection tasks. The instructor will introduce each simulation and then provide time for you to review the simulation on your own in the FSIS Training Site. Please follow the instructions in the simulation and click on the various buttons and targets to complete each simulation. Depending on the strength of your internet connection, the simulation may load slowly.

Link to PHIS Simulations in the FSIS Training Site:

<https://fsistraining.fsis.usda.gov/course/view.php?id=46>

### 1 - PHIS Navigation

This lesson introduces the PHIS navigation process.

**Objective:** Upon completing this lesson, you will be able to describe how to navigate through PHIS features and pages

- Log into PHIS
- Homepage
- My Dashboard tab – Alerts, My Tasks, Inspection Results, Smart Links
- My Establishments tab – My Establishments, Non-Compliance Record, FSA
- My Inspections and Samples tab – Inspection Agenda, Inspection Note, Lab Sample Collection
- Left Navigation Menu

### 2 - SPS Verification Task

This lesson introduces the SPS Verification Task – compliance scenario.

**Objective:** Upon completing this lesson, you will be able to describe how to complete the SPS verification task in PHIS.

- Schedule the SPS Verification Task from the Task List to the Task Calendar
- Document the task
- Inspection Results
- Activity Tab – Select verification activity (review and observation, record keeping, both)
- Regulations Tab – Check mandatory regulations and any other regulations verified
- Create an Inspection Note

### 3 – Pre-Operational SSOP Review and Observation Task

This lesson introduces the Pre-Operational Sanitation Standard Operating Procedures (SSOP) Review and Observation Task – Noncompliance scenario.

**Objectives:** Upon completing this lesson, you will be able to: 1) Describe how to document noncompliances in PHIS, and 2) Describe how to complete the Pre-Operational SSOP review & observation task in PHIS.

- Schedule Pre-Op SSOP Review and Observation Task from the Task List to the Task Calendar
- Document the task
- Inspection Results
- Activity Tab – Select verification activity (review and observation, record keeping, both)
- Regulations Tab – Check mandatory regulations and any other regulations verified, check Regulatory Non-Compliance box
- Create/Edit NR
- Add Noncompliance, check noncompliant regulation(s), type Noncompliance Description
- Print NR, view NR, edit NR, Finalize NR
- Verify Corrective Actions, Complete NR
- Complete the task

#### **4 - Operational SSOP Review and Observation Task**

This lesson introduces the Operational Sanitation Standard Operating Procedures (SSOP) Review and Observation Task – Compliance scenario.

**Objectives:** Upon completing this lesson, you will be able to describe how to complete the operational SSOP review & observation task in PHIS.

- Document the task
- Inspection Results
- Activity Tab – Select verification activity (review and observation, record keeping, both)
- Regulations Tab – Check mandatory regulations and any other regulations verified
- Complete the task

#### **5 - HACCP Verification Task**

This lesson introduces the HACCP Verification Task scenario.

**Objective:** Upon completing this lesson, you will be able to describe how to complete the HACCP Verification task in PHIS.

- Document the task
- Inspection Results
- Activity Tab – Select verification activity (review and observation, record keeping, both)
- Regulations Tab – Check mandatory regulations and any other regulations verified
- Complete task

#### **6 - Poultry Zero Tolerance Verification Task**

This lesson introduces the Poultry Zero Tolerance Task – Compliance scenario.

**Objective:** Upon completing this lesson, you will be able to describe how to complete the Poultry Zero Tolerance Verification task in PHIS.

- Document the task
- Inspection Results
- Activity Tab – Select verification activity (review and observation, record keeping, both)
- Regulations Tab – Check mandatory regulations and any other regulations verified
- Complete task

## **7 - Livestock Zero Tolerance Task**

This lesson introduces the Livestock Zero Tolerance Task – Noncompliance scenario.

**Objectives:** Upon completing this lesson, you will be able to: 1) Describe how to complete the Livestock Zero Tolerance Verification task in PHIS and 2) Describe how to document noncompliances in PHIS.

- Document the task
- Inspection Results
- Activity Tab – Select verification activity (review and observation, record keeping, both)
- Regulations Tab – Check mandatory regulations and any other regulations verified
- Create/Edit NR
- Add Noncompliance, check noncompliant regulation(s), type Noncompliance Description
- Print NR, view NR, edit NR, Finalize NR
- Verify Corrective Actions, Complete NR
- Complete task

## **8 - Scheduling and Submitting a Salmonella/Campylobacter Poultry Parts Sample**

This lesson introduces the scheduling and submitting of a Salmonella/Campylobacter poultry parts sample in PHIS.

**Objectives:** Upon completing this lesson, you will be able to: 1) Describe how to create a lab sampling task in PHIS and 2) Describe how to submit a lab sample in PHIS.

- Filter Task List by Establishment
- Filter Task by Lab Sampling
- Add the Sampling for Chicken Parts – Legs, Breasts, and Wings Task.
- Select the Collection Date and View Laboratory Capacity
- Document the task
- Select Sample
- Complete Sample Collection Data
- Take Questionnaire and Submit
- Print Form
- Submit to Lab

## **9 - Creating Inspection Notes, Meeting Agendas, and MOI**

This lesson introduces how to create inspection notes, agendas, and Memorandum of Interviews (MOIs) in PHIS.

**Objectives:** Upon completing this lesson, you will be able to describe how to create inspection notes, agendas, and MOIs in PHIS.

- Select Establishment
- Inspection Notes
  - Create Note
  - Select Category
  - Enter Text
- Meeting Agendas
  - Create Agenda
  - Select Meeting Date, Time, Subject, and Attendees
  - Comment List
  - NR

- MOI
  - Meeting Agendas
  - MOI - Meeting
  - Agenda Text Box
  - NR
  - Review
  - Finalize
  - Print

## 10 - Livestock Humane Handling Task

This lesson introduces the livestock humane handling task.

**Objective:** Upon completing this lesson, you will be able to describe how to complete a livestock humane handling task in PHIS.

- Document the task
- Inspection Results
- Activity Tab – Select verification activity (review and observation, record keeping, both)
- HATS Tab (Humane Activities Tracking System)
  - Select HATS categories verified
  - Enter Duration (minutes/hours) in 15-minute intervals
- Regulations Tab – Check mandatory regulations and any other regulations verified
- Complete task

## 11 - Establishment Profile – Add a HACCP Plan

This lesson introduces the PHIS Establishment Profile navigation process.

**Objectives:** Upon completing this lesson, you will be able to add a new HACCP plan to an establishment's profile

- Step 1: Click Establishment Profile
- Step 2: Click Open on the establishment row.
- Step 3: Click on the **HACCP Tab** for the establishment.
- Step 4: Click on the HACCP Plans Tab
- Step 5: Click on Add a HACCP Plan above the grid
- Step 6: Click the Signature date and select the date on the calendar
- Step 7: Click on Plan Name and enter the name of the plan
- Step 8: Click on the Processing Categories box for the product type
- Step 9: Click on Add
- Step 10: The HACCP Plan has been added to grid, click Exit Profile

## 12 - Establishment Profile – Updating Production Volume

This lesson introduces the PHIS Establishment Profile navigation process.

**Objective:** Upon completing this lesson, you will be able to explain the steps CSIs take to update an establishment's production volume.

- Step 1: Click Establishment Profile
- Step 2: Click Open on the establishment row
- Step 3: Click on the **Products Tab** for the establishment



- Step 4: Click Open for the Raw-Intact/Raw-Intact Chicken/Chicken/Poultry (Leg, Breast, Wings ONLY)
- Step 5: Click Edit
- Step 6: Click the Drop down arrow for the Average Daily Volume. Select 50,001-250,000. Click Update
- Step 7: Click Save HACCP Volumes. The HACCP Volumes have been updated in the grid.

### **13 - Establishment Profile – Updating and Adding an Establishment Contact**

This lesson will introduce you to the procedure to update and add an Establishment Contact.

**Objective:** Upon completing this lesson, you will be able to explain the steps CSIs use to update and add an establishment contact.

- Step 1: Click Establishment Profile
- Step 2: Click Open on the establishment row
- Step 3: Click on the Facility Tab for the establishment
- Step 4: Click on the Contacts Tab
- Step 5: Click on Open on the contact's row to be updated
- Step 6: Click inside the First Name box, enter the replacement first name
- Step 7: Click inside the Last Name box, enter the replacement last name
- Step 8: Click inside the Email Address box, enter the replacement email address
- Step 9: Click Save
- Step 10: The establishment contact has been edited, to Add a new establishment contact, Click Add a New Contact
- Step 11: Click inside the box for Responsibilities and select from the drop-down menu
- Step 12: Click inside the First Name box, enter the first name
- Step 13: Click inside the Last Name box, enter the last name
- Step 14: Click inside the Phone Number box, enter the phone number
- Step 15: Click inside the Email Address box, enter the email address
- Step 16: Click Yes or No if the person is a Primary Contact
- Step 17: Click Yes or No if the person is an After-Hours Contact
- Step 18: Click Yes or No if the person should receive NR Notification
- Step 19: Click Yes or No if the person is a Billing Contact

Step 20: Click Add button

Step 21: The new contact has been added to grid

## 14 – Hazard Analysis Verification (HAV) Task

This lesson introduces the HAV task.

**Objective:** Upon completing this lesson, you will be able to describe how to complete an HAV task and document a noncompliance in PHIS.

- Document the task
- Inspection Results
- Activity Tab – Select verification activity (review and observation, record keeping, both)
- Regulations Tab – Check mandatory regulations and any other regulations verified
  - Check Regulatory Non-Compliance box
  - Create/Edit NR
  - Noncompliances Tab, Add noncompliance
    - ❖ Check Regulation(s) Found Noncompliant
    - ❖ Type Noncompliance Description, complete the rest of fields
    - ❖ Save, view draft, check Noncompliance Finalized box, print
    - ❖ Check NR completed box after you have verified establishment is back in compliance
- Take Questionnaire
- Complete task

## 15 – Animal Disposition Reporting - Poultry

This lesson introduces the Animal Disposition Reporting (ADR) section in PHIS.

**Objective:** Upon completing this lesson, you will be able to describe how to record a no kill period in the ADR section and describe how to enter poultry slaughter and disposition data in o the ADR section.

- Click on Animal Disposition on the left navigation menu
- Select No Kill Period
  - Select Establishment name, click on Add No Inspected Slaughter Period
  - Enter Start and End dates, select Reason Code, save
- Select Establishment Reporting to enter slaughter data
  - Select Establishment name, date, click on Add Slaughter Record
  - Enter Sub-Class, Lot Number, Head Count, and weights
  - Enter head counts, weights, and Post-mortem Carcass Condemnation Details
  - Repeat steps for each Sub-Class and Lot
  - Print the condemnation certificate for each lot

## 16 – Animal Disposition Reporting - Livestock

This lesson introduces the Animal Disposition Reporting (ADR) section in PHIS.

**Objective:** Upon completing this lesson, you will be able to describe how to report the weight reporting frequency in the ADR section and describe how to enter livestock slaughter and disposition data into the ADR section.

- Click on Animal Disposition on the left navigation menu
- Select Weight Reporting Frequency
  - Select Establishment name then Slaughter Frequency
- Select Establishment Reporting to enter slaughter data
  - Select Establishment name, date, click on Add Slaughter Record
  - Enter Sub-Class, Head Count, and weights
  - Enter head counts, weights, and Post-mortem Carcass Condemnation Details
    - ❖ Option to use Add Multiple Disposition Records
  - Edit Disposition Record as needed
  - Print the condemnation certificate

### **References:**

FSIS Directive 13,000.1 - Scheduling In-Plant Inspection Tasks in the Public Health Information System (PHIS)

FSIS Directive 13,000.2 - Performing Sampling Tasks in Official Establishments Using the Public Health Information System

## Case Studies: Scenario-Based Learning

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Use the information below to navigate through case-study scenarios and apply what you've learned during the Inspection Methods training. If you get stuck or identify a topic you need to revisit further, make a note and continue on with the scenario. You can note the slide number (upper right corner, e.g., **L-1**) for reference.

Don't worry if you make a mistake – you will have multiple opportunities to try if you don't get it right the first time. You can select “Back” to try again. After you complete the scenario, the trainers will review key points and answer any questions you noted.

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**Note:** In each scenario, you can choose any task first. Prior to completing the scenario, you will complete all the tasks.

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1) **Livestock Slaughter/Processing Scenario**

- a. Part I – Familiarize yourself with the establishment
- b. Part II – Complete Livestock Zero Tolerance, Operational SSOP Review and Observation, and SPS Verification tasks

2) **Poultry Slaughter/Processing Scenario**

- a. Part I – Familiarize yourself with the establishment & complete Pre-Op SSOP task
- b. Part II – Complete Poultry Zero Tolerance and Slaughter HACCP tasks

## **#1 - LIVESTOCK SLAUGHTER/PROCESSING SCENARIO**

**L-3** Background: Congratulations! You are a new CSI assigned to a very small livestock slaughter and processing establishment, M8765. It's your first day on the job, and you want to familiarize yourself with the establishment.

**A. *Livestock Scenario Part I – Familiarize***

**L-4** Review the establishment profile. Notes:

**L-7/9** Review establishment programs (HACCP, Sanitation SOPs, Prerequisite programs). Notes:

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**Questions to consider:**

Which SSOP regulations correspond to which parts of the Sanitation SOPs?

What are some examples of this establishment's Prerequisite Programs?

What are the CCPs at this establishment?

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**L-8** Match the Sanitation SOP regulations to the corresponding Sanitation SOP. Notes:

**L-12** Review FSIS Directive 5000.1 for information on conducting an Entrance Meeting.

---

**Questions to consider:**

What types of content would you include in an entrance meeting?

After conducting an entrance meeting, how will you document the meeting? After documenting the meeting, what will you share with the establishment?

---

**L-13** Type the topics you plan to discuss at the entrance meeting. Notes:

**L-16** Review the example MOI. Notes:

**L-17/18** Review your PHIS Task list. Review FSIS Directive 13,000.1.

---

**Question to consider:**

How would you prioritize scheduling tasks in PHIS?

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**B.     *Livestock Scenario Part II – Complete 3 inspection tasks***

**L-20** Choose which task to complete first: Livestock Zero Tolerance, Operational SSOP Review and Observation, or SPS Verification.

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**Note:** you can choose any task first. Prior to completing the scenario, you will complete all three tasks.

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**Livestock Zero Tolerance task**

**L-21** Review FSIS Directive 6420.2 for information on how to conduct a Livestock Zero Tolerance task.

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**Questions to consider:**

What substance(s) must livestock carcasses be free of on the Zero Tolerance task? What are examples of supportable descriptions of fecal and ingesta in each species? How will you determine what number of carcasses to examine on Zero Tolerance?

What will you do if you identify fecal or ingesta on Zero Tolerance? What do you expect the establishment to do if they fail Zero Tolerance?

What regulations will you use to document Zero Tolerance noncompliance? What should your Zero Tolerance NR include to be supportable?

What task should you schedule in response to a Zero Tolerance noncompliance, and why?

---

**L-23** Match the feces descriptions by species. Notes:

**L-25** Conduct the Zero Tolerance task. What are your observations? Notes:

**L-30** Identify the W's in the Livestock Zero Tolerance NR. Notes:

**L-33** Match corrective actions from Zero Tolerance failure to regulations. Notes:

**Operational SSOP Review and Observation task**

**L-39** Review FSIS Directive 5000.1 for information on how to conduct an Operational Sanitation SOP Review and Observation task.

---

**Questions to consider:**

What is the difference between SPS Verification and SSOP tasks?

What are you observing when you conduct an Operational SSOP Review and Observation task? What action would you take if you observe product or food contact surface contamination?

What do you expect the establishment to do if product or food contact surfaces become contaminated? What should your SSOP NRs include to be supportable?

When must an establishment have their SSOP records completed?

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**L-42** Conduct the Operational SSOP Review and Observation task. What actions do you take? Notes:

**L-47/48** Document an SSOP NR. Review the example SSOP NR. Notes:

**SPS Verification task**

**L-35** Review FSIS Directive 5000.1 for information on how to conduct a SPS Verification task.

---

**Questions to consider:**

What is the difference between SPS Verification and SSOP tasks?

What types of facilities are you observing to verify which SPS regulations?

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**L-37** Match the regulations to the SPS picture. Notes:

Once you have completed the Livestock ZT, Operational SSOP Review and Observation, and SPS Verification tasks, you have completed this scenario. Add any additional notes or questions below. Notes:



## **#2 - POULTRY SLAUGHTER/PROCESSING SCENARIO**

**P-3** Background: You are a CSI assigned to a large chicken slaughter establishment, P1357. The establishment slaughters Monday through Saturday. Finished products include whole birds and poultry parts. You're at the establishment bright and early this morning, because you are going to conduct a Pre-Operational SSOP Review and Observation task.

**A. *Poultry Scenario Part I – Familiarize***

**P-4** Review FSIS Directive 5000.4 for information on how to conduct the Pre-Op task.

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### **Questions to consider:**

What type of verification activities will you use when conducting a Pre-Op SSOP Review and Observation task?

How much equipment should you inspect? What equipment should you inspect?

What will you take with you when you conduct Pre-Op?

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**P-5** Review the establishment's Sanitation SOP program. Notes:

**P-11** Review recent NRs. Do you notice any trends? How will you apply this information to Pre-Op? Notes:

**P-12** Choose which equipment you will bring to conduct Pre-Op. Notes:

**P-14/15** Make Pre-Op observations. What do you see? What will you do? Notes:

**P-16** Review the establishment's Pre-Op records. Compare their findings to yours. Notes:

**P-21** After your Pre-Op observations, consider how your observations will be documented. Review FSIS Directive 5000.1 on how to associate noncompliance.

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**Questions to consider:**

Why is it important to associate NRs?

What should you include in the narrative of an NR when documenting an association?

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**P-24** Review an example NR documenting your Pre-Op observations. Notes:

**P-26** Review FSIS Directive 10,250.2 for information on actions you should take when an establishment is assigned to Category 3 for *Salmonella* positive results.

---

**Questions to consider:**

Where can you go to learn more about conducting poultry follow-up sampling?

When should you schedule and conduct poultry follow-up sampling?

---

**P-32** Which topics will you discuss at the weekly meeting? Notes:

**P-33** Review the MOI documented from your weekly meeting. Notes:

**P-34** Review FSIS Directive 5010.1 for information on other topics you may consider discussing at weekly meetings.

**B. Poultry Scenario Part II – Complete 2 inspection tasks**

**P-35** Choose which task to complete first: Poultry Zero Tolerance or Slaughter HACCP.

---

Note: you can choose any task first. Prior to completing the scenario, you will complete all three tasks.

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**Poultry Zero Tolerance task**

**P-36** Review Directive 6420.5 for information on how to conduct the Poultry Zero Tolerance task.

---

**Questions to consider:**

How do you determine how often to conduct a Poultry Zero Tolerance task? Where do you conduct the Poultry Zero Tolerance task?

How many carcasses will you inspect during the Poultry Zero Tolerance task? What procedures will you follow to conduct the Poultry Zero Tolerance task?

What contaminants are you looking for during your Poultry Zero Tolerance task? Which finding will result in noncompliance? What regulations would you cite?

---

**P-42** You perform your Zero Tolerance inspection and identify ingesta on a carcass. What should you do? Notes:

### **Slaughter HACCP Verification task**

**P-45** Review the Slaughter HACCP plan. Review FSIS Directive 5000.1 for information on how to conduct a HACCP task.

---

#### **Questions to consider:**

What CCPs will you verify regulatory requirements for?

What Prerequisite programs will you verify regulatory requirements for? What regulations are you verifying when conducting HACCP tasks?

What are examples of compliance with the HACCP regulatory requirements? With CCP monitoring? Verification? Recordkeeping? Corrective Actions?

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**P-59** Match the recordkeeping regulation to the HACCP regulatory requirements. Notes:

**P-61** Review the establishment's prerequisite programs. Notes:

**P-62** Review the establishment's prerequisite program records. Notes:

**P-66** Review the establishment's corrective actions record. Notes:

Once you have completed the Poultry Zero Tolerance and Slaughter HACCP tasks, you have completed the scenario. Add any additional notes or questions below. Notes:

