



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

Inspection Methods

Student Study Guide

Only this provided printed Student Study Guide may be used during the test. Hand-written notes and highlights are allowed on the provided pages. No additional pages, sticky notes, tabs, paper clips, or anything else added to the study guide is allowed.

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01 Course Introduction

Welcome to the Inspection Methods Training Course!

Class hours: Class hours are from 9:00am to 6:00pm Eastern Time (ET) (adjust for local time zone), lunch break (1 hour) at approximately 1:00pm to 2:00pm ET.

Technical Support: Send chat message using Webex to “All Panelists”, or call 1-833-ASK-OEED (1-833-275-6333) during class hours, or email CFLHelpDesk@usda.gov.

Connect to the class webinar and login each day using the daily webinar link and access code. We recommend that you connect to the audio portion of the webinar using your computer, but you also have the option to connect by phone. You may connect to the webinar up to 10 minutes prior to the start of class.

You may ask questions by typing it into the chat panel to “All Panelists,” clicking on the raise hand button if using your computer audio, or by pushing #2 on your phone to be added to the queue to ask a verbal question.

Ground rules: Start and end the class on time, listen carefully, turn off/mute personal cell phones, stay on topic, respect others, be receptive to new ideas, observe local health and safety precautions, and have fun.

Attendance: Your attendance and being punctual (be on time) is expected daily for the entire class. Attendance will be taken several times daily using the WebEx polling feature—please mark in the poll that you are present. Please send a chat message to the instructors if you have approved leave and include the hours you will be away from the class.

- ☐ **Post-test:** The post-test is administered electronically. There are 54 multiple-choice questions to complete within 75 minutes. Passing score is 70%.
- ☐ The Agency has a zero-tolerance cheating policy.
- ☐ This class is Training as a Condition of Employment (TCOE) for CSI positions (see Directive 4338.1 for details).
- ☐ Test will be proctored on-site at the testing location.
- ☐ Online test is taken using the training laptop provided to you.
- ☐ No electronic devices are allowed to be used or present in the testing area (computers (except the one for the testing), laptops, tablets, cell phones, smart phones, smartwatch, readers, music devices, cameras, etc.).
- ☐ No other programs can be used or open on the laptop while taking the test.
- ☐ Only the provided printed Student Study Guide may be used during the test. Hand-written notes and highlights are allowed on the provided pages. **No** additional pages, sticky notes, tabs, paper clips, or anything else added to the study guide is allowed.
- ☐ No paper, pens, pencils, or writing devices are allowed in the testing area.
- ☐ No talking or interacting with other participants is permitted during testing.
- ☐ Your test result will be reported to you by your District Office or State program as a pass/fail result, they will receive notification of the results within 3 business days after the test date.

Course Registration: On the first day of class, the instructor will guide you to the link to complete the online registration form.

Course Evaluation: On the last day of class, the instructor will guide you to the link to complete the class evaluation form.

FSIS Training Site: Your username and password will be provided to you by your District Office or State program. Connect to the training website daily to access the class information, slides, notes, workshops, and other references at <https://fsistraining.fsis.usda.gov/>. Select the IM 18XX and the IM Resource courses to open/view.

Online Testing Site: Your username and password will be provided to you by your District Office or State program. You will use this link to access the IM Practice Quizzes and the final test at: <https://usgov.questionmark.com/home/200010/assessments/classic>.

IM Electronic Notebook: Each course module has a set of detailed notes. On the first day of class, the instructor will guide you on how to download the electronic notebook files (located in IM Resources) to your computer at: <https://fsistraining.fsis.usda.gov/mod/folder/view.php?id=522>. These same files are also posted on the FSIS website under Inspection Methods Course Materials at: <https://www.fsis.usda.gov/inspection/inspection-training-videos/inspection-technical-training>. These electronic notebook files are more detailed than what is available in this condensed study guide. They provide more information, examples, and references and should be reviewed as part of your training.

Online Learning Tips:

- Understand online learning practices and expectations
- Eliminate distractions
- Create a regular study space, stay organized
- Actively participate, join discussions
- Stay motivated, keep yourself accountable
- Treat an online course like a “real” course
- Identify learning objectives, build a study plan, set goals
- Ask for help when you need it
- Take study breaks

Daily Agenda Outline:

Time (Eastern Time)	Activity
9:00am - 9:30am	Morning briefing
9:30am - 1:00pm	Class instruction
1:00pm - 2:00pm	Lunch break
2:00pm - 2:30pm	Afternoon briefing
2:30pm - 5:30pm	Class instruction
5:30pm - 6:00pm	Evening briefing

02 Statutes (Acts)

FSIS Legal Authority: FSIS has the legal authority to regulate meat, poultry, and egg products. FSIS authority comes from and is based on the Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), and Egg Products Inspection Act (EPIA), which were enacted by Congress. These are known as "Statutes" or "Acts".

Adulterated Product: Product that contains any poisonous or deleterious (harmful or deadly) substance which may render it injurious (harmful) to health. The following are some examples:

- If the product contains any pesticide chemical, food additive, color additive that are prohibited entirely or by amount or determined unsafe by regulation;
- If the product consists in whole or in part of any filthy, putrid, or decomposed substance;
- If the product has been prepared, packed, or held under insanitary (dirty or unclean) conditions;
- If the product from an animal which has died otherwise than by slaughter (for example: died from an illness, accident, poisoned, etc...)
- If the product's container is composed, in whole or in part, of any poisonous or deleterious (harmful) substance which may render the contents injurious to health;
- If the product has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation;
- If any valuable constituent of the product has been in whole or in part omitted or abstracted therefrom.

Sanitation – The development and application of sanitary measures for the sake of cleanliness and protecting health. To ensure that products are handled and held in a sanitary manner, establishments must follow the Hazard Analysis and Critical Control Point (HACCP) regulations. The HACCP regulations require establishments to identify the hazards to health that may arise as a result of their operation and to address those hazards.

Regulations – The documents that clarify the statutes are called regulations. Most of your work will be guided by the regulations. Citations from regulations are used when completing a Noncompliance Record (NR). Chapter III of Title 9 Code of Federal Regulations (CFR) lists the regulations for FSIS and covers Parts 300-592. Sanitation and HACCP are Parts 416 and 417, respectively.

Directives – Directives contain instructions to inspection personnel about how to implement and enforce the rules. Directives provide information about inspection methods, regulatory decision-making, documentation of noncompliance, and appropriate enforcement actions. Directives have no expiration date. Inspection personnel are to follow the information contained in the Directives until they are rescinded or replaced. Directives are numbered by topic area—for example, series 7000 deals with processing information.

Notices - Notices are instructions to FSIS inspection personnel to address a particular problem that has arisen. The need for Notices is often identified by the number of questions about a specific topic from the field. Notices specify an expiration date (usually 1 year). Notices are numbered sequentially based on the fiscal year in which they are issued.

Acts → Regulations → Directives → Notices → Performance

03 Rules of Practice

The **Rules of Practice** were published so that establishments will know the types of enforcement actions FSIS takes, and the processes FSIS uses to accomplish those actions. 9 CFR 500 are FSIS's enforcement regulations.

Compliance means that the establishment's processes are working properly in accordance with the laws and regulations.

Inspection includes all actions the Agency may take to examine the establishment and its processes, products, and systems.

Enforcement actions are those the Agency takes when an inspector determines that the establishment's plans and systems are not in compliance with laws and regulations.

Due process rights mean that a fair "process" or proceeding must take place before the government interferes with an individual's property or actions. This process might include notifications, hearings, or other activities. By following the Rules of Practice regulations, 9 CFR 500, FSIS assures that appropriate due process is afforded.

Types of Enforcement Actions

- **Regulatory Control Action (RCA)** – Any action that inspection personnel take to control product or processes. It is commonly used by in-plant inspection personnel. An example of a regulatory control action is the application of the FSIS reject/retain tag to a piece of equipment that contains residue from the previous day's production, found during pre-op inspection. The inspection personnel that is taking the action must immediately notify the establishment management. This can be done orally or in writing. The written notification will be a noncompliance record (NR). The NR documents the noncompliance, and the description should include any FSIS reject/retain tag numbers issued.
- **Withholding actions** – Withhold (to refrain from granting, giving, or allowing) the marks of inspection. Such actions may be taken against product produced by a particular process or all products in the establishment. The decision to take an immediate withholding action can be made by whomever is in charge for FSIS at the establishment (for example, the IIC or designee), the Frontline Supervisor (FLS); or the District Office (DO).
- **Suspension** – Refers to the interruption in the assignment of inspection personnel to the establishment. A suspension of inspection also has a severe impact on an establishment. Because a federally inspected establishment cannot legally apply marks of inspection to product without an assigned inspector, this action stops all production. It can be applied to the entire establishment, or only to a specific production process. Decision to suspend is made only at the DO level or higher.
- **Withholding Action or Suspension without Prior Notification** – FSIS may take withholding or suspension actions without giving the establishment prior notification if a situation involves an **imminent threat to public health**. Withholding the marks of inspection and suspending inspection services are significant enforcement actions. If FSIS takes a withholding action or

imposes a suspension without providing prior notification, the establishment must be notified orally and then, as promptly (quickly) as the circumstances permit, in writing. The decision to take a withholding action can be made by the IIC or designee, the Frontline Supervisor, or the DO, whereas the decision to suspend is made only at the DO level or higher. The following are situations that FSIS may take a withholding action or impose a suspension without providing the establishment prior notification (FSIS regulation 500.3):

- The establishment produced and shipped adulterated or misbranded product;
- The establishment does not have a HACCP plan;
- The establishment does not have Sanitation Standard Operating Procedures;
- Sanitary conditions are such that products in the establishment are or would be rendered (declared) adulterated.

• **Withholding Action or Suspension with Prior Notification** – If a withholding or suspension action is based on any reason other than those listed in the 500.3 regulation, FSIS must provide the establishment written notice before taking the action. Often these enforcement actions are based on repetitive noncompliance, such as systemic problems with the SSOP or HACCP systems. The following are situations that FSIS may take a withholding action or impose a suspension with prior notification (FSIS regulation 500.4):

- ☐ The HACCP system is inadequate, as specified in FSIS regulation 417.6, due to multiple or recurring noncompliances;
- ☐ The Sanitation Standard Operating Procedures have not been properly implemented or maintained as specified in FSIS regulations 416.13 through 416.16;
- ☐ The establishment has not maintained sanitary conditions as prescribed in FSIS regulations 416.2 through 416.6 due to multiple or recurring noncompliances;
- ☐ The establishment did not collect and analyze samples for *Escherichia coli* Biotype I and record results in accordance with FSIS regulations.

• **Notice of Intended Enforcement (NOIE)** – An NOIE is issued for noncompliances that do not pose an imminent (immediate) threat to public health, but that may warrant a withholding or suspension if notcorrected. The NOIE will be issued to the establishment by the District Manager (DM). The NOIE provides the establishment an opportunity to propose immediate corrective actions and further planned preventive actions. The NOIE notifies the establishment that it has three business days to respond. The DM evaluates the establishment's response to an NOIE and decides whether to accept the establishment's plan, to implement the appropriate enforcement action, or to defer the decision (**defer** means delay the enforcement action to allow the establishment time to implement their proposed corrective actions plan).

• **Suspension held in abeyance** – (Abeyance - a state of temporary inactivity: SUSPENSION) Means that the establishment was under suspension, and the suspension is temporarily lifted, allowing the establishment to operate under mutually agreed upon conditions.

• **Verification Plans** – When the DM decides to defer enforcement following the issuance of a NOIE, or to hold a suspension in abeyance, the Enforcement, Investigations, and Analysis Officer (EIAO) will develop a verification plan. The verification plan (VP) provides a systematic means for inspection program personnel (IPP) to verify that an establishment is effectively

implementing the corrective measures that were proposed by the establishment. **Note:** In this document, the term IPP refers to Consumer Safety Inspectors and Public Health Veterinarians.

- **Appeal Process** – An appeal (request) is part of an establishment's due process (Due process - a judicial requirement that enacted laws may not contain provisions that result in the unfair, arbitrary, or unreasonable treatment of an individual). Any NR or enforcement action may be appealed. The appeal process follows the Office of Field Operations(OFO) chain of command. The OFO chain of command starts with the Program employee who made the finding—for example, the Consumer Safety Inspector (CSI) or the Public Health Veterinarian (PHV). Next in the chain of command is the Inspector-in-Charge (IIC), possibly a supervisory PHV or Mini-Circuit Supervisor; then, Frontline Supervisor (FLS); then, District Manager (DM); then, Executive Associate for Regulatory Operations (EARO); then, OFO Assistant Administrator; then FSIS Administrator. Although FSIS does not enforce any **time limit** for appeals, FSIS recommends that the establishment appeal promptly.
- **Withdrawal of Inspection** – Withdrawal (or taking away) of the grant of inspection is the most severe enforcement action that can be taken against an official establishment. Withdrawal terminates the grant of inspection. Once that happens, no portion of the establishment may operate as a FSIS federally inspected establishment. The final decision to withdraw the grant of inspection is made at the Administrator's level.

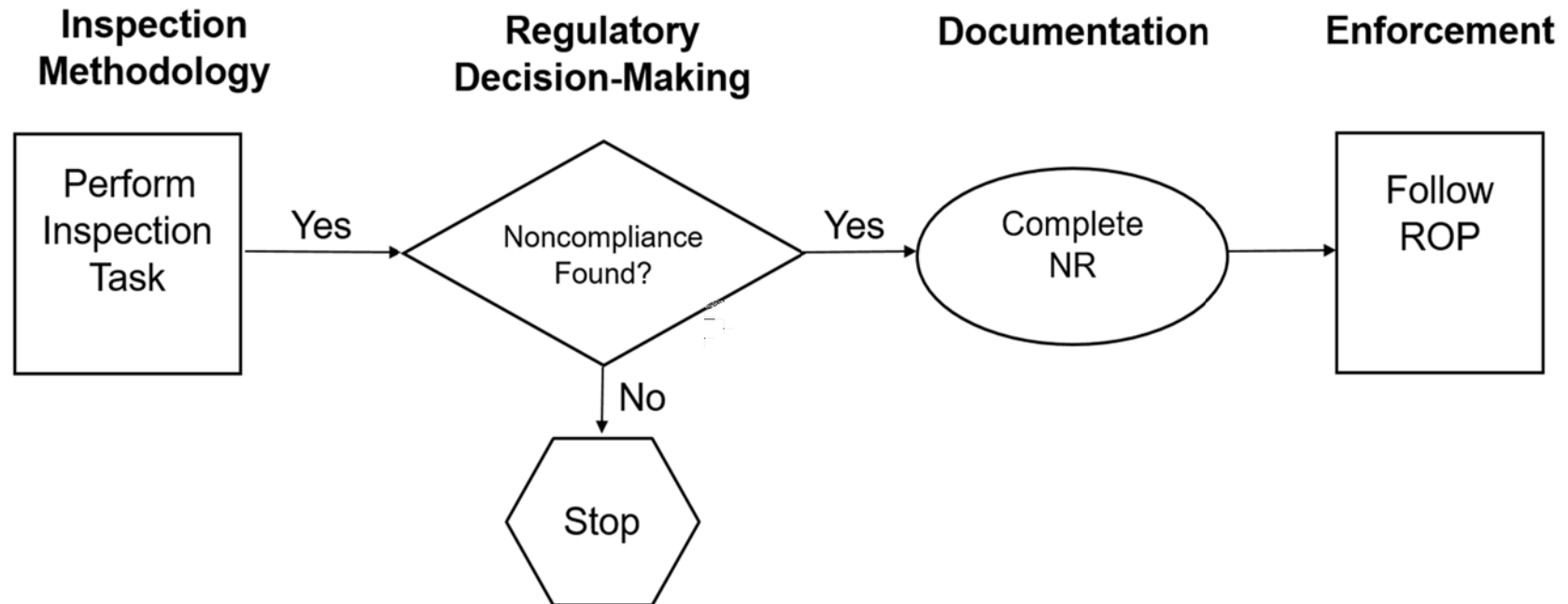
04 Regulatory Process Overview

An establishment's food safety system consists of several different parts, including the HACCP plan, a Sanitation SOP, and other programs, like sanitary dressing procedures. These programs ensure that the product the establishment produces is wholesome and not adulterated. Inspection Program Personnel (IPP) allow products to be labeled with the marks of inspection when they are able to determine that the products are not adulterated.

The diagram on the next page shows the **Regulatory Process**. This diagram is used to illustrate the HACCP-based inspection process used by FSIS inspectors. It includes the following four components:

- **Inspection Methodology**
 - Performing inspection tasks
 - Verifying specific regulatory requirements
- **Decision-making**
 - Gathering (collecting) information, making observations, reviewing documentation, assessing the gathered information and arriving at a supportable compliance or noncompliance determination
- **Documentation**
 - Entering the results of inspection tasks in PHIS
 - Documenting noncompliance on a Noncompliance Record (NR)
- **Enforcement**
 - Following the Rules of Practice (ROP)
 - Providing the establishment with due process

HACCP Regulatory Process



05 Food Safety Systems Fundamentals

System Definition

(Dictionary.com) – An assemblage or combination of things or parts forming a complex or unitary whole: *a mountain system; a railroad system.*

Note: Often systems exist within systems. Example: railroad system within the transportation system (composed of the engine/wagons/rails/employees/train stations/etc... all of those together make the railroad system).

(FSIS definition) – A coordinated body of methods or a scheme or plan of procedure

Food Safety System

Purpose: To produce safe food

Evidence of Failure: Deficiencies/noncompliances that evidence increased risk of producing unsafe food, foodborne illness/injury

Causes:

Design Deficiencies

- Hazards (dangers) or preventive measures not identified;
- Programs/plans are not supported and effective;
- Programs/plans not maintained/reassessed (not re-evaluated routinely, after failures, or upon changes).

Execution Deficiencies

- Poor execution of programs/plans—for example, not performing activities necessary to ensure product/process control, not maintaining records to demonstrate implementation and effectiveness of programs/plans, not taking appropriate follow-up actions to address deficiencies in execution of programs/plans, or not verifying that the programs/plans are being implemented.

Consequences:

- Lack/loss of control, but no resultant food safety hazard
- Isolated event (lower risk) vs. recurring events (higher risk)
- Lack/loss of control resulting in a unsafe food
- May impact another processor's system
- Catastrophic lack/loss of control with food safety hazard AND illness/death

Hazard Analysis

Food Safety Hazard: Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

Reasonably Likely to Occur: A hazard for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls.

Prerequisite Programs

“Prerequisite” means required beforehand, precondition. The World Health Organization defines **prerequisite program** as practices and conditions needed prior to and during the implementation of HACCP and which are essential for food safety. Prerequisite programs provide a foundation for an effective HACCP system. They are often facility-wide programs rather than process or product specific. They may reduce the likelihood of certain hazards.

Food Safety System Basic Components

- HACCP Plan

- Controls food safety hazards that are reasonably likely to occur

- Product and process specific

- Prerequisites

- Measures, procedures, and programs that provide a foundation for the HACCP system

- Facility-wide

- May support determinations that a food safety hazard is not reasonably likely to occur

Systems Thinking Concepts

A system is:

- Composed of many interdependent parts (Remember the train system example covered before)

- Subject to external disturbances

- Dynamic - conditions change

- Conditions may include normal variation or represent loss of control

- Each system is unique

A holistic system is any set (group) of interdependent parts. The parts generally are systems themselves.

Understand the parts in **relation** to the whole (linkages).

Understand how things **influence** one another within a whole (interactions).

Understand the parts of a system in the context of relationships with each other and other systems, **rather than in isolation**.

Purpose, Linkage (connection of one to the other), and Interaction

Throughout or during this course, you should seek to understand how the components of the food safety system relate to each other and how changes or deficiencies in one part of the system may affect the adequacy of other parts of the system. Always consider your findings in the context of the food safety system. What do they indicate about the adequacy of the food safety system? To conduct a proper assessment, you will often need to gather or collect additional information.

Consider whether the system is working or not working. Has adulterated product has been produced and shipped? Are there recurring issues/trends indicating the food safety system is not working? Are there findings that when considered collectively indicate the system isn't working?

Considering the “Big Picture” is crucial to protecting public health.

06 Food Microbiology and Specified Risk Materials (SRM)

Purpose:

This section will focus on helping inspectors develop an understanding of microorganisms that can grow and multiply in meat and poultry products. Understanding food microbes and the effects of microbial contamination is very important to food safety in slaughter and processing establishments and the environmental conditions in which products are produced in the establishments. This section will also cover specified risk materials (SRM) in cattle.

What is microbiology?

Microbiology is a specialized area of biology dealing with organisms too small to be seen without sufficient magnification. Microbiologists study bacteria, fungi, parasites, and viruses, including their interactions with humans, animals, plants, and the environment. Food microbiology is specifically concerned with the desirable and undesirable effects microbes can have on the quality and safety of food products.

What are the 4 basic types of microbes?

Bacteria are small, single-celled organisms that occur in almost any natural environment. Common bacteria are too small to be seen individually without the aid of a microscope. Bacteria can multiply to form groups or colonies on a food source. After a sufficient number of replication cycles, a colony of bacteria can be seen with the naked eye on a petri plate. Viewed under a microscope, different kinds of bacteria will have different shapes or forms.

The fungi consist of two major groups of microbes: molds and yeasts. Molds are multi-cellular organisms. Yeasts are single-celled organisms. Molds and yeasts tend to be significantly larger than bacteria. Both molds and yeasts are widely distributed in nature, both in the soil and in dust carried by air. Molds have a branching filamentous structure, and can develop into colonies visible as a colorful, furry or downy coating on food or surfaces. They reproduce by producing small spores, which are not related to bacterial spores (which will be discussed later). Mold spores can be picked up and spread by air currents. If mold spores settle on suitable surfaces, they will begin to germinate and produce new mold growth. Yeasts are usually egg-shaped and tend to be smaller than molds. Like molds, yeasts can be spread via air currents. They reproduce by a process known as budding. Visible colonies of yeast are generally slimy in appearance and creamy white in color.

Parasites are living organisms that derive nourishment and protection from other living organisms, called hosts. These organisms live and reproduce within the tissues and organs of infected human and animal hosts. There are different types of parasites, and they range in size from single-celled protozoa to multi-cellular worms. They may be transmitted from host to host through consumption of contaminated food and water. Several parasites have emerged as significant causes of foodborne and waterborne illness.

Viruses are much smaller than bacteria. They are too small to be seen with a standard light microscope. An electron microscope is necessary to see viruses. A virus must invade a living

host cell in order to replicate. Once inside the host cell, the viral genetic material directs the host cell's "machinery" to make more virus particles, which interferes with normal host cell function and may result in destruction of the host cell.

What are some common foodborne bacterial pathogens?

Some common foodborne bacterial pathogens are *Salmonella* spp., *Clostridium perfringens*, *Campylobacter* spp., *Bacillus cereus*, *Listeria monocytogenes*, *Staphylococcus aureus*, *Clostridium botulinum*, *E. coli* O157:H7 and non-O157 Shiga toxin-producing *E. coli* (O26, O45, O103, O111, O121, and O145).

Why do some bacteria produce spores?

What is a spore? A spore is "a primitive, usually unicellular, often environmentally resistant dormant or reproductive body produced by plants, fungi, and some microorganisms and capable of development into a new individual either directly or after fusion with another spore" (from the online Merriam-Webster dictionary).

Spore formation in bacteria is a method of surviving in unfavorable conditions. The spore-forming bacteria can resist adverse conditions such as high or low temperatures, and extreme environmental conditions, including cleaning and sanitizing solutions. Examples: *Clostridium botulinum*, *Clostridium perfringens*.

How do bacteria grow?

Microbial growth will focus primarily on bacterial growth. If favorable environmental conditions exist, bacterial growth occurs. (We will use the term "growth" to refer to an increase in microbe numbers, not an increase in size of an organism). Bacteria reproduce by dividing, a process called binary fission. When a bacterial cell is ready to divide, the material within it gradually increases until the cell's volume is almost doubled. The cell constricts in the middle. This constriction deepens until the cell contents are held in two distinct compartments separated by a wall. These two compartments finally separate to form two new cells, which are duplicates of the former cell and each other.

The first phase of growth is called the **lag phase**. The lag phase occurs when a bacterial population first enters a nutrient rich environment. The rate of growth is very slow because the bacterial cells are adjusting to their new environment. In a nutrient-rich environment, such as on a meat or poultry product, the lag phase is generally short; however, the length of the lag phase is the most variable of the four phases. Depending on environmental conditions and characteristics of the particular bacterial species, the bacterial cells begin to rapidly multiply. This phase is called the **log phase** because growth occurs exponentially. Bacterial growth can occur at an exponential rate, i.e., 1 cell becomes 2 cells, the 2 cells become 4, then 8, then 16, then 32, then 64, etc. With each successive replication, the total number of cells doubles. The time it takes for the population of bacteria to double is referred to as doubling time or generation time. This doubling time can vary among species of bacteria, but for most is between 10 to 30 minutes under optimal conditions for growth. **Exponential Growth Example:** Let's assume a particular species of bacteria doubles every 30 minutes. After one hour, a single bacterium of that species becomes four. At the end of two hours, there will be 16 bacteria. After 15 hours, there will be 1,000,000,000 (one billion) cells.

The third phase is the **stationary phase**. In this phase the rate of bacterial growth is the same as the rate of bacterial death, because the population of bacteria has reached its maximum due to limitations in the availability of nutrients and an increase in bacterial waste products.

The fourth phase is the **death phase**. In this phase, more bacterial cells are dying than those that are dividing. There is a net loss in the number of viable bacterial cells in the environment. This is the result of increasingly hostile environmental conditions associated with decreasing availability of nutrients and increasing waste products.

What factors affect bacterial growth?

Like all other living organisms, bacteria require favorable environment to live and grow. There are six basic environmental factors that impact bacterial growth. An easy way to remember these conditions is to use the memory device **FAT TOM**.

Food – The word “food” refers to nutrients available to the microbes, which could be a human food product, product residue on equipment, or organic debris in some non-product contact growth niche. A suitable supply of nutrients is the most important condition affecting growth of bacteria.

Acidity – Most microbes thrive when the pH is near neutral or slightly acidic, but there are exceptions. Most bacteria will not grow at pH levels below 4.6 because the environment is too acidic. Many molds and yeasts can grow at a lower pH than do bacteria. The pH of fresh meat ranges between 5.3 and 6.4 (i.e., high pH or low-acid). Meat with a pH in the 6.0 to 6.4 range spoils faster than meat in the lower pH range of 5.3 to 5.7, because spoilage microbes are more active in the pH range of 6.0 to 6.4.

Temperature – All bacteria, molds, and yeasts have an optimum, maximum, and minimum temperature for growth. Environmental temperature not only impacts the rate of growth of microbes but can determine which microbial species thrive. At temperatures above 140°F most microbes begin to die, although the time needed for cell destruction at a particular temperature will vary for different species of microbes and may depend on other environmental factors such as humidity. In food processing, the temperature range of 41 - 140°F is commonly referred to as the **danger zone**, because the optimum, maximum, and minimum temperature for growth of *most* microbes will fall somewhere within that range. Depending on other factors, the rate of growth of many pathogens may be extremely slow in the 40 to 50°F temperature range.

Time – Permitting sufficient time for microbes to adapt to their environment (lag phase) is necessary before they can enter the rapid growth phase (log phase). The doubling time for most bacterial species is between 10 and 30 minutes under optimal conditions for growth. Bacteria would grow much more slowly in meat and poultry products, especially if those products are properly handled and stored.

Oxygen – Oxygen availability can determine which microbes will be active. Microbes that have an absolute requirement for oxygen are called obligate aerobes. Those that require the total absence of oxygen are called obligate anaerobes. Some microbes are called facultative anaerobes, because they can grow in the presence or absence of oxygen. Molds require oxygen for growth. Yeasts grow best under aerobic conditions, but some can grow slowly under anaerobic conditions. Bacteria that cause food spoilage tend to be aerobes, but those that cause foodborne illness are typically anaerobes or facultative anaerobes.

Moisture – The availability of water in a food (referred to as water activity, or a_w) is an important factor for microbial growth. Nutrients for microbial growth must be in a soluble form for microbes to utilize them. Generally, bacteria have the highest a_w requirements, molds have the lowest, and yeasts are intermediate. It is important to note that a_w is not necessarily equivalent to measures of moisture content (e.g., Moisture Protein Ratio or MPR) in a product. Most moist food products will have greater water availability to support microbial growth than drier food products.

Where are the microbes in the establishment?

Excluding certain areas like the gastrointestinal tract (also known as "gut"), upper respiratory tract, and lower urinary tract, the internal tissues (e.g., muscle tissue) of normal healthy livestock and poultry are generally sterile (free of microbes). Nevertheless, raw and many processed foods contain a variety of different bacteria, yeasts, molds, and viruses. Livestock and poultry, people, equipment, pests, water supplies, food ingredients, and air currents can all be important sources of microbes in the food-processing environment. Soil also contains a variety of microbes that can also contaminate the hides and feathers of live animals. While dressing animals during the slaughter process, these bacteria can easily be transferred from the hide, skin, feathers, and gastrointestinal tract to the carcass itself.

Disease conditions, like mastitis, pneumonia, gastroenteritis, and uterine infections may change the normal microbial flora and ecology in affected organs and tissues, and represent additional sources of potential contamination of the slaughter environment and carcass. People traffic microbes throughout a processing area due to poor hygienic practices, including inadequate handwashing, wearing soiled clothing, and working around product while sick with an infectious disease. Failure to adequately design or implement such procedures and controls creates insanitary conditions with the potential to contaminate product. Equipment can serve as niches (hiding places) for the growth of certain microbes if environmental conditions are conducive to growth and sanitation practices are inadequate.

Some bacteria, including many pathogens, can form **biofilms** on equipment surfaces as multiple bacteria attach to the surface and produce a protective matrix. Biofilms can be difficult to remove with routine cleaning and sanitizing procedures. Bacteria embedded in a biofilm can be up to 1,000 times more resistant to many sanitizers. Inadequate pest management may lead to the contamination of product, equipment, ingredients, and packaging materials. Non-potable or contaminated supplies of water could be sources of microbial contamination. Water overspray from washing equipment or splashing of contaminated water onto product or food contact surfaces can also cause product contamination. In addition, standing water and damp areas of the facility could promote microbial growth and increase the possibility of cross-contamination.

Non-meat and non-poultry food ingredients are possible sources of contamination. Spices and seasonings may be contaminated with pathogens if improperly processed or stored and handled under insanitary conditions. Air currents move dust through a processing facility. The dust can be deposited onto surfaces of the facility, equipment and utensils, employee clothing, and product. Microscopic moisture droplets traveling in air currents can condense out onto cooler surfaces, leading to contamination of those surfaces and formation of condensate that potentially drips onto product or food contact surfaces.

How to control microbes?

There are two fundamental ways to control microbial contamination of products and processing environments. The first involves reducing opportunities for microbes to enter processing environments and come into contact with products. The second involves making the environment for microbes as inhospitable as possible to reduce their numbers and minimize their growth. It is impossible to completely eliminate all microbes from processing environments and food products. However, it is possible for establishments to implement effective control strategies designed to protect against pathogens and the undesirable effects of spoilage organisms.

Contamination can be minimized or avoided altogether by following appropriate sanitation procedures, good manufacturing procedures (GMPs), and procedures for employee hygiene. Good sanitary dressing process control measures in slaughter processes not only minimize contamination of carcasses, but also reduce the level of processing environment contamination. Effective pest control can help prevent the introduction of many microbes into the processing environment. Sound construction of the facility and maintaining its construction will reduce opportunities for microbial contamination of the processing environment. Ensuring appropriate hygienic standards and traffic patterns are followed by all employees working in and around processing areas protects against excessive contamination of the processing environment and product.

Restriction of Growth

Making a microbe's environment as inhospitable as possible can involve a variety of control measures, all of which relate to the FAT TOM factors impacting microbial growth. Effective procedures for cleaning and sanitizing the facility provide the foundation for controlling microbes.

Adequate cleaning and sanitizing procedures will help to ensure that little organic matter is available to support microbial growth. Altering the pH of a microbe's environment may involve the use (and rotation) of acid and alkaline sanitizing agents. Moisture control in the processing environment is an important means of protecting against microbial proliferation. This may occur through measures designed to keep the environment dry, adequate ventilation, or adequate plumbing to properly convey liquid waste out of the processing area. Employee hygiene, airflow, and traffic flow of people and equipment between areas are also important to protect against cross-contamination.

Temperature controls are important in all classes of product. Maintaining products under refrigeration is one of the most important ways to inhibit microbial growth. Cooking product to temperatures adequate enough to eliminate pathogens of concern is another way to control microbes. The time it takes for products to reach a particular temperature is also important in inhibiting microbial growth. Chilling raw, heat-treated, and fully-cooked products as rapidly as possible helps to ensure products do not linger in the "danger zone" for too long, which could result in the outgrowth of bacteria, including spore-forming bacteria and toxin-producing bacteria.

Product pH can also be manipulated, though, to inhibit certain microbes in certain products. For example, acidifying agents (acidulants) may be added to certain products to reduce the pH.

Salt and low water activity in a product can be very effective in controlling the growth of some harmful bacteria, but some organisms (e.g., *Staphylococcus aureus*) can survive in high salt environments.

Reducing the oxygen level through vacuum packaging processes is a common method of enhancing the shelf life of food products. However, vacuum packaging reduces the growth of mainly spoilage microbes. Pathogenic bacteria, such as *Clostridium botulinum* and *Listeria monocytogenes* can still grow in vacuum packaged products.

Ultimately there is no single method of preventing or controlling microbes in food. It requires a so-called **multiple hurdle** approach. This can be represented by compliance with the Sanitation Performance Standards, maintaining effective Sanitation SOPs, and designing and implementing an effective HACCP plan.

Let's talk about foodborne parasites

Some important foodborne parasites are *Giardia duodenalis*, *Cryptosporidium parvum*, *Cyclospora cayetanensis*, *Trichinella spiralis*, *Taenia saginata* (beef tapeworm), and *Taenia solium* (pork tapeworm). Trichinosis (or trichinellosis), caused by *Trichinella spiralis*, was historically an important foodborne illness resulting from the consumption of undercooked pork products. Trichinosis has largely been eliminated due to changes in swine production practices, consumer education, and prescribed treatments for destruction of trichinae in certain classes of pork products (9 CFR 318.10).

Let's talk about prions

What is a prion? A prion is a protein of unknown function that resides on the surface of brain cells (per Sidney Perkowitz from the online Merriam-Webster dictionary).

Prion-associated variant Creutzfeldt-Jakob Disease (vCJD) appears to be of relatively low incidence. BSE in cattle and vCJD in humans are slowly progressive diseases. Initial symptoms in humans are generally psychiatric, e.g., depression. As the disease progresses, neurologic signs appear and worsen to the extent that patients are unable to care for themselves, until death occurs. Cattle can initially display behavioral changes progressing to neurologic signs, the inability to rise, and ultimately death. There are certain cattle tissues considered to be of high risk for prion contamination. These tissues are referred to as specified risk materials (SRMs).

Cattle of All Ages 310.22(a)(2)	Tonsils and Distal Ileum (80 inches of small intestine)
Cattle 30 Months or older 310.22(a)(1)	Tonsils, Distal Ileum, Skull, Brain, Eyes, Spinal Cord, Trigeminal Ganglia, Dorsal Root Ganglia, Vertebral Column excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum

Establishment SRM (Specified Risk Materials) Control Program

SRM must be removed from **all cattle of any age** that are presented for slaughter.

Establishments must identify, remove, denature and dispose of SRM
Specified Risk Materials are inedible and prohibited for use as human food
All of the above safeguard against human exposure to BSE.

Establishments that slaughter cattle or process carcasses or parts of cattle must incorporate written procedures for the segregation, removal, and disposition of SRM into their HACCP plan, Sanitation SOPs or other prerequisite programs (9 CFR 310.22(e)(1)).

IPP verification responsibilities are to:

Review the SRM regulations;
Review the establishment SRM procedures and records;
Through direct observation, ensure that the establishment effectively removes, segregates, denatures and disposes of SRM; and
Document regulatory compliance & noncompliance in PHIS.

07 Sanitation Performance Standards (SPS)

9 CFR 416.1 - 416.6

Purpose:

Proper and effective sanitation is vital to every step of the food manufacturing (making) process. This section will focus on helping the IPP develop a working knowledge of the Sanitation Performance Standards (SPS) regulations in the 9 CFR 416.1 through 416.5. IPP will learn how to perform the Sanitation Performance Standards Verification task using the “GAD” process that is used by FSIS. The GAD process involves gathering information, assessing the information and determining if the establishment complies with the regulations. IPP will also understand their regulatory responsibilities under 9 CFR 416.6.

Facilities that must comply with the SPS regulations:

- Federal and State inspected meat and poultry establishments
- Import/Export facilities
- Identification (ID) warehouses
- Custom-exempt operations

Sanitation Requirements:

- CFR 416.1 - 416.5
- FSIS Directive 5000.1, Revision 5 addresses the Sanitation Performance Standards (SPS) regulations and the SPS Verification task

Purpose of the SPS Verification task:

To verify compliance with the Sanitation Performance Standards (9 CFR 416.1 - 416.5), IPP will inspect conditions in and around the official premises of the establishment, review documents, and inspect the facility and equipment for overall sanitary conditions. The establishment designates the official premises during the grant of application process. IPP must conduct all inspection activities within the physical boundaries designated as the official premises of the establishment.

When performing the SPS task to verify SPS requirements:

IPP should directly observe conditions in **one or more** areas of the establishment. IPP or the IIC will select standards based on the SPS noncompliance history of the establishment. When necessary, IPP will review the following documents: water potability certificate; pesticide use information; EPA registrations, labels, and instructions for proper use; sewage disposal approval letter (when the establishment has a private sewer system); cleaning compounds, sanitizing agents, processing aids, etc.; and documentation describing the safe and correct use of chemicals that are in the establishment.

When performing the task, IPP should:

- Have a working knowledge of specific SPS regulations;
- Ask questions specific to the regulations;
- Directly observe areas relevant to the regulations; and
- Assess the establishment's answers to those questions.

How to determine compliance or noncompliance?

Use professional knowledge and good judgement

- Gather information
- Assess each situation
- Determine if an insanitary condition has occurred.

416.1 General Rules

Sets overall requirement for the SPS, i.e. establishments *must* ensure operations in and around the establishments *do not* lead to insanitary conditions that would contaminate or adulterate product.

416.1 is to be cited in situations where findings indicate that an establishment **systematically** fails to maintain sanitary conditions and that product adulteration may occur as a result.

What does “insanitary” mean?

“A state, condition, or occurrence which may lead to the contamination or adulteration of edible meat or poultry product when it is exposed, processed, handled, stored, or packaged”.

Sanitation Performance Standards:

FSIS Directive 5000.1, Rev. 5 - *Verifying an Establishment’s Food Safety System*

SPS Regulations: 9 CFR Part 416.2 - 416.5:

416.2(a) Grounds and Pest Control- *The grounds about an establishment must be maintained to prevent conditions that could lead to **insanitary conditions**, adulteration of product, or interfere with inspection by FSIS program employees. Establishments must have in place a **pest management program** to prevent the harborage and breeding of pests on the grounds and within establishment facilities. **Pest control substances used must be safe** and effective under the conditions of use and not be applied or stored in a manner that will result in the adulteration of product or the creation of insanitary conditions.*

416.2(b) Construction-

416.2(b)(1) Establishment buildings, *including their structures, rooms, and compartments must be of sound construction, be kept in good repair, and be of sufficient size to allow for processing, handling, and storage of product in a manner that does not result in product adulteration or the creation of insanitary conditions.*

416.2(b)(2) Walls, *floors, and ceilings within establishments must be built of durable materials impervious to moisture and be cleaned and sanitized as necessary to prevent adulteration of product or the creation of insanitary conditions.*

416.2(b)(3) Walls, *floors, ceilings, doors, windows, and other outside openings must be constructed and maintained to prevent the entrance of vermin, such as flies, rats, and mice.*

416.2(b)(4) Rooms or compartments *in which **edible** product is processed, handled, or stored must be **separate** and distinct from rooms or compartments in which **inedible** product is processed, handled, or stored, to the extent necessary to prevent product adulteration and the creation of insanitary conditions.*

416.2(c) Lighting- *Lighting of good quality and sufficient intensity to ensure that sanitary conditions are maintained and that product is not adulterated must be provided in areas where food is processed, handled, stored, or examined; where equipment and utensils are cleaned; and in hand-washing areas, dressing and locker rooms, and toilets.*

416.2(d) Ventilation- *Ventilation adequate to control odors, vapors, and condensation to the extent necessary to prevent adulteration of product and the creation of insanitary conditions must be provided.*

416.2(e) Plumbing- *Plumbing systems must be installed and maintained to:*

416.2(e)(1) *Carry sufficient quantities of water to required locations throughout the establishment.*

416.2(e)(2) *Properly convey sewage and liquid disposable waste from the establishment.*

416.2(e)(3) *Prevent adulteration of product, water supplies, equipment, and utensils and prevent the creation of insanitary conditions throughout the establishment.*

416.2(e)(4) *Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.*

416.2(e)(5) *Prevent back-flow conditions in and cross-connection between piping systems that discharge wastewater or sewage and piping systems that carry water for product manufacturing.*

416.2(e)(6) *Prevent the back up of sewer gases.*

416.2(f) Sewage- Sewage disposal - *Sewage must be disposed into a sewage system separate from all other drainage lines or disposed of through other means **sufficient to prevent backup of sewage into areas where product is processed, handled, or stored.** When the sewage disposal system is a private system requiring approval by a State or local health authority, the establishment must furnish FSIS with the letter of approval from that authority upon request.*

Note: Sewage is "refuse liquids or waste matter usually carried off by sewers" (from the online Merriam-Webster dictionary).

416.2(g) Water supply, water, ice, solution reuse-

416.2(g)(1) *A **supply of running water** that complies with the National Primary Drinking Water regulations (40 CFR part 141), at a suitable temperature and under pressure as needed, must be provided in all areas where required (for processing product, for cleaning rooms and equipment, utensils, and packaging materials, for employee sanitary facilities, etc.). If an establishment uses a municipal water supply, it must make available to FSIS, upon request, a water report, issued under the authority of the State or local health agency, certifying or attesting to the potability of the water supply. If an establishment uses a private well for its water supply, it must make available to FSIS, upon request, documentation certifying the potability of the water supply that has been renewed at least semi-annually.*

416.2(g)(2) ***Water, ice, and solutions** (such as brine, liquid smoke, or propylene glycol) used to chill or cook **ready-to-eat** product may be **reused** for the same purpose, provided that they are maintained free of pathogenic organisms and fecal coliform organisms and that other physical, chemical, and microbiological contamination have been reduced to prevent adulteration of product.*

416.2(g)(3) ***Water, ice, and solutions** used to chill or wash **raw** product may be **reused** for the same purpose provided that measures are taken to reduce physical, chemical, and microbiological contamination so as to prevent contamination or adulteration of product. Reuse that has come into contact with raw product may not be used on ready-to-eat product. **416.2(g)(4)** **Reconditioned water** that has never contained human waste and that has been treated by an onsite advanced wastewater treatment facility may be used on raw product, except in product formulation, and throughout the facility in edible and inedible production areas, provided that measures are taken to ensure that this water meets*

the criteria prescribed in paragraph (g)(1) of this section. Product, facilities, equipment, and utensils coming in contact with this water must undergo a separate final rinse with non-reconditioned water that meets the criteria prescribed in paragraph (g)(1) of this section.

416.2(g)(5) Any water that has never contained human waste and that is free of pathogenic organisms may be used in edible and inedible product areas, provided it does not contact edible product. For example, such reuse water may be used to move heavy solids, to flush the bottom of open evisceration troughs, or to wash antemortem areas, livestock pens, trucks, poultry cages, picker aprons, picking room floors, and similar areas within the establishment.

416.2(g)(6) Water that does not meet the use conditions of paragraphs (g)(1) through (g)(5) of this section may not be used in areas where edible product is handled or prepared or in any manner that would allow it to adulterate edible product or create insanitary conditions.

416.2(h) Dressing rooms, Lavatories, and Toilets:

416.2(h)(1) Dressing rooms, toilet rooms, and urinals must be sufficient in number, ample in size, conveniently located, and maintained in a sanitary condition and in good repair at all times to ensure cleanliness of all persons handling any product. They must be separate from the rooms and compartments in which products are processed, stored, or handled.

416.2(h)(2) Lavatories with running hot and cold water, soap, and towels must be placed in or near toilet and urinal rooms and at such other places in the establishment as necessary to ensure cleanliness of all persons handling any product.

416.2(h)(3) Refuse receptacles must be constructed and maintained in a manner that **protects against the creation of insanitary** conditions and the **adulteration** of product.

416.3 Equipment & Utensils-

416.3(a) Equipment and utensils used for processing or otherwise handling edible product or ingredients must be of such material and construction to facilitate thorough cleaning and to ensure that their use will not cause the adulteration of product during processing, handling, or storage. Equipment and utensils must be maintained in sanitary condition so as not to adulterate product.

416.3(b) Equipment and utensils must not be constructed, located, or operated in a manner that prevents FSIS program employees from inspecting the equipment or utensils to determine whether they are in sanitary condition.

416.3(c) Receptacles used for storing inedible material must be of such material and construction that their use will not result in the adulteration of any edible product or in the creation of insanitary conditions. Such receptacles must not be used for storing any edible product and must bear conspicuous and distinctive marking to identify permitted uses.

416.4 Sanitary Operations:

416.4(a) All food-contact surfaces, including food-contact surfaces of utensils and equipment, must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.

NOTE: Many establishments will comply with the requirements of 416.4(a) through SSOP activities.

416.4(b) Non-food-contact surfaces of facilities, equipment, and utensils used in the operation of the establishment must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.

416.4(c) Cleaning compounds, sanitizing agents, processing aids, and other chemicals used by an establishment must be safe and effective under the conditions of use. Such chemicals must be used, handled, and stored in a manner that will not adulterate product or create insanitary conditions. Documentation substantiating the safety of a chemical's use in a food processing environment must be available to FSIS inspection program employees for review.

416.4(d) Product must be protected from adulteration during processing, handling, storage, loading, and unloading at and during transportation from official establishments.

416.5 Employee Hygiene:

416.5(a) Cleanliness. All persons working in contact with product, food-contact surfaces, and product-packaging materials must adhere to hygienic practices while on duty to prevent adulteration of product and the creation of insanitary conditions.

416.5(b) Clothing. Aprons, frocks, and other outer clothing worn by persons who handle product must be of material that is disposable or readily cleaned. Clean garments must be worn at the start of each working day and garments must be changed during the day as often as necessary to prevent adulteration of product and the creation of insanitary conditions.

416.5(c) Disease control. Any person who has or appears to have an infectious disease, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, must be excluded from any operations which could result in product adulteration and the creation of insanitary conditions until the condition is corrected.

Custom Exempt 303.1a(2)(i) Establishments that conduct custom exempt operations must be maintained and operated in accordance with the provisions of §416.1 through 416.6, except for §416.2(g)(2) through (6) of this chapter, regarding the water reuse and any provisions of Part 416 of this chapter relating to inspection or supervision of specified activities or other action by a program employee. If custom exempt operations are conducted in an official establishment, however, all of the provisions of Part 416 of this chapter shall apply to those operations.

Compliance / Noncompliance

IPP must verify compliance and noncompliance with the SPS regulations. Noncompliance is the failure of an establishment to meet one or more regulatory requirements. Every time the IPP determines that the establishment is not meeting the SPS requirements, the IPP must document the noncompliance on an NR. If the IPP determines that the SPS noncompliance is due to the establishment's repeated failure to maintain sanitary conditions, the IPP should consult with their FLS or IIC to determine if 416.1 should be added to the noncompliance record.

When the IPP finds that any equipment, utensil, room, or compartment at an official establishment is insanitary or that its use could cause the adulteration of product, he or she will attach to it a "U.S. Rejected" tag. Equipment, utensils, rooms, or compartments tagged cannot be used until made acceptable. Only an FSIS program employee may remove a "U.S. Rejected" tag.

08 Sanitation Standard Operating Procedures (SSOP)

416.11 General rules.

Each official establishment shall develop, implement, and maintain written standard operating procedures for sanitation (Sanitation SOP's) in accordance with the requirements of this part.

416.12 Development of Sanitation SOP's.

- (a) The Sanitation SOP's shall describe all procedures an official establishment will conduct daily, before and during operations, sufficient to prevent direct contamination or adulteration of product(s).
- (b) The Sanitation SOP's shall be **signed and** dated by the individual with overall authority on-site or a higher-level official of the establishment. This signature shall signify that the establishment will implement the Sanitation SOP's as specified and will maintain the Sanitation SOP's in accordance with the requirements of this part. The Sanitation SOP's shall be signed and dated upon initially implementing the Sanitation SOP's and upon any modification to the Sanitation SOP's.
- (c) Procedures in the Sanitation SOP's that are to be conducted prior to operations shall be identified as such, and shall address, at a minimum, **the cleaning of food contact surfaces** of facilities, equipment, and utensils.
- (d) The Sanitation SOP's shall **specify the frequency with which each procedure** in the Sanitation SOP's is to be conducted and **identify the establishment employee(s)** responsible for the implementation and maintenance of such procedure(s).

416.13 Implementation of SOP's.

- (a) Each official establishment shall **conduct the pre-operational procedures** in the Sanitation SOP's **before the start** of operations.
- (b) Each official establishment shall conduct all other procedures in the Sanitation SOP's at the frequencies specified.
- (c) Each official establishment shall **monitor daily the implementation** of the procedures in the Sanitation SOP's.

416.14 Maintenance of Sanitation SOP's.

Each official establishment **shall routinely** evaluate the effectiveness of the Sanitation SOP's and the procedures therein in preventing direct contamination or adulteration of product(s) and shall revise both as necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel.

416.15 Corrective Actions.

- (a) Each official establishment shall take appropriate corrective action(s) when either the establishment or FSIS determines that the establishment's Sanitation SOP's or the procedures specified therein, or the implementation or maintenance of the Sanitation SOP's, may have failed to prevent direct contamination or adulteration of product(s).
- (b) Corrective actions include procedures to ensure appropriate **disposition of product(s)** that may be contaminated, **restore sanitary conditions**, and **prevent the recurrence** of direct contamination or adulteration of product(s), including appropriate reevaluation and modification of the Sanitation SOP's and the procedures specified therein or

appropriate improvements in the execution of the Sanitation SOP's or the procedures specified therein.

416.16 Recordkeeping requirements.

- (a) Each official establishment shall **maintain daily records** sufficient to document the implementation and monitoring of the Sanitation SOP's and any corrective actions taken. The establishment employee(s) specified in the Sanitation SOP's as being responsible for the implementation and monitoring of the procedure(s) specified in the Sanitation SOP's shall authenticate these records with his or her initials and the date.
- (b) Records required by this part may be maintained on computers provided the establishment implements appropriate controls to ensure the integrity of the electronic data.
- (c) Records required by this part shall be maintained for **at least 6 months** and made available to FSIS. All such records shall be maintained **at the official establishment for 48 hours** following completion, after which they may be maintained off-site provided such records can be made **available to FSIS within 24 hours of request**.

416.17 Agency Verification.

FSIS shall verify the adequacy and effectiveness of the Sanitation SOP's and the procedures specified therein by determining that they meet the requirements of this part. Such verification may include:

- (a) Reviewing the Sanitation SOP's;
- (b) Reviewing the daily records documenting the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be taken;
- (c) Direct observation of the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be taken; and
- (d) Direct observation or testing to assess the sanitary conditions in the establishment.

IPP will verify that establishments meet **all four** of the following regulatory requirements during the performance of each SSOP task:

- a. Implementation and monitoring
- b. Maintenance
- c. Corrective actions
- d. Recordkeeping

The following table lists the four tasks used to verify compliance with Sanitation SOP requirements.

Inspection Tasks	General Description
Pre-Operational Sanitation SOP Record Review	Use the Recordkeeping verification activity to verify that the establishment implements the procedures in the Sanitation SOP effectively to prevent contamination of food contact surfaces or adulteration of products prior to operations.
Pre-Operational Sanitation SOP Review and Observation	Use the Review and Observation verification activity and the Recordkeeping verification activity to verify that the establishment implements the procedures in the Sanitation SOP effectively to prevent contamination of food contact surfaces or adulteration of products prior to operations. In PHIS, IPP should select the “Both” option on the Activity tab.
Operational Sanitation SOP Record Review	Use the Recordkeeping verification activity to verify that the establishment implements the procedures in the Sanitation SOP effectively to prevent contamination of food contact surfaces or adulteration of products during operations.
Operational Sanitation SOP Review and Observation	Use the Review and Observation verification activity and the Recordkeeping verification activity to verify that the establishment implements the procedures in the Sanitation SOP effectively to prevent contamination of food contact surfaces or adulteration of products during operations. In PHIS, IPP should select the “Both” option on the Activity tab.

The Record Review Tasks: Pre-Operational and Operational

IPP use the recordkeeping verification activity to verify all **four** Sanitation SOP requirements (implementation, maintenance, corrective actions, and recordkeeping) while performing the Pre-Operational and Operational Sanitation SOP Record Review tasks.

During the Sanitation SOP record review tasks, IPP perform the following:

- 1) **Review the written Sanitation SOP** to be familiar with the establishment’s current pre-operational or operational sanitation procedures.
- 2) **Verify that the SSOP continues** to meet the design requirements of §416.1.
- 3) **Verify that the establishment has maintained daily records** that demonstrate that the establishment has implemented the pre-operational and operational procedures as written, monitored those procedures at least daily or at the specified frequency, and taken immediate or corrective action when necessary.

-For instance, **IPP verify that the records** indicate that the establishment conducted monitoring daily prior to the start of operations. If the establishment observed a contaminated food contact surface (residue from previous day’s product) during pre-

operational inspection, IPP verify that the establishment documented that the contaminated surface was re-cleaned, re-inspected and released before product passed over the surface. Similarly, if the establishment has documented the finding of contaminated product or food contact surfaces during operations, IPP verify that the documented corrective actions meet regulatory requirements.

- 4) Verify all the **recordkeeping** requirements of §416.16.

-For instance, IPP verify that the establishment employee responsible for the implementation and monitoring of the procedure has authenticated the records with their initials and date.

The Review and Observation Tasks: Pre-Operational and Operational

IPP use **both** the review and observation verification activity and the recordkeeping verification activity when performing the Pre-Operational and Operational Sanitation SOP Review and Observation tasks. IPP are to verify that all **four** Sanitation SOP requirements (implementation, maintenance, corrective actions, and recordkeeping).

Each time IPP perform the review and observation tasks, they:

- 1) **Should review the written Sanitation SOP** so they are familiar with the establishment's current pre-operational or operational sanitation procedures;
- 2) **Verify** that the SSOP continues to meet the requirements of §416.12;
- 3) **Observe the establishment conducting its monitoring** activities and implementing corrective action when they find that the pre-operational or operational procedures have failed to effectively clean and sanitize food contact surfaces;
- 4) **Inspect one or more areas** and perform an organoleptic examination of some of the establishment's facilities, equipment, and utensils to assess sanitary conditions (sometimes referred to as "hands-on" inspection);
- 5) Compare their findings with the establishment records/findings, (which may not be documented until the start of the next production day for that specific shift), and
- 6) **Verify that the establishment meets the corrective action requirement** of 9 CFR 416.15 when they find that the establishment's Sanitation SOP has failed to prevent product contamination or adulteration.

To perform the Pre-Op or Operational Sanitation SOP Review and Observation task, IPP should have:

- A pen or pencil.
- U.S. Rejected/U.S. Retained tags and some means (tape, string, rubber bands) of affixing these tags to equipment, departments, product, etc.
- A notepad to record their pre-operational findings.

Note: Recommend having a good flashlight to check dark areas or inside pipes/equipment.

Pre-Op Sanitation SOP Review and Observation Task

- IPP not trained in lockout/tagout (FSIS Directive 4791.11) methodology shall not perform pre-op sanitation inspection on any piece of equipment requiring lock out.
- After establishment management informs IPP that an area is ready for FSIS pre-op inspection, IPP perform the review component of Pre-Op Sanitation SOP Review and Observation verification task. They are to inspect areas in the establishment, equipment and utensils, and places on equipment that, if insanitary, would present the greatest risk of transferring pathogens or other contaminants to product (e.g., direct food contact surfaces that are difficult to clean or may serve as microbial harborage sites).
- When IPP have completed their examination of the selected area(s) and equipment, IPP should compare their findings to the establishment's sanitation findings. If the written records are not yet completed, IPP may ask the establishment about its pre-operational findings and any actions taken. However, IPP must verify the recordkeeping requirements before completing the task.
- **When IPP observe contaminated direct food contact surfaces** during the pre-op sanitation verification, they are to:
 - **Reject** the affected equipment by placing a reject tag;
 - **Notify** the establishment, and
 - **Document** the noncompliance on NR.
- The establishment has the responsibility to restore sanitary conditions (clean the contaminated food contact surface) and document the restoration of sanitary conditions under §416.16(a). **Preventive measures do not need to be developed and documented unless product has been contaminated or adulterated by the unclean surface.** IPP should not remove the U.S. Rejected tag until the establishment has restored sanitary conditions.

Operational Sanitation SOP Review and Observation Task

- IPP should select area(s) of the establishment and equipment that presents the **highest risk** for insanitary conditions or product contamination.
- IPP should observe the equipment, employees, and facilities to verify that product contamination is not occurring during operation.
- If IPP observe contaminated direct food contact surfaces or contaminated product, there is Sanitation SOP noncompliance whether there is a procedure written in the establishment's Sanitation SOP to cover that situation or not.
- IPP should inspect direct food contact surfaces of equipment, facilities, and utensils.
- IPP should be aware of other potential sources of product contamination such as condensation, peeling paint, dead-end pipes and scaling rust from overhead fixtures where products are processed, handled, or stored can contaminate products.
- When possible, IPP should also observe the establishment conducting its monitoring activity.

- When IPP have completed their assessment of the sanitation in one or more areas of the establishment, they should compare their findings with the establishment's sanitation findings. If the records are not complete at the time, IPP might ask the establishment if it has conducted monitoring and what observations were made. However, IPP must verify the recordkeeping requirements prior to completion of the task.
- IPP should be aware that there are times the responsible establishment employee might not be able to propose permanent preventive measures immediately. However, in these situations, the establishment should propose a tentative preventative measure of what they will do until they determine a permanent solution.

WORKSHOP #1- Identifying the Basic Elements of the SSOPs

Examples of Pre-Op and Operations SSOPs *Training Purposes Only*

Objective: Carefully read the sample Sanitation SOP below. Evaluate the Sanitation SOP for compliance with §416.11 and §416.12. After you have evaluated the Sanitation SOP, answer the questions listed in the worksheet.

BEEF SLAUGHTER ESTABLISHMENT M41777—Sanitation SOP

Owner – Joe Green

This Sanitation SOP is for Beef Slaughter Establishment M41777 and becomes effective on January 28, 1998

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 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.

(Signature and date of 1/25/98) Joe Green

Modification Log

- 1. (signature and date of Joe Green, 12/11/2018)*
- 2. (signature and date of Joe Green, 6/17/2019)*

WORKSHOP #1- Identifying the Basic Elements

Objective: 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	Student's 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?			

09 Sanitation Scenarios

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 effecting product or food contact surfaces?

Is this a noncompliance?

If so, which regulation?

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 effecting 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?

10 Noncompliance

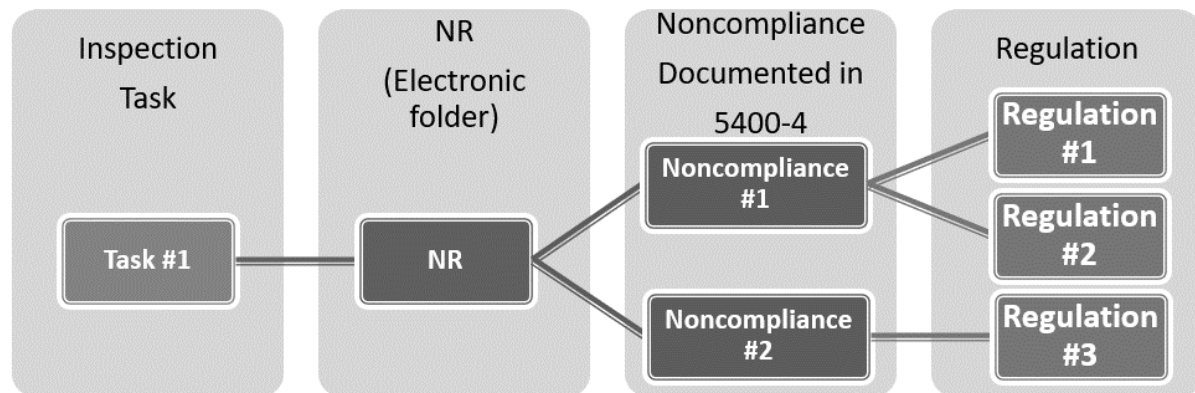
Noncompliance is defined as an establishment's **failure to meet a regulatory requirement**. When IPP find regulatory noncompliance, they are to:

- Notify a representative of establishment management as soon as possible verbally.
- Document the noncompliance on a Noncompliance Record (NR, FSIS Form 5400-4) in PHIS and present the noncompliance to establishment management. The Noncompliance Record is the written notification of the noncompliance.
- Verify that the establishment takes necessary actions to bring itself into compliance with the applicable regulation.

The NR serves as FSIS's official notification and documentation of the establishment's failure to meet one or more regulatory requirements. NRs are legal documents. They are the basis for supporting further enforcement actions that the Agency may take against an establishment. Therefore, it is extremely important that IPP use good documentation practices and follow Agency policy when completing NRs.

IPP must ensure that the written description of noncompliance documented on an NR adequately supports the determination of regulatory noncompliance and the NR is accurately completed. IPP **must** provide establishment management with a copy of the NR. By notifying the establishment of noncompliance with the regulatory requirements both orally and in writing via the NR, IPP are providing the establishment with due process.

Only **one NR** is completed per inspection task when noncompliance is found. However, **more than one noncompliance** may be documented on the NR.



Noncompliance and NRs have a status displayed in PHIS. The noncompliance and NR statuses are defined in the following table.

	Status in PHIS	Definition
Noncompliance (NC)	Open	<ul style="list-style-type: none"> A noncompliance has been documented in PHIS
	Finalized	<ul style="list-style-type: none"> The noncompliance is ready to deliver to establishment management
Noncompliance Record (NR)	Open	<ul style="list-style-type: none"> An NR has been created in PHIS
	Completed	<ul style="list-style-type: none"> All of the mandatory regulations have been verified The establishment has brought itself into compliance with the regulations for each noncompliance in the NR

When documenting noncompliance on a Noncompliance Record (NR), a good method to follow is to determine the **6Ws (While, When, What, Where, Who, and Why)** and then document the details for each one of the Ws.

This is an example outline created using the 6W method. It is an organized way to gather facts and help prepare an NR.

- While** While performing what inspection task?
Identify the scheduled inspection task. Provide brief summary of regulation(s) verified.
- When** When was the noncompliance discovered? Date, time, operation status of the establishment. When did the noncompliance begin? When has this noncompliance happened before?
- What** What is the noncompliance? What were the exact conditions?
Adulterant/contaminant – number, size, shape, color, and consistency.
Environment – leaks, condensation, wall or floor quality. What documents or records were reviewed? What regulatory control actions were taken, if any? What action did the establishment take or propose? A detailed description helps paint a picture for the reader. **Note:** Words like “filthy”, “dirty” or “scummy” are *not* acceptable in describing noncompliant findings. The contamination must be accurately described with respect to size, shape and consistency, such as “2 inch by 5-inch smear of a black oily substance” or “15 to 20 1/4 inch to 1 inch pieces of fat.”

Where	Specific location within the establishment? A room, area within a room, outside. Other locations affected by the noncompliance?
Who	When a noncompliance is discovered, IPP have an obligation to immediately report it orally and then in writing to the establishment, especially when production is stopped and/or when meat, poultry or egg products are retained.
Why	Why is there noncompliance? What regulations were not met? What procedure, plan or program was the establishment not following (e.g., Sanitation SOP, HACCP plan, or prerequisite program)?

IPP are to **associate NRs** when they indicate an ongoing trend of **same-cause** noncompliance or systemic problems with the same aspect of the establishment's food safety system. The **trend** may be caused by the establishment's failure to implement its proposed preventive measures. Sometimes the establishment has implemented its proposed preventive measures; nevertheless, these measures are not effective in preventing the noncompliance from recurring. Frequently, SSOP or HACCP recordkeeping and corrective action NRs or SSOP or HACCP monitoring and corrective action NRs can be associated because they represent repetitive failure of the same aspect of the establishment's food safety system.

The reasons for associating the NR are:

- Notify establishment of ineffective further planned actions
- Document the history or trend of repetitive noncompliance and the establishment's failed further planned actions
- Provide the documentation to support further enforcement actions

Procedures for associating noncompliance:

Document (write up) the **most recent NR number and date** plus the **specific further planned action/corrective measures** that were **either not implemented or were ineffective** at preventing recurrence of the noncompliance **in the description of the noncompliance** (Block 10) of the NR.

Record the reason for the decision to associate the noncompliance in the **Inspection Notes** in PHIS.

11 HACCP Processing Categories

The HACCP (Hazard Analysis Critical Control Point) regulations set out 9 processing categories in which finished product can be identified, 9 CFR 417.2(b)(1):

- (i) Slaughter – all species
- (ii) Raw product – Non-Intact (ground)
- (iii) Raw product – Intact (not ground)
- (iv) Thermally processed – Commercially sterile
- (v) Not heat treated – shelf stable
- (vi) Heat treated – shelf stable
- (vii) Fully cooked – not shelf stable
- (viii) Heat treated but not fully cooked – not shelf stable
- (ix) Product with secondary inhibitors – not shelf stable

A food safety hazard is defined as any biological, chemical, or physical property that may cause a food to be unsafe for human consumption. These pathogens mostly enter the food chain with the live animal, but may also exist in the production environment.

Slaughter Processing Category

This HACCP processing category applies to establishments that slaughter livestock or poultry. Slaughter is the process whereby healthy, live animals are humanely stunned, bled, de-hided, dehaired and eviscerated. The slaughter process has inherent food safety hazards that originate with the live animal. Therefore, the slaughter process has heightened food safety significance.

Slaughter establishments typically produce carcasses which are raw intact finished products. The food safety hazards identified for the slaughter process are also common to the Raw Product - Intact and Raw Product - Non-Intact processing categories.

Most of the food safety hazards inherent in raw processes originate with the live animals that enter the slaughter establishment. These hazards are common in all raw processes. Common hazards include the **biological** hazards of bacterial pathogens, the **chemical** hazard of allergens and drug residues, and the **physical** hazards of foreign material. These hazards could be present in raw product in any step of the food production process. We will now address each of these three categories of hazards in more detail.

The following chart summarizes the common microbiological hazards in slaughter products: beef, lamb, pork, and poultry:

Process Category	Species	Biological Hazards, reasonably likely to be present and cause foodborne illness, denoted by "+"			SRM
		<i>Salmonella</i>	STEC, including <i>E. coli</i> O157:H7	<i>Campylobacter</i>	
SLAUGHTER	Beef	+	+		+
	Sheep, Goat	+			
	Pork	+			
	Poultry	+		+	

The biological hazards of meat and poultry products result from the presence of pathogenic bacteria in and on the live animal or bird, including intestinal contents and exterior surfaces such as hide, hair, feathers, hooves and the gastrointestinal tract contents.

The prevalence of the pathogen ***Salmonella*** in beef, lamb, pork, and poultry carcasses varies greatly. *Escherichia coli* is commonly found as part of the normal bacteria of the intestinal tract of humans and animals. Some strains, notably the **Shiga toxin-producing *E. coli* (STEC)** including ***Escherichia coli* O157:H7**, can cause serious illness in humans. Raw poultry is the major source of ***Campylobacter***.

Bovine Spongiform Encephalopathy (BSE) is a progressive neurological disorder of **cattle** that results from infection by a protein, called a **prion**. High-risk tissues for BSE contamination, known as **Specified Risk Materials (SRM)**, include tonsils and distal ileum for cattle of all ages.

Animals may be presented at slaughter with violative levels of **chemical residues**. This hazard includes chemical residues resulting from use of, or exposure to, drugs, pesticides, and other compounds.

Other examples of **environmental contaminants** that may be consumed by animals include lead, cadmium, mercury, arsenic, dioxins, or polychlorinated biphenyls (PCBs). **Industrial chemicals** such as dioxins may be of concern because they have the potential to cause endocrine effects or interfere with the immune system.

A physical hazard is a physical component of a food that is unexpected and may cause illness or injury to the person consuming the food. Physical hazards, such as pieces of metal, sometimes occur because equipment has not been properly maintained. Product may be received that is contaminated by foreign material, which if not controlled, may subsequently become incorporated into the finished product. Foreign material would include non-animal objects such as metal, wood, rubber, glass, steel, lead, or other objects.

Raw Product - Non-Intact Processing Category

This HACCP processing category applies to establishments that further process product by comminuting product (grinding, injecting product with solutions, or mechanically tenderizing product by needling, cubing, pounding devices or other means of creating non-intact product).

Non-intact product presents an increased food safety concern due to the spread of pathogens throughout the product and pathogen penetration from the surface into the interior of the product. **Beef products pose increased risk of adulteration from Shiga-toxin producing *E. coli* (STEC), including *E. coli* O157:H7.** A very small dose of consumed *E. coli* O157:H7 can result in severe health consequences, and consumers frequently consume beef after preparations that do not destroy this pathogen.

Remember, the distinction between intact and non-intact product depends on whether the meat interior remains protected from pathogens migrating below the exterior surface and whether or not the depth of pathogen penetration is significant.

The **biological hazards** in the non-intact raw product are mostly carried over from the slaughtered carcass. Establishments that further process raw products are dependent on their suppliers to eliminate or reduce microbial hazards because antimicrobial treatments and interventions are most practical when the product is still intact.

Food allergies are responses by the immune system to naturally occurring proteins in certain foods that most individuals can eat without any adverse effects. Allergens are considered chemical hazards. The following “Big 8” foods can cause serious allergic reactions in some individuals and account for more than 90% of all food allergies. They are peanuts, soybeans, milk, eggs, fish, crustacean shellfish, tree nuts, and wheat.

Establishments conducting processes such as needle injection or comminution of product regularly use equipment with numerous moving metal parts. If this equipment is not properly maintained, it can easily lead to metal contamination of product and cause a physical hazard.

Raw Product - Intact Processing Category

This HACCP processing category refers to product that receives further processing directly after the slaughter processing steps or after receiving raw products. It includes all raw products that are intact in their final form.

Finished products such as raw poultry (in whole or in part) or raw meat products such as primal or subprimals are part of the Raw Product - Intact processing category. Beef manufacturing trimmings (e.g., pieces of meat remaining after steaks, roasts, and other intact cuts) are also an example of intact raw beef product. FSIS considers raw products to be intact unless they have undergone any of the processes previously discussed, associated with the Raw Product - Non-Intact HACCP processing category. The distinction between intact and non-intact product depends on whether the interior remains protected from pathogens migrating below the exterior surface and whether or not the depth of pathogen penetration is significant.

The common hazards for raw intact product are the same as those identified in the Slaughter processing category. The common **biological, chemical, and physical hazards** in the intact raw product are mostly carried over from the slaughtered carcass. Establishments must address these hazards as they pertain to and affect their intact raw product.

Thermally Processed - Commercially Sterile Processing Category

This processing category includes canned meat products, some products processed in pouches and semi-rigid containers.

Not Heat Treated - Shelf Stable Processing Category

This process category applies to products that are further processed by a curing, drying, or fermenting step as the sole means by which product achieves food safety. A low-level heat treatment may be applied, as long as the heat treatment is not used as the sole means to achieve food safety. The finished products produced are shelf stable.

Products in this category typically include dried sausage, such as salami and pepperoni. Semi-dry sausages may also be in this HACCP category, depending on the process steps. Dried whole muscle products which are mostly dry cured could also fall into this category. These products include dried hams, such as prosciutto, parma and country ham, and dried intact pieces of meat such as dried pork bellies (pancetta), dried pork shoulders (coppa), and dried beef rounds (bresaola, beef prosciutto, basturma). Products in this category could sometimes also be categorized in the Heat Treated - Shelf Stable processing category, based on the methods by which they are made.

Biological hazards which are common to these products differ from raw products. The lethality step(s) in these products kills the pathogens (e.g., *Salmonella*, *Campylobacter*, *Listeria monocytogenes*, and *E. coli* O157:H7) which may otherwise be present in the raw materials. However, there are other biological hazards of concern as a result of the different ingredients and process steps these products may undergo.

Listeria monocytogenes (*Lm*) is also a potential biological hazard that may re-contaminate the product. This could happen after lethality if products are exposed to food contact surfaces, raw products or contaminated ingredients prior to final packaging.

Common **chemical hazards** include allergens, such as soy or milk byproducts which may be used as ingredients. Lactic acid or acetic acid may be used to speed acid formation. Nitrites are commonly used as part of the curing process and phosphates might also be used for binding, flavor and/or color. These latter chemicals may be considered hazards if they are not used in the proper quantities.

Like non-intact raw products, metal contamination from equipment with small and moving parts could pose potential **physical hazards** as well.

Heat Treated - Shelf Stable Processing Category

This process category applies to product that receives further processing by using a heat treatment in combination with a curing, drying, or fermenting process step to achieve food safety. The heat treatment is the primary means of achieving lethality. Finished products

produced under this processing category are safe to eat without refrigeration or further processing. This processing category typically includes popped pork skins, bacon bits, snack sticks or jerky, summer sausage, Lebanon bologna, thuringer, kippered beef, pickled sausages and rendered products.

Potential **biological hazards** include *Listeria monocytogenes*, which may contaminate the product after lethality.

Common **chemical hazards** include allergens, such as soy or milk byproducts which may be used as ingredients. Chemical accelerants, acidifiers and antioxidants may be used as part of the fermentation process or assist in the quality. These could pose hazardous if not used in proper measurements.

There are no notable physical hazards unique to this process category. However, like non-intact raw products, metal contamination from equipment with small and moving parts could pose potential **physical hazards** as well.

Fully Cooked - Not Shelf Stable Processing Category

This process category applies to establishments that further process products by using primarily a full lethality heat process step (e.g., cooking) to achieve food safety. These products have been processed in a manner that makes them safe to eat, with no further preparation required by the consumer.

Deli meats such as ham, roast beef, and smoked turkey breast all have very similar processes. Cured products, like ham, turkey ham, and corned beef, have nitrite in the solution. Another type of product in this category is the meat salad.

The cooking step in these products kills the pathogens. However, there are other **biological hazards** of concern as a result of the different process steps and procedures these products undergo.

Common **chemical hazards** include allergens, such as soy or milk byproducts which may be used as ingredients. Chemical accelerants, acidifiers and antioxidants may be used as part of the fermentation process or assist in the quality. These could pose hazards if not used in proper quantities.

Like non-intact raw products, metal contamination from equipment with small and moving parts could pose potential **physical hazards** as well.

Heat Treated but Not Fully Cooked - Not Shelf Stable Processing Category

This process category applies to further processed products that are either not ready-to-eat products (NRTE) or raw, otherwise processed products that are refrigerated or frozen throughout the product's shelf life. These products are produced using the criteria of one of the two following heat processing steps. The heat processing step is not adequate to achieve food safety; therefore, products may be partially cooked or heated, such as to set batter on a raw product. The other criteria is that the heat processing step is adequate to achieve food safety;

however, product is further processed, assembled, or packaged so that the cooked product contacts non-ready to-eat product ingredients. In this case, the final product is in a form that is not edible without additional preparing to achieve food safety.

Products in this category include: not ready-to-eat bacon, cold smoked sausage and partially cooked battered and breaded poultry.

Common **biological** hazards and controls for these products will be similar to the hazards for raw products because these products have not undergone a lethality step to rid the product of harmful pathogens.

See previous discussions about **chemical and physical hazards** and controls. Hazards and controls will vary based on the product and how it is processed.

Products with Secondary Inhibitors - Not Shelf Stable Processing Category

This process category is seldom used and applies to product that has been further processed by curing or using other ingredients that inhibit bacterial growth. It should only be used when these types of product don't fit into any of the other 8 categories.

Inspection of Fish of the Order *Siluriformes*

Background

The program covers domestic slaughter and processing establishments and import reinspection. In 2008, Congress made amendments to the FMIA to transfer inspection of "catfish" from FDA to USDA/FSIS. Congress made further amendments to the FMIA in the 2014 Farm Bill to clarify that "all fish of the order *Siluriformes*" (which includes catfish) are subject to inspection by FSIS.

The 2015 Final Rule created regulations 9 CFR 530-561 which requires mandatory inspection of official establishments that prepare or process amenable fish. The full FSIS enforcement period began in 2017 for both domestic and import inspection programs.

Amenable Fish Species

Section 601(w)(2) was added to the FMIA and specified all fish of the order *Siluriformes* as amenable species under the act. FSIS has regulatory jurisdiction over all fish of the order *Siluriformes* produced for human food. The *Siluriformes* includes the family *Ictaluridae* (e.g., channel catfish and blue catfish) (historically grown in the United States) as well as other catfish-like fish species (historically imported). Common names for some of these other catfish-like species are basa, tra, and swai.

Organisms are classified according to the following hierarchy: Domain, Kingdom, Phylum, Class, Order, Family, Genus, and Species.

Siluriformes is an order of bony fish that includes all catfish and catfish-like species. As you may know the name catfish refers to the long barbels, or feelers, which are present about the mouth of the fish and resemble cat whiskers. Altogether, the Order *Siluriformes* comprises

nearly 2,900 species in about 35 Families. Several species within the families *Ictaluridae*, *Pangasiidae*, and *Clariidae* are important food fish.

Products labelled as “**catfish**” must be of the family ***Ictaluridae***. Other species may only be labeled by their common or usual name. All of these fish are desirable food fish. Once a fish has been de-headed, eviscerated, and skinned or filleted, it is difficult to accurately distinguish one family or species from another on visual exam. The agency has genetic-based species testing for that purpose.

12 HACCP Seven Principles

FSIS requires all establishments that produce federally inspected meat and poultry products to design and operate HACCP (**Hazard Analysis and Critical Control Point**) systems. The seven principles of HACCP, which encompass a systematic approach to the identification, prevention, and control of food safety hazards include:

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

Principle 1: Conduct a Hazard Analysis.

- **A thorough hazard analysis** is the **key** to preparing an effectively designed HACCP plan.
- **A hazard is a biological, chemical, or physical** agent that is reasonably likely to occur and will cause illness or injury in the absence of its control.
- During the development and design of the hazard analysis, establishments must consider all three types of hazards – biological, chemical, and physical – at each step they identify in the production process. Once the establishment has identified potential hazards, these hazards are evaluated to determine if each one is reasonably likely to occur (RLTO), or not reasonably likely to occur (NRLTO).
- If the establishment determines that **the hazard is reasonably likely to occur, a critical control point must be developed** to address the hazard, either at that step or later in the process.
- If the establishment determines the hazard is not reasonably likely to occur, they must provide justification for this decision.
- **A Prerequisite Program** is a procedure or set of procedures that is designed to provide basic environmental or operating conditions necessary for the production of safe, wholesome food. The programs provide a foundation for the development and implementation of an effective HACCP system.

Principle 2: Determine Critical Control Points

- A **critical control point** is defined as a point, step, or procedure in a food process at which control can be applied, and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.
- For **each** hazard that is determined to be reasonably likely to occur, the establishment must identify critical control points and corresponding critical limits that are measurable or observable.

Principle 3: Establish Critical Limits

- **Critical limits (CL)** are the parameters (maximum and/or minimum) that indicate whether the control measure at the CCP is in or out of control.
- **CL is a maximum or minimum value** to which a biological, chemical, or physical parameter must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of a food safety hazard. Critical limits must be actual values that can be measured or quantified.

Principle 4: Establish Monitoring Procedures

- **Monitoring is a planned sequence of observations or measurements** to assess whether a **CCP is under control** and to produce an accurate record for future use in verification. Every CCP that is in the HACCP plan must be monitored to ensure that the critical limits are consistently met and that the process is producing safe product. Establishments must determine how often they need to monitor CCPs.
- **There are three objectives to monitoring:**
 - To track control of the process. This allows the establishment to identify trends in the process that may be leading to loss of process control. If monitoring detects a trend, establishments can take appropriate measures to restore process control before there is a deviation from the critical limit;
 - To determine when the process has deviated from the critical limit. This information lets the establishment know that process control has been lost and that appropriate corrective actions must be taken;
 - To provide a written document to be used in verification. Monitoring results must be recorded on official HACCP records, and such records serve as the basis for verification activities.

Principle 5: Establish Corrective Actions

- The corrective actions must be determined for each CCP in cases where the CL is not met.

Principle 6: Establish Recordkeeping and Documentation Procedures

- Establishment must ensure that the HACCP system has an effective recordkeeping system.

Principle 7: Establish Verification Procedures

- HACCP systems must be systematically verified.

13 HACCP Regulatory Process

The HACCP system, referenced in 9 CFR 417.4, is defined in 9 CFR 417.1 as “the HACCP plan in operation, including the HACCP plan itself”. The HACCP plan in operation includes the:

- Hazard analysis;
- HACCP plan;
- supporting documentation including prerequisite programs used to make decisions in the hazard analysis, and
- HACCP records generated on an ongoing basis.

IPP must focus on the overall effectiveness of the establishment’s HACCP system.

HACCP Regulatory Process

- **Inspection Methodology (Procedure)**
 - Performing HACCP inspection tasks
 - Verifying specific HACCP regulatory requirements during the performance of the HACCP inspection task
- **Decision-making (GAD)**
 - Gathering information, making observations, reviewing documentation, assessing the gathered information and arriving at a supportable compliance or noncompliance determination.
- **Documentation**
 - Entering HACCP inspection task results (observations and determinations) in PHIS
 - Documenting noncompliance on a Noncompliance Record (NR)
 - Associating noncompliance from the same cause
- **Enforcement**
 - Following the Rules of Practice (ROP)
 - Providing the establishment with due process

FSIS Responsibilities

FSIS responsibilities for verifying an establishment food safety system are outlined in **FSIS Directives 5000.1** and **5000.6**.

The HACCP inspection tasks appear on the establishment’s inspection Task List as **routine** tasks according to the specific HACCP process categories (listed in 9 CFR 417.2(b)) entered in the Establishment Profile in PHIS. IPP may initiate **directed** HACCP inspection tasks when they observe HACCP regulatory noncompliance or are instructed to do so by their supervisor.

HACCP Inspection Tasks

IPP perform two HACCP inspection tasks to verify that establishments are complying with 9 CFR Part 417:

- **The Hazard Analysis Verification (HAV) task** directs the IPP to review the establishment's hazard analysis for one HACCP plan, the HACCP plan, and any prerequisite programs or other documentation used to support the decision that a food safety hazard is not reasonably likely to occur in the process.
- **The HACCP verification task** focuses the attention of the IPP on the execution or implementation of the establishment's HACCP plans, prerequisite programs and other supporting programs, i.e., implementation of the establishment's HACCP system. IPP perform a HACCP verification task for each of the HACCP process categories listed in the establishment's profile.

Both HACCP verification tasks can be performed as a routine or directed task.

Each HACCP task has two verification components:

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

IPP use either component or a combination of the components to verify regulatory compliance.

Regulation 9 CFR 417.5(f) requires the establishment to make all such records available for official review.

Regulatory Decision-Making - A Thought Process

When IPP perform both of the HACCP inspection tasks, they need to use the regulatory thought process described below.

Gather, Assess, and Determine or GAD

IPP are to **gather (collect)** all available information to help them determine regulatory compliance.

IPP are to **assess (evaluate)** the significance and meaning of information gathered.

IPP are to **determine (decide)** whether the information supports a finding of regulatory compliance.

14 The Hazard Analysis Verification (HAV) Task

The **Hazard Analysis Verification (HAV) Task** is a work method that provides IPP with a powerful approach to verifying compliance with certain requirements of 9 CFR 417, specifically those that pertain to certain foundational elements of an establishment's HACCP system. These foundational elements are:

- A flow chart and hazard analysis that **matches the actual production processes** in the establishment;
- A hazard analysis in which the establishment accurately considers **applicable food safety hazards** given the nature of the process, product, and intended use of the product and determines whether each hazard is reasonably likely to occur (RLTO);
- Critical control points (**CCPs**) for hazards that are reasonably likely to occur in the process and documentation supporting those CCPs;
- Documentation (prerequisite programs) **supporting any decision** that a food safety hazard is not reasonably likely to occur (NRLTO) in the process;
- Evidence supporting the validity of the HACCP system; and
- Reassessment of the HACCP system annually and anytime changes occur that could affect the hazard analysis or HACCP plan.

Examples of technical and scientific support the establishment can use are Regulations, Pathogen Modeling Program (PMP), Processing Authority (PA), Challenge Studies, In-plant data, Agency compliance guidance documents, and other decision-making documents.

Examples of support documents the establishment can use to support a decision that a hazard is not reasonably to occur are: LOG (Letters of Guarantee); COA (Certificates of Analysis); product temperature controls; and microbial testing programs. IPP are to review the support documents while performing the HAV task.

Examples of Non-compliances IPP may find while performing the HAV task are:

- The establishment's flow chart does not accurately represent all the steps in the establishment's production process. Noncompliance with 417.2(a)(2).
- The establishment's flow chart does not accurately describe product flow. Noncompliance with 417.2(a)(2).
- The hazard analysis identifies a hazard reasonably likely to occur (RLTO) but does not have an associated CCP at or after the point where the hazard is introduced. Noncompliance with 417.2(c)(2).

- The establishment does not have documentation to support the development of CCPs, critical limits, or monitoring and verification procedures. Noncompliance with 417.5(a)(2).
- The establishment does not maintain validation data. Noncompliance with 417.4(a)(1).
- The establishment did not perform a reassessment at least once in the previous calendar year. Noncompliance with 417.4(a)(3).

HAV Task Summary Table

Refer to Directive 5000.6 for additional information about each step.

Step	Description	Verification Questions	Regs
1	Review flow chart and compare to production process.	<ul style="list-style-type: none"> • Does the flow chart represent the actual production process? 	417.2(a)(2)
2	Review the hazard analysis and consider guidance in the FSIS Meat and Poultry Hazards and Controls Guide (HCG).	<ul style="list-style-type: none"> • Does the flow chart or hazard analysis identify the intended use or consumers of the product? • Does the hazard analysis appear to consider the relevant food safety hazards for the establishment's process, product, and intended use? • For each hazard, does the establishment consider it RLTO or NRLTO? 	417.2(a)(2) 417.2(a)(1)
3	For each hazard the establishment considers RLTO, verify that the HACCP plan includes one or more CCPs to control it. <i>If no hazards are reasonably likely to occur, skip to step 4.</i>	<ul style="list-style-type: none"> • Does the establishment have one or more CCPs to control the hazard in each product or process where it is reasonably likely to occur? • Does the establishment have information to support the CCPs, CLs, monitoring and verification procedures? 	417.2(c)(2) 417.5(a)(2)
4	For each hazard the establishment considers NRLTO, determine what evidence the establishment uses to support the decision, including prerequisite programs and other supporting programs (e.g., written programs, records, and employee activities).	<ul style="list-style-type: none"> • Does the establishment prevent the hazard by implementing a prerequisite or other supporting program (SSOP, GMP, SOP, etc.)? – <i>proceed to step 5.</i> • Does the establishment support the decision with other documentation besides a prerequisite or other supporting program? – <i>proceed to step 6.</i> • Does the written program appear to be designed to prevent the relevant hazard? • Do the records and your observations indicate the program is consistently being implemented as written? 	417.5(a)(1)

		<ul style="list-style-type: none"> Do the records and your observations indicate that the program continues to prevent the relevant hazard on an ongoing basis? 	
5	Review other supporting documentation	<ul style="list-style-type: none"> Does the establishment have copies of the documents referenced in the hazard analysis? Do the documents appear to apply to the current establishment process? 	417.5(a)(1)
6	Review establishment validation documents, including scientific supporting documents and validation data.	<ul style="list-style-type: none"> Does the establishment maintain documents to support the scientific or technical basis for the CCPs and prerequisite programs used to support decisions in the hazard analysis? Does the establishment maintain in-plant validation data for the life of the plan? 	417.4(a)(1)
7	Verify reassessment requirements. Check most recent signature date for each HACCP plan.	<ul style="list-style-type: none"> Has the establishment reassessed at least once in the most recent calendar year? Has the establishment reassessed, if necessary, in response to any changes that could affect the hazard analysis? Has the establishment reassessed, if necessary, in response to any unforeseen hazard? Has the establishment documented the results of the reassessment? 	417.4(a)(3) 417.3(b) 417.4(a)(3)(ii)
8	Document your findings in PHIS.	<ul style="list-style-type: none"> No problems detected – document HAV task results in PHIS. Clear case of noncompliance – document HAV task results and NR in PHIS and notify your supervisor. Concerns about the establishment HACCP system – discuss situation with your supervisor for assistance in determining how to proceed. Document HAV task results in PHIS. 	

15 HACCP Verification Task

Introduction

The HACCP verification task is for verifying that an establishment complies with the requirements of 9 CFR Part 417. There are nine HACCP verification tasks. Each task corresponds to a specific HACCP processing category.

The HACCP Verification Task

Expectations of IPP in Conducting the HACCP Verification Task

IPP are to verify that the establishment implements its HACCP system in accordance with the regulations in 9 CFR Part 417 by performing the HACCP verification task.

IPP must be familiar with the establishment's hazard analysis, HACCP plan, and any prerequisite or other programs that the establishment uses to support the decision(s) that specific food safety hazards are not reasonably likely to occur.

IPP use the recordkeeping and/or the review and observation components to verify that an establishment is effectively implementing the procedures set out in its HACCP plan.

IPP are to verify that establishments are meeting all the HACCP regulatory requirements.

IPP will document their findings in PHIS, including any noncompliance they find when performing their verification activities.

If IPP cannot complete the HACCP verification task in one day, know the steps to take until the task can be completed.

4 Regulatory Requirements

- Monitoring
- Verification
- Recordkeeping
- Corrective Actions

Performing the HACCP Verification Task

1. Select a product type within the specified HACCP process category and a specific production for the selected product type.

Specific production is a term that is used to refer to whatever method the establishment uses to group product, e.g., product produced during a specific period of time, a specific production lot, or other designated product. FSIS does not determine the method used to define specific production; this is an establishment's responsibility.

2. Review the HACCP plan for the selected product type.
- 3-5. Verify that the monitoring, verification, and recordkeeping HACCP regulatory requirements have been met for **all CCPs** in the HACCP plan for that **specific production**.
6. Verify the implementation of any **prerequisite programs** or other programs that apply to the specific production.
7. Verify that the **corrective action** HACCP regulatory requirement has been met.
8. Verify that the **pre-shipment review** requirement for that specific production has been met.
9. Consider any implications of noncompliance and document the HACCP verification task in PHIS.

Regulatory Reference

Requirement	Regulatory References	Component
Monitoring	417.2(c)(4) <u>Monitoring Requirement</u>	Rk R&O
Verification	417.2(c)(7) <u>Verification Requirement</u> 417.4(a)(2)(i)(ii)(iii) <u>Verification Activities</u>	Rk R&O
Recordkeeping	417.2(c)(6) <u>Recordkeeping System</u>	Rk
	417.5(a)(3) <u>HACCP Records</u>	Rk
	417.5(b) <u>Records Authenticity</u>	Rk R&O
	417.5(d) <u>Computerized Records</u>	Rk
	417.5(e)(1) and (2) <u>Record Retention</u>	Rk
	417.5(f) <u>Official Review</u>	Rk
	(Prerequisite Program Implementation) 417.5(a)(1) <u>Supporting Documentation</u>	Rk R&O
	417.5(c) <u>Pre-Shipment Review</u>	Rk R&O (on occasion)
Corrective Action	417.3(a) Deviation from a critical limit 417.3(b) Deviation not covered by a specified corrective action/unforeseen hazard	Rk R&O

Monitoring

NACMCF Monitoring Definition

Note: NACMCF = National Advisory Committee on Microbiological Criteria for Foods

- Monitoring is a planned sequence of observations or measurements taken to assess whether a CCP is under control and produce an accurate record for future verification.

The regulation that applies to monitoring is:

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

Methodology

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

Taking Measurements at Critical Control Points

IPP should occasionally take measurements at certain critical control points in the process (i.e., perform a hands-on – review component) to verify that product meets the critical limit. When IPP take measurements to verify that product meets the critical limit, they are to use the calibrated instrument that the establishment uses for the monitoring or verification activities.

FSIS Responsibilities

- IPP verify HACCP regulatory requirements.
- IPP should be familiar with the monitoring procedures and frequencies in the current HACCP plan.
- Visualize what is occurring at the CCP, seek clarification.

Observing Establishment Employees

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

Verification

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

The regulations that apply to verification procedures and frequencies are:

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

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

Methodology

IPP verify the verification requirement by performing the HACCP verification tasks. They can use either the recordkeeping, or review and observation component, or both.

Thought Process

- Gathering information by asking questions
- Assessing the information
- Determining regulatory compliance

Review Verification Records

- IPP should review the verification records to determine compliance.
- IPP should verify that it contains the actual values and observations.

Review the HACCP Plan

- Every HACCP plan must contain verification procedures.
- Establishment sets frequencies.
- Establishments must calibrate instruments.

Assess Information

- Look at the establishment's HACCP plan.
- Review HACCP plan.
- Review HACCP records.
- Observe establishment employees.

Observing Establishment Employees

- IPP must observe establishment employees performing the verification activities listed in the plan.
- Is the establishment verifier doing activity as per the regulations?
- Is the establishment performing verification at the infrequency set out in the HACCP plan?
- Directly observe any corrective actions that need to be taken.

Observe Product Sampling

- Even if the product sampling is not included in the HACCP plan, we would review results.

Recordkeeping

IPP verify the recordkeeping requirements when performing HACCP verification tasks. IPP verify recordkeeping requirements by reviewing the following:

- **The HACCP plan**
- **HACCP records**

Components

- IPP may use the recordkeeping and review and observation components.

Thought Process

- Gathering information by asking questions
- Assessing the information
- Determining regulatory compliance

Recordkeeping System

The regulatory requirement for a recordkeeping system is:

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

IPP verify this requirement using the recordkeeping component while performing the HACCP verification task.

- Verify compliance with 417.2(c)(6).
- Verify that HACCP Plan lists all records used to document the monitoring of critical control points.
- Verify that it contains the actual values and observations.

HACCP Records Requirement

The regulatory requirement for HACCP records is:

9 CFR 417.5(a)(3)—The establishment shall maintain: Records documenting the monitoring of CCP and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to

a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot. Each of these records shall include the date the record was made.

IPP will verify compliance with this regulation by performing the HACCP verification task. IPP will use the recordkeeping component to verify this regulation.

Records Authenticity

The regulatory requirement for record authenticity is:

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

IPP will verify compliance with this regulation by performing the HACCP verification task. They are going to use the recordkeeping and the review and observation components.

Computerized Records

The regulatory requirement for computerized records is:

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

IPP will verify compliance with this regulation by performing the HACCP verification task using the recordkeeping component.

Record Retention

The regulatory requirements for record retention and off-site storage of records are:

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

IPP will verify compliance with this regulation by performing the HACCP verification task using the recordkeeping component.

Official Review Records

The regulatory requirement for making establishment records available to IPP upon request for official review is:

9 CFR 417.5(f) *Official Review—All records required by this part and all plans and procedures required by this part shall be available for official review and copying.*

IPP will verify compliance with this regulation by performing the HACCP verification task using the recordkeeping component.

Supporting Documentation - Prerequisite Programs and Other Supporting Programs

The regulatory requirement that addresses the use of prerequisite programs to support decisions in the hazards analysis is:

9 CFR 417.5(a)—*the establishment shall maintain the following records documenting the establishment's HACCP plan: (1) the written hazard analysis prescribed in §417.2(a) of this part, including all supporting documentation;*

IPP verify this requirement using both the review and observation and the recordkeeping components while performing the HACCP verification task.

If a hazard is reasonably likely to occur, **must have a CCP**. If the hazard is considered not reasonably likely to occur, a prerequisite program may be used as support.

Regulatory Requirements

- Regulatory requirement - 9 CFR 417.2(a)(2) and 9 CFR 417.5(a)(1).
- Results of testing and monitoring activities related to the production of product are subject to FSIS review.
- Prerequisite program data and records are also reviewed during the Review Establishment Data procedure.

Prerequisite Programs

- Used by establishments to support the decision in their hazard analyses that a particular potential hazard is not one that is reasonably likely to occur.

NRLTO

- There is no regulatory requirement that the prerequisite program must be written.
- If not in writing, establishment would probably not be able to support the decision the hazard is not reasonably likely to occur.

Monitoring

- Establishments are not required to “monitor” or “verify” prerequisite programs.
- IPP cannot cite a “monitoring” noncompliance in prerequisite program.
- IPP **do not** verify compliance with specific regulatory requirements for monitoring, verification, and recordkeeping.
- There are no specific regulations for monitoring activities or recordkeeping practices for prerequisite programs.

Less Than Perfect

- Less-than-perfect execution may or may not be a threat to product safety.
- IPP should discuss less-than-perfect implementation of supporting programs with establishment management at weekly meeting.
- The establishment's response should be documented in the Memorandum of Interview (MOI).

Corrective Actions

Establishment must implement the corrective actions when

1. There is a deviation from a critical limit.
2. Unforeseen hazard has occurred.
3. Whenever an event occurs that requires corrective action.

IPP are to verify that the establishment implements corrective actions that meet the regulatory requirements.

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

A HACCP noncompliance is the failure to meet any of the regulatory requirements of 9 CFR Part 417. If a HACCP noncompliance occurs, an establishment is expected to take immediate and further planned actions to bring itself back into compliance with regulations.

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

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

Pre-Shipment (before shipping) Review Requirement

The regulatory requirement for pre-shipment review is:

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

Produced and Shipped

- Product is “**produced and shipped**” when the establishment completes the pre-shipment review, even if the product is still at the establishment.

Methodology

- Mostly record keeping will be used.
- There is a lot of flexibility in meeting this requirement.
- **No regulation addresses how the review is to be conducted or when the review must be done.**

Regulatory Requirement

The pre-shipment review must be signed and not just initialed. Recording the time when the review performed is not a regulatory requirement.

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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

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Slaughter Number	Feces, ingesta, milk present? (Y or N)*	Performed by	Date: 2-8-12 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	

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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

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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	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, 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)

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Thermometer Calibration Log			Calibrate to 32° F in slush ice water		
Thermometer ID #	Temperature	Adjustment Required?	Date	Time	Initials
A1	32	No	1-2-12	5:23 am	NM
A2	32	No	1-2-12	5:25 am	NM

Product Temperature Log			Critical limit 40°F or below	Date: 1-2-12
Time	Temperature	Initials	Comments	Verification
6:20 am	36	NM		
7:30 am	38	NM		Direct observation, results as per HACCP plan JP 7:30 am, 1-2-12

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HACCP Plan for fermented semi-dry sausages			
CCP #1 – Biological	Critical Limit	Monitoring Procedures and Frequency	Verification Procedures and Frequency
Fermentation (pH and temperature)	Achieve a pH of 5.2 or less within 12 hours from the start of the fermentation process for <i>S. aureus</i> control, to prevent <i>C. botulinum</i> and <i>C. perfringens</i> growth, and to suppress the growth of <i>Listeria monocytogenes</i> during the shelf life Room temperature not to exceed 90°F	Production foremen will enter the start and finish time for the fermentation process on the fermentation log. QC will select three samples from different locations of each batch of product, blend or emulsify the sample, and measure the pH using a pH meter. The highest result will be recorded on the pH log. Production foreman will observe the room temperature recording chart once per shift and enter the result on the fermentation log.	QC supervisor will review fermentation and pH logs and observe QC selecting samples, measuring pH and recording the result and the production foremen recording results. Maintenance personnel will check the accuracy of the recording chart thermometer probe and chart and calibrate as needed.

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Pathogen Reduction Log							
Date	Lot No.	Time	Solution Conc. (%)	Pressure (psi)	Corrective Actions	Monitored by	Verified by *
2-1-2012	1	0730	OK	OK	-	TDM	*PP
*direct observation verification-results as per HACCP plan							

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Thermometer Calibration Log Calibrate to 32° F while in slush ice water							
Date	Time	Dept.	Thermometer ID	Personal Thermometer Reading	Adjustment Required? (Yes or No)	Initials	Comments
2/15/2012	PM	Carcass Cooler	2B	32°F	No	TDM	

Reprocessing Log					
Time	Product ID	Results of Inspection	Monitor Initials	Verification procedure and results	Corrective Actions or Comments
0645	Lot 1	0	BK		
0750	Lot 1	0	BK		
0840	Lot 2	1	CH		½ inch smear of green fecal material
0955	Lot 2	0	BK		
1330	Lot 3	0	CH		
1430	Lot 4	0	CH		

16 Slaughter Food Safety Standard

The Food Safety and Inspection Service (FSIS) published in FR 97-067N notification that the Agency views its “**zero tolerance**” for visible fecal material as a food safety standard. In slaughter establishments, fecal contamination of carcasses is the primary avenue for contamination by pathogens, including Shiga toxin-producing *E. coli* (STECs), *Salmonella*, and *Campylobacter*.

Pathogens may reside in fecal material, both in the gastrointestinal tract and on the exterior surfaces of the animal or bird going to slaughter. Without proper handling and sanitary dressing procedures during slaughter and processing, the edible portions of the carcass can become contaminated with bacteria capable of causing illness in humans. The organisms may spread directly from carcass to carcass or indirectly by hands, utensils, or equipment.

Enforcing Food Safety Standard for Livestock Postmortem

References: FSIS Directive 6420.2, Regulations 9 CFR 310.17(a), 310.18(a), and Part 417.

The contaminants that are covered by the food safety standard in **livestock** slaughter are **feces, ingesta, milk**. Carcasses, and head meat, cheek meat and weasand meat must be free of these contaminants.

On-line IPP verify the removal of contamination while examining heads, viscera, carcasses, and carcass parts during post-mortem inspection. If on-line IPP observe contamination on heads, viscera, carcasses and carcasses parts, IPP do not pass the carcass or part until all of the contamination is promptly removed in a satisfactory manner. IPP verify that livestock slaughter establishments are complying with 310.17(a), and 310.18(a).

Off-line IPP are to perform the Livestock Zero Tolerance Verification task on carcasses and head, cheek, and weasand meat at a minimum of **one time per slaughter shift**.

FSIS verify the food safety standards for livestock carcasses **at or after the postmortem rail inspection station and before the final wash**, or any additional trimming, washing, or application of any interventions.

FSIS verify the food safety standard for **head meat, cheek meat, and weasand meat** in livestock slaughter operations **at the completion of the harvesting process, after all of the establishment controls and interventions**. This verification may occur at the time of packaging or when the product is placed in a container for storage.

Enforcing the Food Safety Standard for Poultry Postmortem

References: FSIS Directive 6420.5, FSIS Regulation 381.65(f), and part 417.

The contaminant that is covered by the food safety standard in **poultry** slaughter is **feces**.

At poultry slaughter, the fecal contamination checks are performed at either pre-chill testing station or any location after final trimming prior to the chiller tank in establishments operating under traditional inspection.

Off-line IPP are to conduct the Poultry Zero Tolerance task **at least two** fecal contamination checks for each evisceration line for every shift.

Note: Poultry major portions and parts are not subject to poultry zero tolerance verification but are subject to slaughter HACCP verification.

Documenting Compliance with the Zero Tolerance Task

When IPP **do not observe** any fecal material, ingesta, or milk on livestock carcasses or on head, cheek, or weasand meat, or feces on poultry carcasses during the verification, and no other regulatory noncompliance is observed, they **select the mandatory regulation and any HACCP regulations they verified on the “Regulations” tab**. IPP mark the zero-tolerance task as ‘**Inspection Completed**’ at the bottom of the Inspection Results page.

Documenting Noncompliance with the Zero Tolerance Task

If IPP **find feces, ingesta, or milk on livestock** carcasses or head meat, cheek meat, or weasand meat while performing the livestock zero tolerance verification task, or find **feces on poultry** carcasses while performing the poultry zero tolerance verification task, IPP are to:

- Verify regulatory requirements associated with 9 CFR 310.18(a) (livestock) or 381.65(f) (poultry) and any HACCP regulations verified during zero tolerance verification task;
- Notify the establishment that a zero tolerance noncompliance with 9 CFR 310.18(a) or 381.65(f) exists;
- Document the noncompliance on an NR citing 9 CFR 310.18(a) or 381.65(f) and 9 CFR 417.2(c)(4) if a deviation from a critical limit has occurred (the establishment failed to adequately monitor at a CCP to ensure compliance with the critical limit);
- For poultry zero tolerance failures include a statement that the establishment is not preventing feces from entering the chiller on the NR;
- Document noncompliance with any additional HACCP regulations that were verified during the zero tolerance task on the same NR, and
- In PHIS select the mandatory 9 CFR 310.18(a) or 9 CFR 381.65(f) regulation plus any HACCP regulations that were verified while performing the task on the “Regulations” tab of the Inspection results page.

Note: When IPP determine zero tolerance noncompliance while performing the zero tolerance verification task, they are to perform a Slaughter HACCP Verification task to verify that the establishment performs corrective actions for the affected product in accordance with 9 CFR 417.3(a).

HACCP System Verification after Positive Zero Tolerance Findings

After notifying the establishment of the zero-tolerance noncompliance, off-line IPP are to:

- Schedule either a directed Slaughter HACCP or Operational SSOP Review and Observation verification task in PHIS;
- Indicate “zero tolerance noncompliance” as the reason for performing the directed task in PHIS; and
- Verify the establishment has performed all the required corrective actions in accordance with 9 CFR 417.3(a), 417.3(b), or 416.15(b) and 417.3(b) and is properly implementing its HACCP system.

Note: If IPP find zero tolerance failures on livestock carcasses past the final rail or on poultry carcasses, major portions, or parts at or beyond the pre-chill testing station **while performing inspection tasks other than the zero tolerance task (“stumble-on” occurrences)**, they are to document the noncompliance under the appropriate PHIS task (Slaughter HACCP or Operational SSOP Review and Observation verification task).

The System Approach in Enforcement

If IPP find **repeated zero tolerance noncompliances** and determine that these findings are from the **same cause or indicate a systemic issue**, the current NR is to be associated with the most recent zero tolerance or related NR. When associating NRs for the same cause, IPP are to follow the methodology set out in FSIS Directive 5000.1.

If the findings do not show the same cause, IPP are not to associate the NRs.

17 *Salmonella* & *Campylobacter* Testing

The purpose of the microbiological performance standards for the reduction of *Salmonella* in raw products is to allow FSIS to verify whether establishments have effective process controls to address *Salmonella*.

FSIS originally selected *Salmonella* as the target organism because it is a commonly reported cause of foodborne illness and is present in all major species.

Salmonella bacteria are the most frequently reported cause of foodborne illness.

Campylobacter species, specifically *C. jejuni* and *C. coli*, are most often isolated from the intestinal tract of poultry as well as in poultry products. *Campylobacter* bacteria are the second most frequently reported cause of foodborne illness, and *Campylobacter jejuni* is the most common strain causing illness.

Salmonella and *Campylobacter* contamination of raw poultry products occurs during slaughter operations, as well as during the live animal rearing process. Contamination can be minimized with the use of proper sanitary dressing procedures and by the application of antimicrobial interventions during slaughter and fabrication of the carcasses into parts and comminuted product. In addition, if raw poultry is improperly handled during food preparation, *Salmonella* and *Campylobacter* can cross-contaminate other foods or food contact surfaces.

Salmonella and *Campylobacter* verification sampling is conducted in establishments by FSIS inspection program personnel (IPP). IPP will collect samples using ongoing scheduled sampling (routine sampling), employing a moving window approach to assess process control for all *Salmonella* and *Campylobacter* performance standards.

Poultry carcasses:

- (1) Young chicken carcasses including broilers, fryers, roasters, and Cornish game hens, as described in 9CFR 381.170(a), and
- (2) Young turkey carcasses

NRTE ground and other comminuted poultry sampling program:

NRTE comminuted poultry is any non-breaded, non-battered, raw NRTE chicken or turkey product that has been processed to reduce the particle size, which may or may not contain added ingredients. NRTE comminuted poultry includes:

- Ground (ground product group category) – Ground chicken or turkey for any purpose (e.g., packed for consumer or for any type of further processing); or
- Mechanically Separated (Mechanically Separated product group) – mechanically separated chicken or turkey, as defined in 9 CFR 381.173; or

- Hand or mechanically deboned and further chopped, flaked, minced, or otherwise processed to reduce particle size. Chicken or turkey product, other than ground or mechanically separated falls under the “Other Comminuted” product group (sausage, patties, meatloaf, and other non-breaded and non-battered comminuted products).

NRTE comminuted chicken product may be derived from any age chicken, including young chickens (broilers, fryers, and roasters), fowl, capons, and roosters, as defined in 9 CFR 381.170(a)(1).

NRTE comminuted turkey product may be derived from any age turkey, including young turkeys, yearling turkeys, and old turkeys, as defined in 9 CFR 381.170(a)(2).

When an establishment processes all its products into ready-to-eat (RTE) product or diverts all of its raw products (including NRTE comminuted poultry) to another federally inspected establishment for further processing into an RTE product, FSIS will exclude the establishment from the *Salmonella* verification-testing program schedule.

If an establishment states that the intended use of all product produced is RTE product, then IPP are to verify the intended use while performing the appropriate HACCP task. IPP are to verify, either by observing or by reviewing records, that the entire product is actually processed into RTE product in the establishment.

The *Salmonella* and *Campylobacter* performance standards apply to the establishment’s overall process control, not to individual products. Products are not tested to determine their disposition, but rather to measure the effectiveness of the slaughter and grinding process in limiting contamination. Establishments do not have to hold product or recall product based on results of the *Salmonella* and *Campylobacter* samples.

Salmonella and *Campylobacter* performance standard verification samples are taken as part of a moving window and the results are used to determine if an establishment is meeting the performance standard on a continuous basis.

In conclusion, establishments fail to meet the standards when verification samples are found to exceed the maximum allowed percent positive during a 52-week analysis period (moving window).

The purpose of the *Salmonella* and *Campylobacter* verification-sampling program is to verify the establishment’s process control for **all applicable products**. All eligible products produced at an establishment will be scheduled for sampling during the month under routine sampling.

For Category 3 – IPP and supervisors will receive an alert entitled, “Failure to Meet a *Salmonella* Performance Standard”, through the PHIS dashboard. During the next weekly meeting, IPP will discuss with plant management the failure to meet the *Salmonella* performance standard and that FSIS will be collecting follow-up samples; document in an MOI. In addition, IPP are to determine if:

- Corrective actions have been identified and implemented as written, as per 9 CFR 417.3;
- Establishment has reassessed its HACCP system and modified its HACCP plan, including supporting documentation (417.3(b) and 381.65(g)).

The follow-up samples will be assigned for raw poultry carcasses, chicken parts, and NRTE comminuted poultry products under the project codes below:

F_CH_CARC01 (for young chicken carcasses)
 F_TU_CARC01 (for young turkey carcasses)
 F_CPT_LBW01 (for raw chicken parts)
 F_CH_COM01 (for NRTE comminuted chicken product)
 F_TU_COM01 (for NRTE comminuted turkey product)

FSIS Directive 10,250.1 describes the sampling steps appropriate to the product class sampled. For NRTE comminuted poultry products and raw chicken parts, IPP are to follow instructions as stated in the "IPP Help" menu under FSIS Applications. Following is a brief narrative for the procedures described in Directive 10,250.1 that the IPP will be carrying out when collecting the samples.

IPP can review the status and results of the sampling through LIMS Direct. You can access the link for LIMS under the FSIS Applications short cut on your FSIS government computer.

18 Raw Beef Sampling

In raw beef, the pathogen of concern is the Shiga-toxin producing *E. coli* group (STEC). *E. coli* O157:H7 is a foodborne pathogen, but it is not the only one; other serogroups are pathogenic as well. It is a food safety hazard that establishments need to consider in their hazard analysis if slaughtering, receiving, grinding, or otherwise processing raw beef products. Non-intact raw beef products such as ground beef or mechanically tenderized beef which are contaminated with *E. coli* O157:H7 or one of six STECs or intact raw beef intended for non-intact are considered adulterated.

Sampling programs are designed to verify that HACCP systems are effective in controlling harmful microorganisms in meat and/or poultry products.

Definitions

Alternative - Alternative sampling and alternative lotting.

Recall - An establishment's voluntary removal of distributed meat or poultry products from commerce.

Sample - Collection of products that represents a larger amount of product.

Sampled lot - Amount of product represented by the sample.

The establishment determines their lotting procedures. Establishments must support how they identify adulterated product when they experience a positive sample result.

Samples are selected **randomly** from the type of product requested. Select day, shift, and time within the collection dates indicated in PHIS establishment Task List. Sample during all shifts that the establishment operates. Samples are collected after all antimicrobial interventions are applied to the production lot to be sampled, except for any microbiological testing intervention. Take samples prior to freezing—an exception is when the freezing step is a CCP in the HACCP plan. Collect in their final packaged form, using aseptic technique. If the product is not in its final package, you *must* put the grab samples in the **sterile** Whirl Pak bags.

PHIS task name will identify the sampling project code. Determine eligible products, focusing on the establishment's process(es), and allow adequate time for the establishment to hold the sampled lot, but not enough time for them to alter their normal processes—less than 1 days' notice (if it does not cause undue hardship to the plant), 1 days' notice is sufficient, but possibly 2 days' notice if necessary. If more than 2 days' notice is requested, contact your supervisor. IPP collect supplier information for each sample taken, at the time the sample is taken. The goal of traceback is two-fold: (1) to ensure all affected product is quickly accounted for and (2) to trace it back to the originating slaughter plant. The DO will use the supplier information to identify the originating slaughter facility, if the sample result is confirmed positive. Information that needs to be collected for source materials from other establishments includes name of the beef components or information that clearly identifies the source material. Document the source material and foreign supplier information in a memorandum of interview (MOI) in PHIS and maintain the MOI in the official file. Provide a copy to establishment management. You also make a note of any information that the establishment is unable to provide in the MOI.

Positive *E. coli* O157:H7 results go through 3 stages of analysis: Potential, Presumptive, and Confirmed. Any presumptive or confirmed positive must be maintained under establishment control. Consider the possibility that the establishment may have moved the product off-site but did not transfer ownership of the product, and therefore the establishment did not yet complete the pre-shipment review. If the establishment has a written program to divert all product that FSIS samples to cooking, IPP are to issue an NR, unless the establishment *also* tested the same lot of product and found a positive. The establishment must take corrective action per 9 CFR 417.3. If the establishment does not take corrective action, then issue an NR. Use a directed HACCP Verification task for the appropriate HACCP category, raw ground, or raw not-ground. Cite 9 CFR 417.4(a) (Verification regulation - because sampling is considered a verification of the overall effectiveness of the system) and 301.2. When writing NRs, associate where appropriate.

CSIs are to look over the Sanitation SOPs for days of production to see if there was a problem. CSIs use the “risk based” approach. Perform a directed Beef Sanitary Dressing task for sampled beef manufacturing trimmings and other components in slaughter establishments.

Raw beef products confirmed positive for *E. coli* O157:H7 or a non-O157 serogroup may be moved off-site for proper disposition, under appropriate controls. Product may be transferred to **another official establishment for further processing to destroy the pathogen**. Establishments may opt to dispose of the product through **rendering** or disposal in a **landfill**. As part of the follow up HACCP Verification task, verify that the establishment maintained records identifying the official establishment, renderer, or landfill operation that received positive product. When the product is destined for a **landfill or rendering operation**, it moves **under company controls**. When the product is shipped **to another official establishment**, establishments may use their own company seals or move the product under USDA seals or FSIS Form 7350-1. Documentation from the official establishment, landfill operation, or renderer **must show** that the positive product was further processed to destroy *E. coli* O157:H7 or the specific product was destroyed. The establishment cannot complete the pre-shipment review until it receives documentation from the official establishment showing proper disposal.

If you are the IPP at the establishment that receives components positive for *E. coli* O157:H7, you have verification to perform. Verify the HACCP plan includes adequate lethality treatment to destroy the pathogen, and that the establishment has supporting documentation validating the effectiveness of the lethality treatment. When raw beef products are confirmed positive, FSIS will conduct verification activities at supplier establishments, particularly the originating supplying slaughter establishment that produced the source materials, trimmings, components, or primal cuts that were used to produce the positive product. The DO will contact the IIC at **each** of the supplying establishments, including the originating supplying slaughter establishments. The IIC at the supplying establishment will ensure that a HACCP Verification task is performed to verify that the supplier met all the HACCP regulatory requirements.

Each time that an FSIS, or other Federal or State sample of raw beef product tests positive for *E. coli* O157:H7 or non-O157 STEC serogroups, IPP will receive a directed sample task for **16 follow-up samples to sample product from the establishment that produced the positive raw beef product**. IPP will also receive a directed sample task for 16 follow-up samples when FSIS follow-up samples of beef trimmings or other raw beef patty components or ground beef test positive for *E. coli* O157:H7 **or** when an originating slaughter establishment is the **sole**

supplier or a **repeat** supplier of the source materials implicated in positive sample result. For low volume establishments, **8 follow-up samples** need to be collected. **DO NOT** wait for the establishment to complete the corrective actions. Collect follow-up samples from the same type of product that tested positive. If the establishment is not producing the product that tested positive, collect follow-up samples from BMT or other components. Collect a maximum of 2 follow-up samples per shift per day from different lots (up to 4 samples per day for a 2-shift establishment). At a minimum collect 3 samples per week. **Do not** collect a follow-up sample and a routine verification sample from the same product lot.

FSIS continues to collect samples after a positive follow-up sample result until the FSIS laboratory finds no positive sample results. PHIS automatically assigns the requested follow-up sampling tasks. If an originating slaughter establishment was the **only supplier = 16 follow-up samples**, if multiple originating slaughter establishments supplied source materials for the positive product or they are a **repeat supplier = 16 follow-up samples**, when a supplier is not the sole supplier or a repeat supplier, a **single follow-up** sample is collected from the supplier for **each** source material used in the positive raw beef product.

There **is no** regulatory requirement for establishments to have their own *E. coli* O157:H7 sampling and testing program. Many establishments do sample raw beef products for a variety of reasons. You are to review the results of the establishment's testing programs related to its food safety systems on a weekly basis and document it on Review of Establishment Data task. The establishment does not have to tell you when it gets a positive result, but it **must** always implement corrective actions, and IPP should verify them. If the establishment uses cooking to eliminate *E. coli* O157:H7 as a food safety concern, the establishment's HACCP plan must address the presence of O157:H7. CCP and critical limits must be designed to eliminate *E. coli* O157:H7.

19 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.

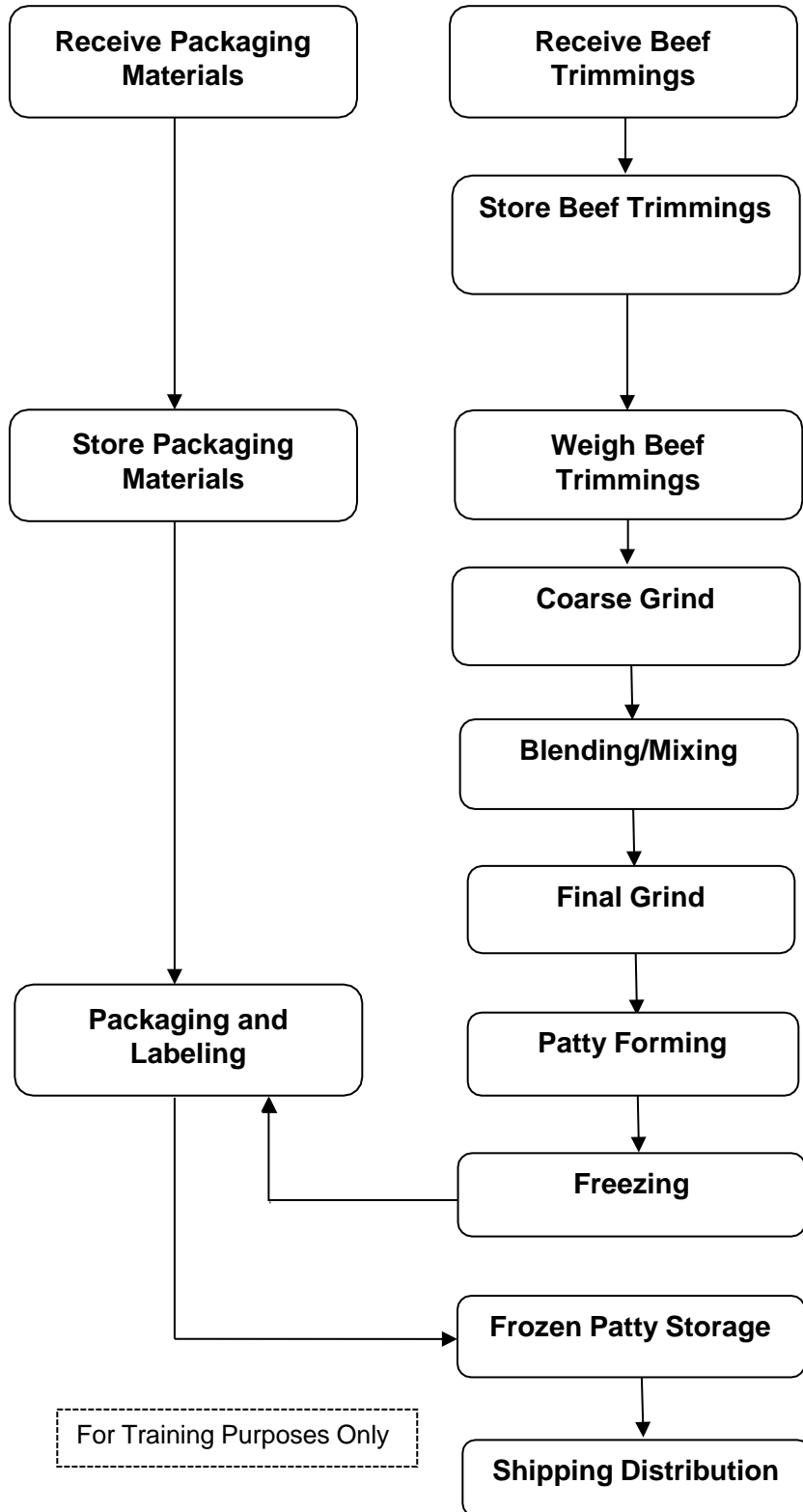
Consider:

- 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°F , the supplier may provide evidence which demonstrates the temperature of the beef trimmings from time of shipping to receipt was above 40°F for no more than 2 hours but never above 50°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 UnAc)	Receiving Initials
1-25-2019	Open Beef	5 combos 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.
<i>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.</i>				
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>		

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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20 Sampling Requirements to Demonstrate Process Control in Slaughter Operations

Each official establishment that slaughters **livestock, other than swine, or ratites is required to test for *Escherichia coli* Biotype I**, also known as “**generic *E. coli***.”

Establishments that slaughter **poultry, other than ratites, and swine are required to perform microbiological sampling and analysis**, for example, testing for *Salmonella*, *Campylobacter*, or indicator organisms such as aerobic plate count (APC), total coliform, Enterobacteriaceae, and *Escherichia coli*, Biotype I, also known as generic *E. coli*.

The purpose of generic *E. coli* testing is to verify the effectiveness of sanitation and process control in slaughter establishments.

FSIS has developed performance criteria for some species (not all of them), and specifies approved sampling techniques, such as for beef using excision sampling.

- There are two sampling methods that are used: excision and sponging.
 - Excision – This is the method described in the regulation; rarely used because it is a destructive method, only need to excise the surface, so it's not necessary to do a deep cut.
 - Sponging – The most commonly used since it is a non-destructive method.
 - Hide-on carcasses are **not** excised – The regulations are specific that these are only sponged.

Performance criteria – These are numbers published in the regulations that represent the highest expected microbial loads on carcasses when the slaughter process is under control. The **performance criteria** give livestock slaughter establishments **guidance (not enforceable)** about the effectiveness of their slaughter sanitary dressing procedures in preventing fecal contamination. Test results that meet the criteria in the regulations provide evidence that the establishment is maintaining adequate process control for fecal contamination and sanitary dressing.

If the Agency does not have performance criteria published for the species being tested or for the sampling technique being used, establishments must **use statistical process control (SPC) to develop criteria to compare their samples results**. The performance criteria in the regulations are referenced as “m” and “M” values. Thus, cattle establishments collecting excision samples must use the m/M values prescribed in the regulations. However, most establishments use sponging, so this means most establishments must use SPC. There are practically no establishments which can use m/M because it is only applied to excision sampling. Establishments must **use statistical process control (SPC)**, i.e., develop their own criteria, to evaluate their test results when they slaughter **species or use sampling techniques for which the Agency has not developed performance criteria**.

Establishment Procedures - The establishment is to collect samples from the type of livestock that it slaughters in the greatest number. Livestock samples are collected after they have been in the cooler for 12 hours or more. However, carcasses can be selected while on the rail or after the final wash and set aside in a convenient spot in the cooler for testing after 12 hours. For hot boning: Samples are taken after the final wash prior to boning. Samples are taken before the carcasses enter the processing department.

There are 3 required sample sites or anatomical locations on the carcass, which are the **flank, brisket, and rump**.

The frequency is based on the number of carcasses. Regulations require that carcasses for sampling be selected at random.

Generic *E. coli* tests are reported as a quantity or bacterial concentration. The units of measure must match the testing technique used to ensure that results are reported correctly.

IPP perform the livestock Generic *E. coli* task, select the regulatory requirement to verify and determine whether the establishment is in compliance or noncompliance with the regulations.

- IPP are to verify that the establishment maintains daily records documenting the implementation and monitoring of its procedures, makes these records of the tables and charts with generic *E. coli* test results available for review, and retains these records for one year.
- If IPP find noncompliance, they are to notify the establishment and document the noncompliance in an NR citing the appropriate regulation.
- Establishment test results that show lack of process control should be considered in conjunction with other information, like sanitary dressing procedures, zero tolerance, SSOP, and any other HACCP performance criteria.
- Further enforcement action might be necessary if the establishment has repetitive NRs, or if the establishment's corrective actions are ineffective. IPP are to discuss with their immediate supervisor the need to take an enforcement action outlined in FSIS Directive 5000.1.

21 Humane Handling Verification for Livestock and Good Commercial Practices for Poultry

The Humane Methods of Livestock Slaughter Act (HMSA) of 1978 made mandatory the humane slaughter and handling of livestock in connection with slaughter of all food animals slaughtered in USDA inspected establishments.

The two approved methods of slaughter are:

1. Livestock must be rendered insensible to pain on the first application of the **stunning** device before being shackled, hoisted, cast, or cut. This means that the animal must be unconscious and unable to feel pain before it is “stuck” (veins and arteries severed so it bleeds out) before it is shackled and hoisted into the air, or before it is dropped onto a table/floor.
2. The **ritual** requirements of any religious faith that prescribes a method of slaughter where the animal suffers loss of consciousness by anemia of the brain caused by the simultaneous and instantaneous severance of the carotid arteries with a sharp instrument. This method is known as ritual slaughter. In ritual slaughter, the animal’s throat is cut from side to side with a sharp knife, deeply enough for the major arteries and veins to be severed. Examples of ritual slaughter include Jewish (kosher) slaughter and Islamic (halal) slaughter.

Humane Activities Tracking System (HATS) Categories

The HATS categories covered while performing the Livestock Humane Handling Verification task include the following:

- I. Inclement (severe) Weather
- II. Truck Unloading
- III. Water and Feed Availability
- IV. Antemortem Inspection
- V. Suspect and Disabled
- VI. Electric Prod/Alternative Object Use
- VII. Slips and Falls
- VIII. Stunning Effectiveness
- IX. Conscious Animals on the Rail

Recording Time in HATS (Humane Activities Tracking System)

You are to accurately and completely record the time that you spend on the nine specific HATS categories.

- Record the total time spent verifying each HATS category, in quarter hour increments, rounding up to the next quarter hour.
- There should be an entry of at least one-quarter hour in HATS Category IV – “Antemortem Inspection” for every slaughter shift except in very small establishments (see below).

- In addition, verify one or more of the other HATS categories during each slaughter shift. Ensure that, over time, all HATS categories are verified, and the appropriate time recorded.
- During normal operations, the total maximum time entered across all HATS categories will generally not exceed the total operational hours for that respective shift.

At many very small establishments, the total amount of inspection time spent on HATS procedures, including observations at antemortem inspection, may only total .25 hour. Therefore, they should record .25 hour per day in a different HATS category each slaughter day.

Twenty-Eight Hour Law

The **Animal and Plant Health Inspection Service (APHIS) Twenty-Eight Hour Law** requires transporters to stop at least every 28 hours to provide animals with food, water, and rest, and those who do not are in violation of this law. If livestock arriving on transport vehicles appear exhausted or dehydrated, IPP need to ask establishment management if the truck driver stopped within 28 hours to provide food, water, and rest to the livestock. IPP are to contact the APHIS Area Veterinarian-in-Charge (AVIC) via their FSIS chain of command if establishment management or the truck driver is unwilling to supply that information. Note that these situations are likely to be uncommon, but be aware that the provision exists if you have concerns.

Handling of Livestock

Animals that are disabled, non-ambulatory, or designated as U.S. Suspect must be segregated into a separate pen. The pen must protect these animals from adverse weather conditions until you make your antemortem disposition, because the weakened state of these animals renders them less resistant to even “normal” weather conditions. This means that you need to take into account the geographic location of the facility, the season, and the current weather conditions when determining if the covered pen meets regulatory requirements.

The regulations strictly prohibit dragging a conscious animal that is disabled or unable to walk. Establishment personnel must either stun these non-ambulatory disabled animals before dragging them or move the animals by placing them on a skid, stone boat, bucket lift, or some other type of equipment that is suitable for moving a conscious disabled animal.

Stunning

There are some general principles that apply to all stunning methods

1. Stunning equipment must be maintained in good repair. Equipment in poor repair can interfere with the rapid and effective application of the stunning blow. This can result in an incomplete or unsuccessful stun.
2. Effective stunning requires effective restraint. If an animal is not effectively restrained, it will be much more difficult to locate the stunning blow with a high degree of accuracy. The stunning area should be designed and constructed to limit the free movement of animals.
3. A well-trained and experienced establishment employee must operate stunning devices. The employee must be able to accurately and consistently position the stunning devices so that the animal is rendered immediately unconscious.

4. Animals need to be delivered to the stunning area with a minimum of excitement or discomfort. It is more difficult to place the stunning device accurately, and the method of stunning may not work as effectively, on an excited or injured animal.

With any stunning method, it is important to observe the amount of time it takes for the animal to begin bleeding out (“sticking”) after being stunned. Although there is no regulatory requirement for this time period, if the “stun-to-stick” interval is prolonged, it could result in animals regaining or beginning to regain sensibility on the bleed rail.

The regulations describe four acceptable methods for producing a state of surgical anesthesia (surgical anesthesia is defined as a state where the animal feels no painful sensations). The four acceptable methods are:

- Chemical (carbon dioxide - CO₂)
- Mechanical (captive bolt)
- Mechanical (gunshot)
- Electrical (electrical current)

Ritual Slaughter (HMSA - Humane Methods of Slaughter Act)

The ritual slaughter cut and the handling and restraint that immediately precedes that cut is often called the “ritual bubble”. The activities that occur within that “ritual bubble” fall under Section 1906 of the HMSA and are protected as part of the Constitutional right of religious freedom. This does not mean that Agency personnel are to ignore completely what happens within the “ritual bubble”—what it means is that Agency personnel don’t enforce humane handling regulations within that “ritual bubble”.

It is important to understand that ritual slaughter establishments are required to meet all the humane handling regulatory requirements *except* stunning prior to shackling, hoisting, throwing, cutting, or casting. A few ritual slaughter establishments elect to apply one of the approved stunning methods either before or after the ritual cut. In such establishments, IPP *will* also verify the stunning effectiveness HATS category. All animals must be unconscious or insensible to pain prior to any dressing procedures such as head skinning, leg removal, ear removal, horn removal, or opening hide patterns.

Assessing Unconsciousness

Livestock must remain insensible to pain (unconscious) from the time they are stunned until they are dead.

Some of the signs that an animal might be returning to sensibility include (but not limited to):

1. Rhythmic breathing.
2. Eye reflex in response to touch. This sign is not used for electrically stunned animals. Also, be very aware of safety if using this method to check insensibility.
3. Spontaneous natural eye blinks without touching the eye or eye area.
4. Tense and moving tongue or lips.

If you observe an animal regain consciousness after stunning, you must contact your supervisor immediately.

Odd-Hour Verification Visits

The IIC, in conjunction with the FLS and DVMS, determines how frequently IPP need to perform odd-hour inspection to observe the livestock facilities and handling practices.

Systematic Approach

There is no regulatory requirement for an establishment to use a systematic approach to humane handling and no requirement that such approach, if used, be in writing. However, an establishment may choose to develop and implement in a robust way a written animal handling program that effectively addresses the four aspects of a systematic approach that FSIS outlined in the 2004 Federal Register Notice. For a systematic approach to be considered “robust” it would have to be written. These four steps are:

1. Conduct an initial **assessment** of where, and under what circumstances, livestock may experience excitement, discomfort, or accidental injury while being handled in connection with slaughter, and of where, and under what circumstances, stunning problems may occur;
2. **Design** facilities and implement practices that will minimize excitement, discomfort, and accidental injury to livestock;
3. **Evaluate** periodically the handling methods the establishment employs to ensure that those methods minimize excitement, discomfort, or accidental injury and evaluate those stunning methods periodically to ensure that all livestock are rendered insensible to pain by a single blow; and
4. **Respond** to the evaluations, as appropriate, by addressing problems immediately and by improving those practices and modifying facilities when necessary to minimize excitement, discomfort, and accidental injury to livestock.

If the establishment has a robust systematic approach, FSIS will take that into consideration should it be necessary to determine how to proceed when an incident occurs that involves egregious inhumane treatment.

Enforcement

The thought process that you should follow when performing the Livestock Humane Handling Verification task includes:

1. Is there noncompliance?
2. If so, is it egregious?
3. What action should be taken?

If you observe a humane handling noncompliance, you must take immediate action if animals are being harmed. For example, if you observe an employee driving livestock with an instrument (e.g., the edge of a shovel, a pointed metal prod) that can cause injury, you must stop that action from continuing.

Once that is done, your next step is to decide if the noncompliance is egregious or non-egregious because the actions you take will be dictated by that determination. An egregious

humane handling violation is so serious that it warrants an immediate suspension of the assignment of inspectors under the authority of the Rules of Practice (9 CFR 500.3(b)).

Non-egregious Noncompliances

When a noncompliance is observed, 9 CFR Part 313.50 specifies a progression of enforcement actions allowing for an escalating response by IPP when the establishment does not comply with the humane slaughter of livestock regulations.

- First, notify establishment managers of the humane handling noncompliance, if not already done when addressing the needs of the animal.
- Second, request that establishment managers immediately correct the situation and take the necessary steps to prevent recurrence.
- Third, document the noncompliance on a noncompliance report (NR).

If necessary, take a regulatory control action (RCA) to prevent further injury to the animal or to prevent injuries from occurring to other animals. You will also take the appropriate regulatory control action if you do not receive an adequate response or corrective actions to the NR or if the noncompliance observed continues to occur. The appropriate regulatory control action depends on the nature of the noncompliance. Remember that the goals of applying a tag are to control the situation and prevent further injury or distress to animals.

- If the noncompliance is the result of facility deficiencies, disrepair, or equipment breakdown, but is not immediately causing injury or distress to livestock, attach a U.S. Retained/Rejected tag to the noncompliant equipment/pen/etc. Noncompliance examples include holes in pen floors or fences that can trap/injure an animal's legs or feet.
- If the noncompliance is the result of establishment employee actions in the handling or moving of livestock and animals are being injured or treated inhumanely, attach the tag either at a point specific to the location and nature of the violation or to the alleyways leading to the stunning area. Noncompliance examples include animals driven faster than a normal walking speed or animals slipping and falling because of slick floors.

The tag will remain in place until the establishment operator implements appropriate immediate actions and measures to prevent recurrence. The tag shall not be removed by anyone other than an inspector. All livestock slaughtered prior to the tagging may be dressed, processed, or prepared under inspection.

Whenever a non-egregious noncompliance of the humane slaughter requirements is observed, inspection personnel must document the incident on a NR and send a copy to the DVMS at the District Office. It is important that it clearly and specifically describe exactly what was observed, including any response by the animal (if the noncompliance involved animal discomfort or injury). Specify all the relevant regulations that pertain to the incident. At the top of Block 10 (where the noncompliance is described) on the NR, list the HATS category you were performing when you saw the noncompliance. If the noncompliance is covered by a second HATS category, note both categories on the NR.

If the establishment continues to have noncompliances or does not adequately correct previously documented noncompliances, the IIC is to communicate this to the FLS and DVMS. The IIC will work with the FLS and DVMS to determine if a Notice of Intended Enforcement (NOIE) should be issued for multiple noncompliances.

Egregious Noncompliances

So, what is an egregious noncompliance? Webster's Dictionary defines "egregious" as "conspicuously bad or flagrant." The Agency defines it as "any act or condition that results in severe harm to animals."

If you observe a noncompliance that you believe is egregious, your next set of actions will depend on whether or not you are the IIC. If you *are* the IIC, place a U.S. Retained/Rejected tag at the appropriate place and inform establishment managers that you are communicating with the FLS, District Office and DVMS to discuss the incident and recommend that a suspension without notification is imposed in accordance with 9 CFR 500.3(b).

If you *are not* the IIC, attach a U.S. Retained/Rejected tag at the appropriate place, and inform establishment managers that you are taking a regulatory control action and that no more animals can be slaughtered until you contact the IIC. Whichever action is taken, all livestock slaughtered before the action may be dressed, processed, or prepared under inspection.

NOTE: Regardless of whether or not you are the IIC, your *very first* step—even before applying a tag—is to stop the activity that is causing harm to animals.

The IIC will immediately notify the FLS, District Office and the DVMS of the incident to discuss and recommend a suspension action.

The IIC will also document the facts that serve as the basis of the suspension action on a noncompliance record (NR) and promptly provide that information electronically to the DO and the DVMS for their use. The NR will form the basis of the Notice of Suspension documented by the DVMS and DO staff and of the Administrative Enforcement Report.

Poultry Good Commercial Practices (GCP) Verification Activities

Poultry (chickens, turkeys, ducks, fowl, etc.) are not subject to the humane handling regulations as discussed above for livestock. Rather, compliance or noncompliance is determined based on a single regulation that prescribes that birds must be slaughtered under a well-controlled process that ensures they are bled out and no longer breathing by the time they enter a scald tank. 9 CFR 381.65(b) reads as follows:

"Poultry must be slaughtered in accordance with good commercial practices in a manner that will result in thorough bleeding of the carcasses and ensure that breathing has stopped prior to scalding. Blood from the killing operation must be confined to a relatively small area."

IPP assigned to poultry slaughter facilities are expected on a daily, per shift basis when the establishment slaughters, to perform a Poultry Good Commercial Practices task.

If the poultry are stunned prior to bleeding, check the stunning equipment to ensure it is functioning properly. Poultry that have been effectively stunned will have an arched neck and tucked-in wings posture.

Check in the bleeding area to determine if the bleeding equipment is functioning properly. One way that you might be alerted to problems with the bleeding equipment is if the line inspectors report an increased number or clusters of cadavers at inspection stations or increased numbers of bruised wings or legs.

Once a week, IPP are to randomly select a day to review establishment records documenting adherence to good commercial practices. This review takes the place of observation in the receiving through pre-scald areas. Recognize that establishments are not required to maintain written records of good commercial practices. If records are not kept, IPP are to visit the receiving through pre-scald areas as above.

Enforcement

During poultry handling and slaughter, IPP are to document through NRs or MOIs establishment failure to follow GCP. From a regulatory perspective, adherence to GCP is a process control issue and not a bird-by-bird performance standard issue.

If the establishment is not following good commercial practices, and birds are dying other than by slaughter, you are to document a noncompliance record citing 9 CFR 381.65(b), using the Poultry Good Commercial Practices task in PHIS. IPP are to write NRs for GCP noncompliance only when they can demonstrate that an establishment has lost **process control** and that there is an ongoing trend of bird dying otherwise than by slaughter.

Poultry Mistreatment MOIs

Poultry mistreatment MOIs are issued when the establishment is mistreating birds up until the kill step, but the mistreatment event does not demonstrate that the establishment's process is out of control. The MOI documents the discussion between IPP and the establishment management about the poultry mistreatment event. In addition, you are to document the discussion and any planned actions on the part of the establishment in a MOI. Give a copy of the MOI to establishment managers, keep a copy in the inspection file, and send a copy to the DVMS.

DVMS - District Veterinary Medical Specialist

The District Veterinary Medical Specialist (DVMS) will review the MOIs and GCP NRs and determine if additional action is warranted. The correlation includes review to determine accuracy and consistency of documentation. In specific situations, after review of mistreatment MOIs, the DVMS may need to notify appropriate state officials.

If you have questions or concerns about what you observe during poultry slaughter, contact the DVMS for guidance.

22 Sanitary Dressing

Inspection program personnel (IPP) who perform off-line slaughter verification duties are to use the PHIS Beef Sanitary Dressing task to verify compliance with the sanitation performance standards. You need to gather as much information as possible for a sound regulatory decision about the system. As IPP enter the kill floor, they observe the process, review plant records and results, FSIS records and results, NRs, pathogen testing results, generic *E. coli* testing results, online IPP feedback, weather conditions, etc. The thought process should use the systems-based approach to make compliance determinations.

System: A defined procedure or set of procedures designed by an establishment to provide control of operating conditions that are necessary to produce safe, wholesome food.

The procedures establishments follow typically include observing or measuring system performance, analyzing the results to set control criteria, and acting when needed to ensure that the system continues to perform within the control criteria. The procedures would include planned measures taken by the establishment in response to any loss of process control. In addition, the procedures can be used as support for decisions made in the hazard analysis.

Process Control: Practice of handling carcasses by establishment employees and machinery, throughout the slaughter process, in a manner that produces a clean, safe, wholesome meat food product in a sanitary environment.

Contamination can originate from two sources: Substances not related to the species being slaughtered like oils, rail dust, condensate, and unidentified foreign material, or substances related to the species being slaughtered, like digestive content, milk, ingesta or bile. Establishments need to prevent the creation of insanitary conditions and prevent the contamination of carcasses and parts to meet regulatory requirements.

Effective sanitary dressing and process control procedures lay the foundation for the critical control points (CCPs) that prevent, eliminate, or reduce to an acceptable level food safety hazards that are deemed reasonably likely to occur in the slaughter process. It is the responsibility of the establishment to reduce *E. coli* O157:H7 to below detectable levels, and reducing the amount of contamination that is present on a carcass helps the establishment accomplish that.

Establishments must operate and be maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure the product is not adulterated, as required by 9 CFR 416.1-416.5. Establishments that slaughter cattle must do so in a manner designed to prevent contamination from occurring at any step in the process. SPS plays a role, especially with regard to equipment/utensils, sanitary operations, employee hygiene. SPS is the most appropriate category for addressing incidental contamination.

The plant can be innovative (creative) so long as they meet the expected performance standards. Each establishment must design their own procedures. Effective sanitary dressing and process control procedures, coupled with effective decontamination and antimicrobial intervention treatments, are needed to prevent the creation of insanitary conditions. Establishments that fail to control these procedures and treatments create the potential for carcass contamination in their food safety systems. Establishments may elect to maintain written sanitary dressing and

process control procedures as part of their HACCP Plan, Sanitation SOP, Good Manufacturing Practices (GMP), or other prerequisite programs. If the sanitary dressing procedures are used to support decisions made in the hazard analysis in accordance with 9 CFR 417.5(a)(1), establishments must maintain records addressing the sanitary dressing and process control program. The records must demonstrate that the program is effective and thus decisions made in the hazard analysis can be supported on an on-going basis. Establishments have flexibility on how they demonstrate effective sanitary dressing and maintain records. The CCP for livestock zero tolerance will be at the final rail, but this does not mean that this is the only location where the plant should address visible contamination.

Verification of a food safety system requires that IPP evaluate production operations by looking at all aspects of those operations and assessing the interactions between them. IPP accomplish this through observation of the implementation of a variety of plans and procedures and through the review of documents associated with those plans and procedures. When the information gathered suggests that the establishment has lost process control, IPP are to determine if the establishment has taken measures to restore process control.

FSIS has identified the points in the slaughter process where carcasses are most vulnerable to contamination. This was determined through scientific literature review as well as best practice guidance created by industry. The steps are: live receiving/holding, sticking, hide removal, wash cabinets, bunning, head removal, rodding the weasand, evisceration, carcass splitting, and head and cheek meat processing. When cattle arrive, there is an increased potential for contamination with enteric pathogens such as *E. coli* O157:H7 and *Salmonella* due to their presence on the hide and in feces. Stressors cause increase shedding of pathogens like *E. coli* O157:H7.

An intervention is a step in the process added for the purpose of eliminating/reducing a hazard to an acceptable level. How well the establishment performs its sanitary dressing procedures impacts whether the antimicrobial intervention treatments will be effective and accomplish their intended results. Intervention may be sprayed solution of water and/or chemicals, a shower, some sort of drip application, steam vacuum device, a combination of all of these—the multiple hurdle approach. Each one of these interventions has a certain capability. Sanitary dressing directly impacts whether antimicrobial treatments will accomplish intended results. When incoming contamination overwhelms the antimicrobial properties of the intervention treatments, reduction of *E. coli* O157:H7 may no longer meet the standard of reduction to an undetectable level.

FSIS has questions about the establishment's ability to support the food safety system as the hazard analysis anticipates, unless the establishment has: documentation that supports that the food safety system at slaughter, including sanitary dressing procedures coupled with all intervention treatments, is effective under the actual conditions that apply in its operation; the establishment has reassessed its system in response to new or revised procedures or interventions that have been implemented and has determined that no changes were needed. If the establishment determines it can prevent contamination through its **SOP, GMP or other prerequisite program**, it needs to include support in the hazard analysis.

Before you make a compliance (meets regulatory requirements) determination, base it on in-plant observations, your own test results, establishment results, FSIS results, and communication with other inspectors; on-line IPP and PHV/SPHV findings, historical information; NRs, MOIs, ongoing noncompliance related to zero tolerance, increased contamination based on environmental conditions, positive pathogen results, and feedback from on-line IPP indicating increased contamination.

Regulations to cite include 9 CFR 310.18(a) for carcass contamination, and 9 CFR 416.1 (remember: only cite this regulation in response to egregious and repetitive insanitary conditions, and only in consultation with your IIC and FLS). Include in the description of the noncompliance the appropriate SPS regulations to address the source(s) of the insanitary condition. Noncompliance is not likely to be documented in response to one contamination incident or one single point in the process. Review NRs to determine if a trend is developing. NRs can be associated as necessary in accordance with the instructions in FSIS Directive 5000.1.

23 Review Establishment Data Task

Establishments may conduct certain testing or monitoring activities that are not a part of their HACCP plans or Sanitation SOPs. For example, establishments may perform testing or monitoring activities as a part of a prerequisite program or conduct product testing to comply with certain specifications of its customers. Data generated by such activities may not even be referenced in a hazard analysis. Nonetheless, these activities may provide information relevant to the effectiveness of establishments' food safety systems. In other words, the data may raise questions or concerns about the adequacy of an establishment's hazard analysis.

Whenever the results of testing and monitoring activities provide information relevant to the adequacy of decisions made in a hazard analysis, FSIS considers records of these results to be supporting documentation for that hazard analysis. Such records must be maintained by the establishment and made available for FSIS review. A prudent establishment will consider the significance of this information with respect to the overall effectiveness of its food safety system and respond to the results as necessary.

IPP should be aware of all monitoring and testing related to food safety conducted by an establishment, including monitoring and testing not referenced in the hazard analysis and not included as components of the establishment's Sanitation SOPs or HACCP plan. **FSIS Directive 5000.2, Rev. 2** specifies that at least once per week IPP, are to review the results of any such monitoring and testing. In this training module, we discuss the methodology for reviewing such data. The Review Establishment Data task helps IPP gain a full understanding of the establishment's food safety system. Considering the significance of this information in the context of the establishment's food safety system may identify potential vulnerabilities that otherwise may not be recognized when performing other HACCP and sanitation inspection tasks.

Records Subject to the Review Establishment Data Task

The *Federal Meat Inspection Act* (Section 642) and the *Poultry Products Inspection Act* (Section 460(b)) both establish the legal authority for requiring establishments to maintain a broad range of records. In addition, the Acts provide FSIS the authority to access any required records as necessary. FSIS has made clear to the regulated industries that IPP have the authority to **access all establishment records that could disclose the existence of an insanitary condition** which needs to be addressed in an establishment's HACCP plan, Sanitation SOPs, or prerequisite programs.

The regulatory authority to have access to records, which may have some bearing on the hazard analysis, derives directly from 9 CFR 417.5(a)(1), which states that an establishment must maintain the written hazard analysis prescribed in 9 CFR 417.2(a) and all supporting documentation. Furthermore, establishments are required by 9 CFR 417.5(f) to make all records required by 9 CFR 417 available for official review.

The purpose of a hazard analysis is to identify all relevant hazards and to determine which are reasonably likely to occur (RLTO) in the production process (9 CFR 417.2(a)(1)). A hazard analysis (and any documentation supporting the decisions in that hazard analysis) is not intended to be a static document. At any time, additional information or data may call into question the adequacy of an establishment's hazard analysis. This information or data may not

be specifically referenced in the hazard analysis or generated through implementation of the establishment's HACCP plan or Sanitation SOPs.

FSIS Directive 5000.2 specifies that IPP have access to any type of record maintained by the establishment if the record relates to the establishment maintaining its food safety system. Establishments must decide what type and frequency of testing is necessary to support the decisions made in its hazard analysis. Thus, the establishment decides which testing programs are necessary to ensure food safety and which testing programs are unrelated to food safety. **However, the establishment would have to explain to IPP why certain test records are not related to food safety and do not impact the hazard analysis.** If IPP learn of a testing program and have questions about whether records of that testing program should be included in the Review Establishment Data task, they should seek guidance from their supervisors and askFSIS.

NOTE: The Review Establishment Data task targets records of monitoring and testing results that bear on food safety, not product quality concerns. Certain regulatory product quality concerns would be verified through non-food safety, other consumer protection (OCP) tasks instead of the Review Establishment Data task.

Obviously, IPP should question why the results of any testing for pathogens conducted to meet purchase specifications or for other purposes would not affect the hazard analysis. It is not unusual, though, for many establishments to conduct testing of non-product contact surfaces or finished product for generic microbes such as aerobic plate counts (APCs), generic coliform bacteria, or other non-pathogenic microbes. Establishments may use such testing to provide information about product quality (e.g., shelf life) or to meet certain customer purchase specifications. Generally, such test results can also have implications for food safety. For example, if non-pathogen test results are used to ensure that the production process controls the overall level of microbes in the product, such test results may affect the hazard analysis, because the production process may be modified in response to microbial levels. In these situations, the test results should be made available to IPP for review. If purchase specifications call for testing of non-pathogens and the results are for information purposes only, those results would not affect the hazard analysis and generally would not have to be made available to IPP for review.

The types of records subject to the Review Establishment Data task are not limited to records of microbial testing. For example, some establishments may include metal detection in their process to meet some customer purchase specification. The establishment's hazard analysis may reference preventive maintenance programs and visual checks for metal contamination as support for metal being not reasonably likely to occur, but not include the customer-required metal detection program as additional support. Nonetheless, the metal detection program has implications for food safety in such an establishment, and records associated with the metal detection program should be made available to IPP for review.

In addition to the results of any monitoring or test results, IPP also have access to any written procedures associated with those results. This would include information such as the methods of sample collection and analysis or the procedure for conducting some monitoring activity.

Performing the PHIS Review Establishment Data Task

At least once a week IPP should schedule and perform the Review Establishment Data task in PHIS. IPP review the results of any testing that the establishment has performed that may have an impact on the establishment's hazard analysis.

Gathering Information

When reviewing such monitoring and test results, inspection program personnel are to consider questions such as:

1. Is there documentation (paperwork) that supports the frequency of the testing that the establishment employs?
2. If the establishment uses the testing to reflect the effects of a prerequisite program do the results support the decision-making for the design of the program?
3. At what point in the process does the testing occur?
4. Does the establishment use the test results in a manner that checks the proper execution of some activity at the point in the process where the testing occurs?
5. Do the results indicate that a food safety concern may be developing?
6. Is the establishment reacting to the situation? If so, what is it doing?
7. Do results indicate that a potential food safety concern is decreasing?
8. If pathogen or indicator organism positive results have decreased, does the establishment plan to reduce testing frequencies? If so, how it will ensure that such modifications to its testing program will not affect the likelihood of finding pathogens?
9. Are there operational results that correlate with the testing results? For example, does a reduction in microbial counts coincide with a new cleaning regimen, or conversely, has there been an increase in microbial counts during a time when the establishment failed to adequately implement some Sanitation SOP activities?

Assessing Information

A negative response to any of the questions above does not automatically mean there is a noncompliance or inadequate hazard analysis. IPP are to consider all available information in order to make any determination as to whether there is a basis for concern about how the establishment is implementing its system, or about how it is reacting to the results of its testing. However, IPP are not to write a noncompliance record on the basis of their review of these records. IPP should keep in mind that the Agency's policy is to encourage establishments to do testing and to address any problems that exist.

At weekly meetings with establishment management (see FSIS Directive 5000.1 & FSIS Directive 5010.1, Rev. 1), IPP are to raise any questions they have regarding any tests results that may have an impact on the establishment's hazard analysis. When necessary, inspection IPP are to raise concerns, through supervisory channels, to the District Office.

Documenting the Review Establishment Data Task

As part of documenting the weekly Memorandum of Interview (MOI), IPP are to indicate that they conducted the Review Establishment Data task, and that they discussed, if indicated, any concerns with the establishment at the weekly meeting. In the MOI, IPP are to:

1. Briefly list what tests results they reviewed and for what time period;
2. Describe the specific concerns, if any, that they discussed with the establishment; and
3. State how the establishment responded.

Anytime IPP have concerns about how an establishment responds to what was discussed at the weekly meeting or have questions about whether a particular type of data is available to the Agency, they are to raise those concerns or questions through supervisory channels. Frontline Supervisors will periodically review the documentation above and raise any concerns with the in-plant team and, as necessary, the District Office. Based on the concerns raised by IPP through supervisory channels, District Offices may determine that an Enforcement Investigation Analysis Officer (EIAO) needs to conduct a food safety assessment (FSA) to assess factors such as what the tests results reveal about food safety, and whether the design of testing, procedures or prerequisite programs are adequately supported by the decisions made in the hazard analysis.

Once IPP have conducted the Review Establishment Data task, discussed any concerns with plant management, and included the items above in the MOI, they are to indicate within PHIS that the inspection task has been completed.

Refusal of Access to Records

IPP have reported that establishments have refused to give them access to the results of equipment swab tests, microbiological testing of marinade solutions that are to be reused, and *Salmonella* testing. Establishments have refused to give access to these testing results on the grounds that the results are trade secrets—the testing is done for customers who do not want the results shared with the Agency, and the Agency is only entitled access to records upon which the establishment affirmatively relies.

The argument that the testing is a trade secret does not provide a basis not to share the information with FSIS. FSIS has authority and responsibility to protect trade secret information under the *Freedom of Information Act*. Such authority is meaningless unless the Agency has access to such information. The fact that a customer does not want the information shared with the Agency is irrelevant. The Agency's HACCP regulations have the force and effect of law and thus must be followed by the establishment.

If the IPP have questions about whether a particular type of data is available to the Agency, they are to advise their supervisor of the situation. As indicated above, an establishment is obligated to provide access to HACCP plans and other establishment data by 9 CFR 417.5(f). If an establishment refuses to provide access to its HACCP plan or other supporting documentation for review and recording of information into PHIS, IPP are to record a noncompliance, citing 9 CFR 417.5(f). IPP are then to discuss this noncompliance with establishment management at the next weekly meeting, and document that fact and any establishment response in the MOI. If the establishment continues in its refusal, IPP are to immediately contact their Frontline Supervisor, who will in turn inform the District Manager (DM) of the establishment's refusal. The

DM, or designee, will contact establishment management and discuss the issue. If the establishment continues to refuse, the DM will instruct IPP to take an official control action by withholding inspection as defined under 9 CFR 500.1(b). The DM will then document the incident in a letter to the establishment, officially informing it that FSIS has withheld inspection under 9 CFR 500.3(a)(6) because the establishment has interfered with an FSIS inspector performing his/her inspection duties. The DM will lift the withholding action when the establishment has provided its HACCP plan and supporting documentation to IPP for review.

24 Ready to Eat and Shelf Stable Products Process Familiarization

Fully Cooked-Not Shelf Stable. This category applies to establishments that further process products by using primarily a full lethality heat process step (e.g., cooking) to achieve food safety. The finished products are not shelf stable and must be frozen or refrigerated for food safety purposes. These products also **meet the definition of Ready-to-Eat (RTE)** as defined in 9 CFR 430.1.

RTE (Ready to Eat) product is a meat or poultry product that is **in a form that is edible without additional preparation** to achieve food safety and may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes. RTE product is not required to bear safe handling instructions or other labeling that directs that the product must be cooked or otherwise treated for safety and can include frozen meat and poultry products.

Heat Treated-Shelf Stable. This category applies to establishments that further process by using a heat treatment processing step as the primary means to achieve food safety, in combination with curing, drying, or fermenting processing steps. The finished products are shelf stable and are not required to be frozen or refrigerated for food safety purposes.

Shelf Stable (SS) product is free of microorganisms (pathogens and spoilage) capable of growing in the product at non-refrigerated conditions at which the product is intended to be held during distribution and storage. Shelf-stability is primarily achieved through drying or low water activity (a_w).

Not Heat Treated-Shelf Stable. This category applies to establishments that further process by curing, drying, or fermenting to achieve food safety. Establishments in this category may apply a low-level heat treatment. The finished products are shelf stable and not required to be frozen or refrigerated for food safety purposes.

Cooking is a very important step, because it is here that any pathogens (e.g., *Salmonella*) that may be in the product will be eliminated and the numbers of spoilage bacteria will be lowered to an acceptable level. This is called a **lethality** treatment. The cooling process is also known as **stabilization**.

Shelf stable **dried meat** snacks have a **low moisture** content (22-24%) and **low water activity**. A water activity limit of ≤ 0.85 should control growth of all bacterial pathogens of concern as well as mold for products stored in the presence of oxygen; however, if the product is vacuum packaged in an oxygen-impervious packaging (anaerobic environment), the water activity limit could be ≤ 0.91 .

Establishments can use **multiple hurdles**, which is a combination of critical operational parameters to achieve lethality (multiple steps to kill pathogens) to control a food safety hazard. Examples of multiple hurdles include the combination of high salt content and drying in the dry-cured ham process, and the combination of fermentation (increased acidity to control *Staphylococcus aureus*), cooking or smoking (optional), and drying in the fermented, dry sausage process (controls multiple pathogens including *Clostridium botulinum* and *Clostridium perfringens*). **Drying** in the fermented, dry sausage process is also important because it helps the products meet their standard of identity and controls the outgrowth of *Clostridium botulinum* and *Clostridium perfringens* so that drying achieves stabilization and the cooling step is unnecessary.

25 Lethality and Stabilization

Ready-to-Eat (RTE) products are meat or poultry products that are edible without additional preparation to achieve food safety. Two main processes which are critical for achieving safety in RTE products are known as lethality and stabilization. They are used to control the biological hazards in RTE products.

The **lethality (cooking)** treatment is defined as the process step or steps used to **destroy pathogenic** microorganisms in a product to make the product safe for human consumption.

After the product is cooked, spores of *Clostridium botulinum* and *C. perfringens* that survive the cooking process can germinate, becoming vegetative cells that can multiply to hazardous levels if cooling is inadequate. Rapid cooling from 130°F to 80°F is necessary to prevent the growth of *Clostridium* bacteria. The processes that establishments employ to limit the growth of spore-forming bacteria are called **stabilization (cooling)**.

The most common stabilization is cooling. However, other treatments, such as lowering the product pH through fermentation or marination, prevents the growth of *Staphylococcus aureus*. Drying or salt-curing to reduce the water activity or adding antimicrobials may also be used in combination with heating or each other to destroy pathogens. The use of multiple treatments to achieve lethality or stabilization is called the **multiple hurdle concept**.

For certain RTE products, FSIS has established regulatory performance standards because they have a higher public health risk. These products have historically been associated with foodborne illnesses caused by specific pathogenic bacteria or their toxins (*Salmonella*, *L. monocytogenes*, *E. coli* O157:H7, *C. perfringens*, and *C. botulinum*).

The **lethality** performance standards require establishments to treat certain RTE products to ensure a specific **log₁₀ reduction** of *Salmonella* microorganisms.

Performance standards are quantifiable pathogen reduction levels or growth limit requirements set by FSIS for lethality and stabilization of certain products. **Targets** are limits set by establishments to produce safe products.

Examples of Regulatory Performance Standards:

Lethality: 6.5-log reduction of *Salmonella* for cooked beef, roast beef, cooked corned beef.

Stabilization: No multiplication of *C. botulinum* and no more than 1-log increase of *C. perfringens* throughout the product shelf life.

FSIS Compliance Guidelines provide guidance to industry and may be used to support CCPs and critical limits in a HACCP plan. For example, “Appendix A” provides support for lethality (time, temperature, and humidity for cooking processes) and “Appendix B” for stabilization (cooling options). The Jerky Guideline describes requirements for lethality (heat and humidity) prior to drying.

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?

26 Food Ingredients of Public Health Concern

Introduction

FSIS is responsible for verifying that establishments have adequate in-plant ingredient controls and appropriate product labeling that lists ingredients in descending order of predominance by common or usual name.

Food Allergies

Exposure to specific proteins in certain food ingredients, not a direct harmful effect from the ingredient itself, can trigger a severe immune system reaction in individuals with food allergies. An allergic reaction is a hypersensitive, aggressive immune system response with symptoms that include tingling in the mouth, tongue and throat swelling, breathing difficulty, hives, vomiting, abdominal cramps, diarrhea, drop in blood pressure, and unconsciousness. In severe cases, life-threatening allergic responses called “anaphylactic reactions” may result in death. No conclusive scientific evidence exists that defines a necessary minimum threshold level for a food allergen to cause an adverse reaction. In most cases, the presence of an undeclared substance that is a known allergen, even in trace amounts, poses a significant public health risk and a potentially catastrophic allergic reaction in an allergic individual.

The FDA has identified eight foods (“Big 8”) and any ingredients that contain protein derived from these eight foods as major food allergens. The foods that account for approximately 90% of food allergies are:

- **Milk**
- **Eggs**
- **Fish** (e.g., bass, cod, or flounder)
- **Crustacean shellfish** (e.g., crab, lobster, or shrimp)
- **Tree nuts** (e.g., almonds, pecans, or walnuts)
- **Peanuts**
- **Wheat**
- **Soybeans**

NOTE: Attachment 1 in FSIS Directive 7230.1 provides a comprehensive list of ingredients and products that may be derived from the “Big 8” food allergens.

According to FDA estimates, food allergies result in 30,000 emergency room visits, 2,000 hospitalizations, and 150 deaths each year. While these reactions can be treated, there is no cure for food allergies. To avoid consequences, consumers with a food allergy rely on accurate labeling of food products to strictly avoid foods containing the allergen.

Food Intolerances

Some individuals may be intolerant of certain food and color additives. The adverse effects of food intolerances, which are often confused with allergic reactions, are generally not life-threatening and do not involve the same immunological mechanisms. Nevertheless, they can have significant public health consequences.

Lactose is a sugar molecule in milk and milk product derivatives. Some people are deficient in lactase, an enzyme in the intestinal tract that breaks down lactose. People with lactose intolerance experience gas, bloating, cramping, and sometimes diarrhea.

Sulfites are added ingredients used as to preserve food and prevent browning of processed fruits, vegetables, and shellfish. People with sulfite intolerance can experience chest tightness, hives, stomach cramps, diarrhea, breathing problems, and an increased risk of having asthma symptoms for sensitive people with asthma.

FD&C Yellow No. 5, a color additive also known as tartrazine, is used in a variety of food products. Tartrazine can cause symptoms similar to an allergic reaction (i.e., hives and swelling) in intolerant consumers.

Monosodium Glutamate (MSG) is added to a number of meat and poultry products as a flavor enhancer. Some individuals report headache, chest tightness, nausea, diarrhea, and sweating following consumption of MSG-containing products.

Gluten is the protein found in cereal grains (e.g., barley, rye, oats) that helps give dough its elasticity. Individuals who are intolerant to gluten have a condition known as celiac disease. Symptoms may include fatigue, bloating, cramping, chronic diarrhea, nutrient malabsorption, and, although not an allergic reaction, inflammation and damage to the lining of the small intestine.

Nitrate and **nitrites** are different nitrogen compounds used as curing agents in many meat and poultry products (e.g., hotdogs, bologna, salami, other processed meats) to inhibit the growth of *Clostridium* spp. and contribute to the characteristic flavor and color of cured products. Consuming nitrate or nitrite compounds may cause headache and hives in some people. The amount of nitrite or nitrate added to a product is restricted by regulation because excessive concentrations can be toxic.

Some product formulations include only naturally occurring sources of nitrite or nitrate (e.g., celery juice powder, parsley, cherry powder, beet powder, spinach, sea salt) and must be labeled appropriately (e.g., "uncured" bacon product that includes a declaration on the product label stating, "Uncured Bacon, No Nitrates or Nitrites added except those naturally occurring in___") because naturally occurring sources of nitrite or nitrate do not inhibit the outgrowth of *Clostridium* spp. as well as the highly purified chemical forms. In addition, cured products generally bear a statement such as "Not Preserved, Keep Refrigerated Below 40°F at All Times." Exceptions to the refrigeration handling statement include finished products that have been sufficiently dried according to other requirements or contain an amount of salt sufficient to achieve an internal brine concentration of ≥10%.

NOTE: FD&C coloring agents (e.g., Red No. 3 and Red No. 40 added to cures as a tint to distinguish nitrite-containing compounds from salt) do not need to be declared on the product label since their use is considered incidental and does not function as a color additive in the meat or poultry product. Similarly, release agents used on grills, loaf pans, cutters, or other hard production surfaces are generally considered to be a processing aid and their incidental use is not required to be declared on the product label.

Establishment Responsibilities

The establishment is responsible for researching all ingredients used in its product formulations and determining if an ingredient may trigger a food allergy. FSIS expects establishments to employ appropriate food safety procedures (i.e., HACCP plans, SSOPs, or other prerequisite programs) that ensure added ingredients match the product formula and all ingredients are properly and accurately disclosed on the product label.

Ongoing sanitary measures must prevent cross-contact between allergenic and non-allergenic products, equipment, and utensils, and ensure accurate label declarations on products that contain allergens. Cross-contact can be avoided through effective controls and appropriate use of ingredients, such as checking ingredient containers at receiving for damage, ensuring proper identification and control of allergenic ingredients and products throughout production, effective sanitation measures, training employees to work with allergens, and adhering to product formulations.

In addition to inadequate sanitary controls, accidental application of inaccurate labels to properly formulated products poses a threat to sensitive consumers. The establishment can ensure accurate product labeling by changing labels when changing product formulations, reviewing incoming non-meat/non-poultry ingredient labels for changes, discarding obsolete labels after a change in product formulation, reviewing newly printed labels for accuracy, controlling labels to ensure application of the correct label, maintaining adequate identification controls of product containing an allergenic ingredient that is intended for rework, and declaring an allergen indirectly added to the product.

NOTE: the following information may be helpful when reviewing an establishment's hazard analysis and supporting documentation regarding the use of highly refined edible oils.

1. Highly refined edible oils (e.g., soybean oil, peanut oil) are plant-based oils that have been processed and rendered virtually free of allergenic proteins and are safe for the food-allergic population to consume.
2. Allergen-containing products cooked or par-fried in highly refined edible oils may leave traces of allergenic proteins behind in the oil. Establishments that reuse the same oil to cook or par-fry products should consider the potential hazard oil reuse might pose to food-allergic consumers.

Label Declarations

Under FMIA and PPIA, all ingredients used to formulate meat or poultry products generally must be declared by its common or usual name in the ingredients statement on the product label. With few exceptions, a meat or poultry product is considered to be misbranded if it contains permitted ingredients that are not declared on product labels.

The need for accurate, informative product labeling is especially important for individuals with allergies or food intolerances. FSIS supports the use of voluntary statements on labels to further alert people with sensitivities or intolerances to the presence of specific ingredients (e.g., a label statement such as, "Contains: milk, wheat gluten" or a product label specifying, "Contains sodium caseinate (from milk)" to alert milk allergic consumers that an ingredient contains or is derived from milk).

On a limited case-by-case basis, the FSIS Labeling and Program Delivery Staff (LPDS) may permit the use of factual labeling statements about a product's manufacturing environment. However, the Agency does not consider the casual use of an elective statement about a product's manufacturing environment as helpful to consumers and does not promote good manufacturing practices under a HACCP system.

Factual Labeling Statements

With the exception of ingredients consistent with the FDA's definition of a processing aid or incidental additive, all ingredients listed on labels of incoming food and food ingredients must be declared on finished product containers. Official establishments must list an allergenic ingredient in the product label ingredients statement if a formulation component used contains a known allergen (e.g., soy lecithin in a release agent). All ingredients listed in a "may contain" or "produced in a facility" statement must be listed on the final label unless the establishment has (1) contacted the supplier and confirmed, preferably in writing, that the statement is a cautionary statement and no such ingredient is in the product; and (2) included a written statement in its hazard analysis supporting why the "may contain" or "produced in a facility" statement is not documented on the finished meat or poultry product label.

FSIS will consider any non-misleading symbols, statements, or logos to inform consumers of the presence of ingredients of public health concern in meat or poultry products. An establishment may submit such a request to the Agency as a policy inquiry but not as label-approval submission.

NOTE: Some chemicals mentioned in this handout may be classified as "generally recognized as safe" (GRAS) for human consumption. Although this module focuses on the addition of ingredients reported to cause adverse health effects in some individuals, establishments must consider all potential chemical food safety hazards, including ingredients that are GRAS, in their hazard analyses.

Factual Labeling Statement Example:

An official establishment uses chopped peanuts in making a dry, Thai-style meat sauce mix. The processing environment must remain dry during operations. Since the production equipment cannot be washed, peanut dust may become airborne and unavoidably contaminate other meat or poultry products manufactured in the same production area. In such situations, a statement about the manufacturing environment as described above or the use of a "may contain (name of allergenic ingredient)" statement has been approved by LPDS. However, it is not acceptable to use this type of statement to address poor SSOPs, such as potential cross-contamination between different products due to inadequate equipment wash between production.

Inspection Program Personnel Responsibilities

Establishments are expected to have effective controls and preventive measures to address all potential chemical hazards, including food allergens and other ingredients of public health concern. IPP will verify that the establishment addressed allergens as a potential chemical food hazard in its hazard analysis, has support for decisions made in its hazard analysis, and implemented effective controls based on those decisions.

IPP must be up to date and aware of the establishment's controls and preventive measures for allergens and ingredients of public health concern. Multiple inspection activities (e.g., HAV task, HACCP Verification task, Review of Establishment Data task, Pre-operational and Operational SSOP tasks, General Labeling Task, and "Big 8" Formulation Verification task) may be necessary to verify that an establishment's food safety system meets regulatory requirements for allergens and ingredients of public health concern. IPP will issue an NR under the appropriate inspection task if the establishment:

- Fails to address a potential chemical food safety hazard in its process;
- Does not have adequate documentation on file to support decisions made in its hazard analysis for hazards that are not reasonably likely to occur;
- Fails to adequately implement its SSOPs or other prerequisite programs to support a decision that a chemical food safety hazard is not reasonably likely to occur;
- Fails to appropriately declare any allergen or other ingredient of public health concern on the product label.

"Big 8" Formulation Verification Task

The "Big 8" Formulation Verification task provides IPP with a method for verifying that establishments are accurately controlling and labeling the eight most common food allergens. Performing the task as described in FSIS Directive 7230.1 includes reviewing records, observing production processes, and responding to specific task-related questions in PHIS.

IPP assigned to establishments that produce products in any of the HACCP processing categories other than slaughter must determine whether the establishment produces any products that may contain any of the "Big 8" food allergens. Review the preventive and control measures developed by the establishment to verify that such measures are being effectively implemented and product label ingredients are consistent with product formulation records. Depending on its processes and decisions made in its hazard analysis, an establishment's preventive and control measures to control allergens may be in its HACCP plan, Sanitation SOPs, or a prerequisite program.

For establishments in which the "Big 8" Formulation Verification task is relevant, the task will appear monthly as a routine Priority 3 task on the Establishment Task List in PHIS. IPP will perform the routine verification task on each shift in establishments with multiple shifts. In establishments that produce more than one product, IPP are to use the chart from Directive 7230.1 (page 5) to prioritize product selection. Whether or not the establishment produces products containing a "Big 8" allergen, IPP are to apply the priority list to all products in an eligible establishment.

NOTE: Examples of multi-ingredient components include sauces, condiments (e.g., ketchup, mustard), seasoning packets, flavorings, spice mixes, soup bases, or other combinations of two or more ingredients mixed together. Additional considerations regarding multi-ingredient seasonings or spices, processing aids, incidental additives, release agents, and "may contain" or "produced in a facility" statements on incoming food and food ingredients are outlined in FSIS Directive 7230.1.

To perform a routine "Big 8" Formulation Verification task, IPP must first schedule the task in advance and determine which products will be produced on that date. Next, they must select a product for the task, which may require coordinating with IPP on other shifts to avoid selecting

the same product for consecutive tasks. Always attempt to select products that have not been selected previously unless there has been a change in supplier, ingredients, formulation, or the establishment produces a very limited number of products.

NOTE: If FSIS Directive 7230.1 task criteria does not apply to the operation, IPP are to find the “Big 8” Formulation Verification task on the Establishment Profile/Inspection Tasks page for the establishment and disable the task in accordance with FSIS Directive 13,000.1.

After selecting a product, IPP are to obtain that product’s specific product formulation from the establishment for verification in accordance with 9 CFR 318.6 and 9 CFR 381.180. The “Big 8” Formulation Verification task may be performed using a combination of the recordkeeping and review and observation inspection components. Performing the task involves:

1. Reviewing product formulation records and observing product formulation process steps to verify that all ingredients used in the production of the product are consistent with the intended product formulation;
2. Reviewing the product label to verify that all ingredients used in formulating the product are declared in the ingredients statement by common or usual name and in descending order of predominance;
3. Observing that the appropriate label is applied to the product;
4. Observing that the applied label is consistent with the establishment’s label approval on file.

As part of documenting the task in PHIS, IPP will respond to specific questions related to this task located on the “additional info” tab of the task documentation page. Attachment 2 of FSIS Directive 7230.1 provides more information regarding these questions.

If there are any indications of increased risk of undeclared allergens in the establishment, the “Big 8” Formulation Verification task may be performed more frequently as a “for cause” directed task. Before scheduling additional “Big 8” Formulation Verification tasks, IPP should discuss with their supervisor the circumstances and any concerns of increased risk of undeclared allergens.

Documenting Noncompliance with the “Big 8” Formulation Verification Task

IPP are to document noncompliance on an NR in PHIS under the “Big 8” Formulation Verification task whenever they determine that a meat or poultry product contains a “Big 8” allergen not declared in the ingredients statement on the product label. IPP will cite the relevant food safety regulation(s) in 9 CFR 317.2(f) for products bearing the meat inspection legend or 9 CFR 381.118 for products bearing the poultry inspection legend. In addition, IPP must always notify their supervisor when they identify such noncompliance so that a recall request determination can be made. “Big 8” noncompliance examples can be found on slide 21 of the accompanying module in the FSIS Training Site.

NOTE: If IPP identify concerns when performing the “Big 8” Formulation Verification task and believe a directed HAV task should be performed, they are to discuss those concerns with their supervisor.

Documenting Noncompliance for Other Undeclared Ingredients

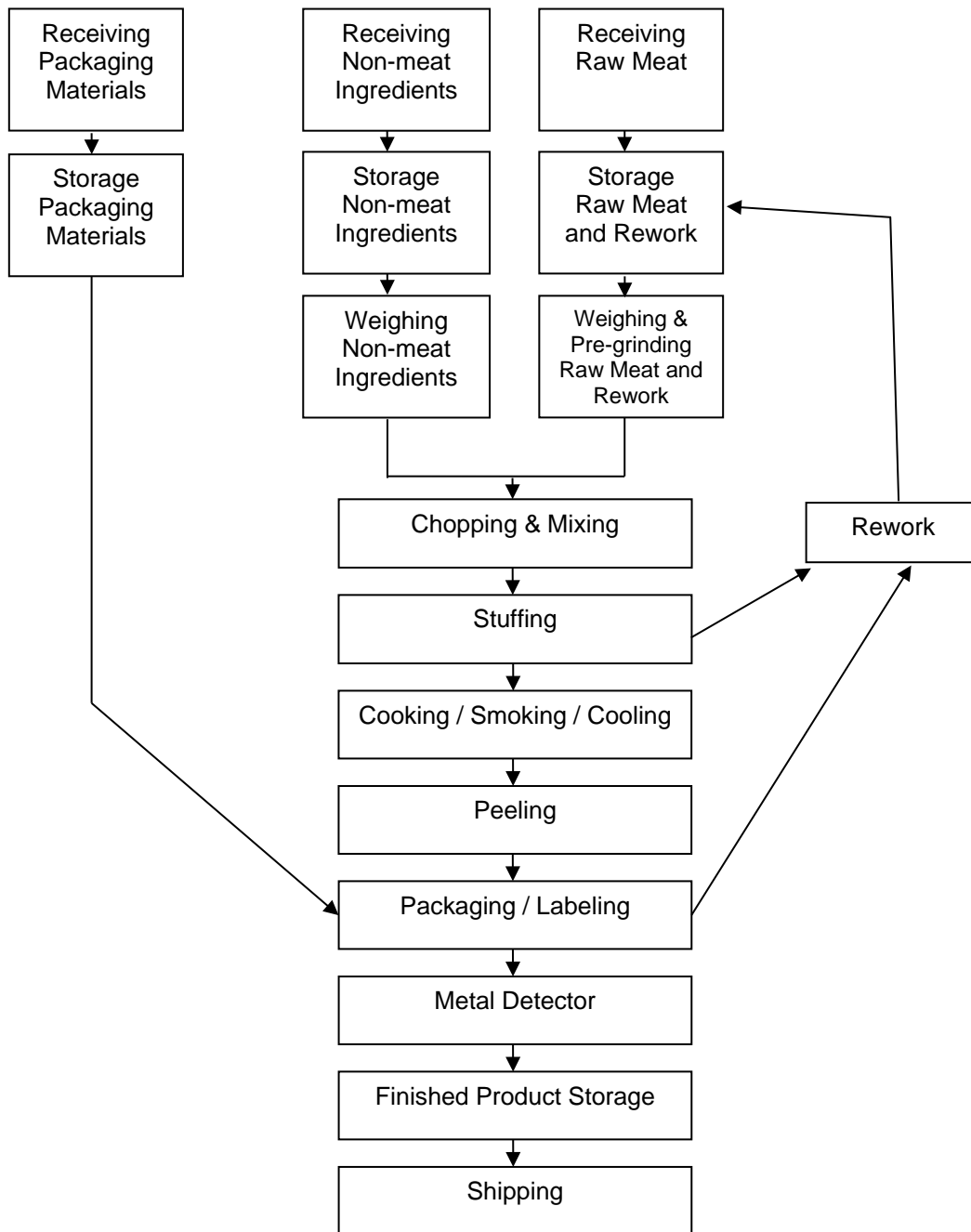
If IPP determine that a product contains an ingredient not declared in the ingredients statement but it is not a “Big 8” allergen, a directed General Labeling task should be scheduled to document General Labeling noncompliance with 9 CFR 317.2(f) for products bearing the meat inspection legend or 9 CFR 381.118 for products bearing the poultry inspection legend.

Other Actions

IPP may need to take regulatory control of product at the official establishment as necessary to prevent the product from entering commerce. IPP should always contact the FLS for guidance any time they have reason to believe any product bearing labels that fail to declare one of the “Big 8” food allergens or any other ingredient of public health concern has entered commerce. An immediate withholding action on the process may be necessary and a product recall may be requested by the Recall Management and Technical Analysis Staff (refer to FSIS Directive 8080.1 for more information on recalls).

27 RTE-SS Hazards and Controls Workshop

Hot Dog Flow Diagram



No returned product accepted.

(Training Example Only)

Hot Dog - Hazard Analysis – ...EXCERPT...

(Training Example Only)

Process Step	Potential Food Safety Hazard	RLTO	Basis	If RLTO, What Control Measures?	Is this Step a CCP?
Receiving - raw meat	B-Pathogen growth <i>Salmonella</i> , STECs, <i>Campylobacter</i> , <i>Trichinella spiralis</i> <i>Clostridium botulinum</i> and <i>Clostridium perfringens</i> (Clostridia) C-None P-Metal, rubber, plastic, wood in incoming raw product	No Yes Yes No	Temperature Control Program Receiving Inspection Program	Vegetative pathogens and Trichinae eliminated at the Cooking CCP <i>Clostridium</i> growth and toxin formation prevented with Chilling CCP and Temperature Control Program	No
...
Cooking & Smoking	B-Pathogens and parasites C-None P-None	Yes		Cooking at temperatures sufficient to eliminate pathogens and parasites	Yes-1B
Cooling	B- <i>Clostridium</i> growth B-Contamination with <i>Lm</i> and potential subsequent growth C-None P-None	Yes No	Brine SOP for salt concentration, temperature, and microbial testing for <i>Listeria</i> spp.	Rapid cooling to ensure no growth of <i>C. botulinum</i> & less than one log growth of <i>C. perfringens</i>	Yes-2B
...

Hot Dog HACCP Plan (Training Example Only)

CCP	Critical Limits	Monitoring Procedures	Verification Procedures	Records	Corrective Actions
1B Cooking	Internal temp at least 160°F	Every 2 hours, internal temperature checked by floor supervisor using hand held digital thermometer, two temps taken from each (upper and lower) chain of continuous cooker/smoker/cooler unit checked at specified access point "B"	Accuracy of all thermometers checked prior to each shift Once per shift QC will observe one internal temp monitoring procedure Daily, QC supervisor will review monitoring records and other records required by 417.5(a)(3)	Cooking log Thermometer log Corrective Actions log	QC will take Corrective Actions per 417.3
2B Cooling	Cooler brine medium kept at or below 28°F. Chain speed not to exceed 100 racks per minute. Internal temp reduced from 130°F to less than 40°F in 90 minutes or less	Every 2 hours cooler brine medium checked at specified access point "A" Every 2 hours chain speed checked Every 2 hours internal product temperature at exit checked using hand held digital thermometer, two temps taken from each (upper and lower) chain of continuous cooker/smoker/cooler All three monitoring checks done by floor supervisor	Accuracy of all thermometers checked prior to each shift Once per shift QC will observe one internal temp monitoring, one brine temp check, and one chain speed check procedure Daily, QC supervisor will review monitoring records and other records required by 417.5(a)(3)	Cooling log Thermometer log Corrective Actions log	QC will take Corrective Actions per 417.3

28 Ready-to-Eat (RTE) Sanitation

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

Establishments are responsible for producing product that is free from any pathogen.

The pathogen *Listeria monocytogenes* (*Lm*), one species of *Listeria* bacteria, is of particular concern because it has potentially fatal consequences. *Lm* is a biological food safety hazard that an establishment producing post-lethality exposed RTE products must control through its HACCP plan or prevent in the processing environment through Sanitation SOPs or some other prerequisite program. RTE product is considered adulterated if it contains *Lm* or if it comes into direct contact with a food contact surface that is contaminated with *Lm*.

Lm is spread very easily by direct contact with a contaminated surface. ***Lm* can survive and grow in cool, damp environments**, such as those found in processing areas, coolers, or floors. Incomplete removal of product debris can provide nutrients and a place of attachment which allows bacterial growth.

Establishments need to keep equipment **dry** to reduce the growth of *Lm*.

Lm can form biofilms on solid surfaces, such as stainless steel and rubber, and can survive adverse conditions on apparently smooth surfaces. Biofilms protect the bacteria embedded in the biofilm from sanitizers.

Dust generated by **construction and other disruptive activities** can establish contamination on food contact and other environmental surfaces.

29 *Listeria monocytogenes* (*Lm*) Regulations

Introduction

Listeria monocytogenes (*Lm*) is a widespread pathogen capable of surviving under various environmental conditions. It can be found in the soil, on plant materials, animal feedstuffs, and the intestinal tract of various mammals and birds. *Lm* is very tolerant of freezing, drying, salt, and heat, and will grow at temperatures as low as 31.3°F or as high as 113°F. It can adapt to significant changes in pH values and reproduce at a pH as low as 4.39 and as high as 9.4. *Lm* can also reproduce with a water activity (a_w) as low as 0.92.

Lm can produce a disease called listeriosis. The infective dose of *Lm* is believed to be fewer than 1,000 organisms. High risk groups include pregnant women and their fetuses, young children, the elderly, and immunocompromised people. An individual with a mild *Lm* infection may have general flu-like symptoms, including nausea, vomiting, and diarrhea. However, severe infections can lead to septicemia, meningitis, encephalitis, and death. Infections during pregnancy may result in a miscarriage or stillbirth.

A common link in *Lm* outbreaks is contamination of RTE products in the post-lethality environment prior to packaging. *Lm* can contaminate a food processing environment from slaughter animals, ingredients, equipment, personnel, pallets, or other means. Once *Lm* contaminates the processing environment, it can establish in drains, on processing equipment, and in refrigeration units. The organism can also form a durable biofilm.

Lm may cross-contaminate RTE product exposed to the post-lethality environment due to inadequate sanitary practices. Dust, movement of personnel, and equipment associated with construction projects (e.g., air handling system repairs, removal of walls, repairs to plumbing systems) create opportunities for *Lm* to cross-contaminate post-lethality exposed product. An establishment may need to implement additional sanitation practices and containment procedures for any construction projects in or around processing areas where post-lethality exposed products are handled and packaged.

FSIS considers *Lm* to be a significant foodborne pathogen of great potential public health concern that must be controlled by establishments producing post-lethality exposed RTE products. FSIS has developed regulatory requirements specifically for controlling *Lm* in post-lethality exposed RTE products. In addition, the agency has developed *Lm* sampling programs as part of its public health strategy for protecting consumers against *Lm*.

Listeria Rule

On June 6, 2003, FSIS published an interim final rule ("*Listeria* Rule") that requires establishments producing post-lethality exposed RTE products to prevent adulteration by *Lm*. 9 CFR 430.4(a) identifies *Lm* as a hazard that establishments producing RTE products exposed to the post-lethality environment must control through a HACCP plan or prevent in the processing environment through an SSOP or other prerequisite program. It states that RTE product is adulterated if it contains *Lm* or comes into direct contact with a food contact surface contaminated with *Lm*. 9 CFR 430.4(b) identifies three alternatives that establishments are to choose from in order to control *Listeria* in post-lethality exposed RTE product. IPP are responsible for using appropriate HACCP or SSOP verification tasks to verify establishment compliance with 9 CFR 430.4(b).

Definitions

9 CFR 430.1 provides a several definitions that are specific to ready-to-eat (RTE) products. Two RTE product definitions are ***deli products*** and ***hotdog products***. A deli product is an RTE meat or poultry product that is typically sliced, either in an official establishment or after distribution, and assembled in a sandwich for consumption. A hotdog product is an RTE meat or poultry frank, frankfurter, or wiener product with a standard of identity defined in 9 CFR 319.180 and 319.181. A risk assessment performed jointly by FSIS and the FDA indicated that on a per serving basis, deli meats and hotdogs (not reheated) posed the greatest risk of illness and death from *Lm*.

A ***lethality treatment*** is the initial process RTE meat and poultry products undergoes to eliminate or reduce the number of pathogenic microorganisms on or in a product. Examples of lethality treatments that will make an RTE product safe for human consumption include cooking or the application of an antimicrobial agent or process that eliminates or reduces pathogenic microorganisms.

The ***post-lethality processing environment*** is the area in an establishment into which product subjected to an initial lethality treatment has been routed. The product may be exposed to the environment through slicing, peeling, re-bagging, cooling semi-permeable encased product in a brine solution, or other procedures.

Post-lethality exposed product is RTE product that comes into direct contact with a food contact surface in the post-lethality processing environment after an initial lethality treatment. Only post-lethality exposed RTE products are subject to 9 CFR 430.

The following three terms are associated with the three *Listeria* control alternatives used to control or prevent *Lm* in an RTE product in the post-lethality environment:

- ***Post-lethality treatment*** (PLT) - an additional lethality treatment, following the initial lethality treatment, applied to the final product or sealed package of product to reduce or eliminate the risk of *Lm* contamination during post-lethality exposure. Examples of post-lethality treatments include steam pasteurization, hot water pasteurization, radiant heating, and high pressure processing (HPP). Some antimicrobial agents may also function as post-lethality treatments.
- ***Antimicrobial agent*** - a substance in or added to an RTE product that suppresses or limits growth of *Lm* in the product throughout the shelf life of the product. Examples of antimicrobial agents used in RTE products are sodium lactate, potassium lactate, and sodium diacetate. FSIS Directive 7120.1 identifies additional antimicrobial agents approved for use in the production of RTE meat and poultry products.
- ***Antimicrobial process*** - an operation (e.g., freezing) applied to an RTE product that suppresses or limits the growth of *Lm* in the product throughout the shelf life of the product. Drying and fermenting are operations that may be applied to a product to make it RTE and subsequently suppress or limit the growth of *Lm*.

Note: the post lethality treatment should demonstrate at least 1-log decrease of *Lm* before the product is released into commerce and the antimicrobial agent or process should demonstrate no more than 2-logs growth of *Lm* over the shelf life of the product.

While not defined in 9 CFR 430.1, **indicator organism** is defined in 9 CFR 430 as a species of bacterium used to determine if the sanitary conditions of food processing equipment, production areas, or storage rooms allow for the presence of objectionable microbes (i.e., pathogens).

Establishment Responsibilities

An establishment that produces post-lethality exposed RTE meat and poultry products must maintain its facility in a sanitary manner. The sanitation program must be designed and implemented to prevent contamination of food contact surfaces (FCS) and adulteration of RTE product with *Lm* and other pathogens in the post-lethality environment. The establishment must conduct a hazard analysis designed to control FCS contamination and adulteration of RTE products. Any hazards considered reasonably likely to occur must be included in a HACCP plan and the effectiveness of the RTE processes validated. The establishment should incorporate procedures for accurately labeling RTE products, including identifying product for rework. The hazard analysis, HACCP plan, supporting documentation, and prerequisite programs should be maintained and made available to FSIS upon request.

Sampling Program

Under 9 CFR 430.4(b)(2)(iii)(A) and (3)(i)(A), establishments that produce post-lethality exposed RTE products are required to provide for FCS testing in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Lm* or indicator organism. While sampling is not required under Alternative 1 or Alternative 2, Choice 1, FSIS recommends the establishment collect from each post-lethality exposed production line a minimum of 2 *Lm* FCS samples per year (every 6 months) under Alternative 1 and a minimum of 4 *Lm* FCS samples per year (quarterly) under Alternative 2, Choice 1. FCS sampling is required for Alternative 2, Choice 2 and Alternative 3. The minimum required sampling frequency from each post-lethality exposed production line under Alternative 2, Choice 2 is 4 *Lm* FCS samples per year (quarterly) and once per month (monthly) under Alternative 3. For establishments that produce RTE deli products and hot dogs under Alternative 3, the minimum FCS sampling frequency from each post-lethality exposed production line is monthly in very small establishments, every 2 weeks for small establishments, and weekly in large establishments. 9 CFR 430.4 requires establishments to identify the size, location, and frequency of the FCS sites to be *sampled and provide* an explanation of why the testing frequency is sufficient to ensure that *Lm* will be effectively controlled.

IPP Responsibilities for Verifying Compliance with 9 CFR Part 430.4

In order to verify compliance with 9 CFR 430.4, IPP must be familiar with the establishment's RTE products and processes. If necessary, establishment management should be asked if they produce any RTE product that is exposed to the environment following the initial lethality step.

IPP should ask the establishment which of the three *Listeria* control alternatives was chosen for each post-lethality exposed RTE product produced. If necessary, plant management should be advised that initial validation results supporting the effectiveness of the selected alternative must be made available to FSIS upon request.

IPP should verify that the establishment is meeting the requirements of the alternative it selected by performing the appropriate SSOP or HACCP tasks. If the establishment decides to produce different products using different alternatives, the inspector should verify that each post-lethality exposed RTE product meets the requirements for the alternative selected.

In addition to verifying the effectiveness of the *Listeria* control alternatives selected, IPP will verify that the establishment is maintaining sanitary conditions sufficient to prevent product contamination, including *Lm*. Sanitation is the foundation for controlling *Lm* and without it, no alternative will successfully control *Lm*.

Note: See Attachment 1 for *L. monocytogenes* control requirements and Attachment 2 for summaries of the *Listeria* control alternatives and their requirements.

Alternative 1 - 9 CFR 430.4(b)(1)

Alternative 1 uses 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 *Lm*.

Alternative 1 Compliance Example

While verifying that an establishment is meeting the requirements of Part 430 and Alternative 1, you review the establishment's hazard analysis for sliced semi-dry sausage products (e.g., Genoa salami, sandwich pepperoni, etc.). You determine that the fermentation, heating, drying, and packaging steps have been identified as CCPs in the hazard analysis and were incorporated into a HACCP plan. The hazard analysis and HACCP plan identify lowered acidity (pH) through the use of bacterial starter cultures and lowered water activity from drying as measures to limit the growth of *Lm* in the finished product throughout the shelf life of the product. A steam pasteurization process after the product has been vacuum packaged was identified as a post-lethality treatment to reduce or eliminate *Lm* contamination. There are critical limits at the respective steps for pH, water activity, and time and temperature exposure for the steam pasteurization process. You request the supporting documentation for the critical limits and the establishment provides scientific literature and the results of challenge studies conducted by a processing authority. Supporting documents show that the pH and water activity in the product allows no more than a 2-log increase of *Lm* during its refrigerated shelf life and that the surface steam pasteurization treatment is effective in achieving at least a 1-log decrease of *Lm* from the post-lethality contamination. Based upon your review, you determine that the establishment is in compliance with 9 CFR 430.4(b)(1).

Alternative 2 - 9 CFR 430.4(b)(2)

Alternative 2 uses either a post-lethality treatment (which may be the antimicrobial agent or process) that reduces or eliminates microorganisms on the product OR an antimicrobial agent or process that suppresses or limits the growth of *Lm*.

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

- **Alternative 2, Choice 1** - The establishment chooses to use a post-lethality treatment (which may be an antimicrobial agent) that reduces or eliminates *Lm* on the product.
- **Alternative 2, Choice 2** - The establishment chooses to use an antimicrobial agent or process that suppresses or limits the growth of *Lm*.

Alternative 2 Compliance

Example 1: An establishment's product line includes chicken salad and ham salad. It hermetically seals containers filled with these RTE salad products, the containers are batch loaded into cylinders, the cylinders enter a chamber, and the products undergo HPP. You are reviewing the establishment's hazard analysis and HACCP plan for these products to verify compliance with the requirements for Alternative 2, Choice 1 as specified in 9 CFR 430. In its hazard analysis, the establishment concluded that *Lm* was a hazard RLTO in the post-lethality processing environment. The establishment identified the HPP as its post-lethality treatment and included it in its HACCP plan as a CCP. The critical limit is time at a specific pressure level. In reviewing supporting documents for the CCP, you determine there are other critical parameters associated with this type of treatment, including product temperature before high pressure processing and water fill level of the pressure chamber. You request additional documentation supporting that the establishment achieves these additional critical parameters. The establishment provides documents that show the product temperature is consistently 40°F or less at the packaging step and that the pressure chamber water level is monitored to ensure that the required level of pressure can consistently be achieved in the process. You conclude that the establishment is in compliance with 9 CFR 430.4(b)(2).

Example 2: You are verifying that the establishment is meeting the requirements of Part 430 and Alternative 2, Choice 2. You review the establishment's hazard analysis for fully cooked frozen breaded chicken products and find that the cooking and chilling steps have been identified as CCPs in the hazard analysis and were incorporated into a HACCP plan. In addition to these CCPs, *Lm* was considered a potential hazard NRLTO at the packaging step because of the *Listeria* control measures in the establishment's SSOP to prevent *Lm* in the post-lethality processing environment. You request the supporting documentation for the decision made in the hazard analysis and the establishment provides a scientific document that identifies the temperature that would inhibit *Lm* growth in the finished product throughout the shelf life of the product. The establishment also provides the verification procedures and associated records it uses to demonstrate that products are frozen below the level that the scientific validation document establishes as preventing the growth of *Lm*. The records for the past several months show that the product is achieving the frozen temperature needed to suppress the growth of *Lm* and is labeled with the instructions "Keep Frozen." You review the establishment's SSOP and records and find that the establishment is testing food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Listeria* spp. The establishment has identified the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food contact surface for *Listeria* spp., the size and location of the sample sites, and the testing frequency. It also provided a thought process as to why the testing frequency it selected is sufficient to ensure that effective control of *Lm*, or an indicator organism, is maintained. Based upon your review, you determine that the establishment is in compliance with 9 CFR 430.4(b)(2).

Alternative 3 - 9 CFR 430.4(b)(3)

Alternative 3 involves the use of sanitation measures alone to prevent *Lm* in the processing environment and on the RTE product. There are separate FCS sampling requirements for deli meat and hot dogs produced under this alternative.

Alternative 3 Compliance

Example 1: You are verifying that the establishment is meeting Part 430 and Alternative 3 requirements. You review the establishment's hazard analysis for fully cooked breakfast type products (e.g., bacon, sausage patties, sausage links, etc.) packaged and sold refrigerated. You find that the cooking and chilling steps have been identified as CCPs in the hazard analysis and were incorporated into a HACCP plan. *Lm* was considered a potential hazard NRLTO at the packaging step because the establishment has *Listeria* control measures in a prerequisite program to prevent *Lm* in the post-lethality processing environment. You request the supporting documentation for the decision that *Lm* is NRLTO in the post-lethality environment. You review the establishment's prerequisite program and records and find that the establishment is testing food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Listeria* spp. It also has identified the conditions under which it will implement hold-and-test procedures following a positive test of a food contact surface for *Listeria* spp., the size and location of the sample sites, and testing frequency. The establishment provided a thought process as to why the testing frequency it selected is sufficient to ensure that effective control of *Lm*, or an indicator organism, is maintained. Based upon your review, you determine that the establishment is in compliance with 9 CFR 430.4(b)(3).

Example 2: You are verifying that the establishment is meeting the requirements of Part 430 and Alternative 3. You review the establishment's hazard analysis for fully cooked deli and hot dog type products (e.g., franks, sliced ham, sliced bologna, sliced roast beef, sliced turkey breast, etc.) packaged and sold refrigerated. You find that the cooking and chilling steps have been identified as CCPs in the hazard analysis and were incorporated into a HACCP plan. *Lm* was considered a potential hazard NRLTO at the packaging step because the establishment has *Listeria* control measures in its SSOP to prevent *Lm* in the post-lethality processing environment. You request the supporting documentation for the decision that *Lm* is not likely to occur in the post-lethality environment. You review the establishment's SSOP and records and find that the establishment is testing food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Listeria* spp. The establishment has identified the conditions under which it will implement hold-and-test procedures following a positive test of a food-contact surface for *Listeria* spp., the size and location of the sample sites, and the testing frequency. It also provided a thought process as to why the testing frequency it selected is sufficient to ensure that effective control of *Lm*, or an indicator organism, is maintained.

You find that the establishment verifies the effectiveness of the corrective actions it takes with respect to sanitation after an initial positive test on a food contact surface in the post-lethality processing environment through follow-up testing, including a targeted test of the specific site that is the most likely source of contamination by the organism, and other additional tests in the surrounding food contact surface area. When the establishment obtains a second positive test during this follow-up testing, it holds the lots of product that may have become contaminated by contact with the food contact surface until a test result indicates that the sanitation problem is corrected. The establishment only releases into commerce the lots of product that may have become contaminated with *Lm* from the food contact surface after it has sampled and tested the lots for *Lm* using a sampling method and frequency that will provide a level of statistical confidence that ensures that each lot is not adulterated with *Lm*. The establishment considers sampled product lots that test positive for *Lm* as adulterated and withholds them from entering commerce. The establishment destroys the held product, or reworks the held product using a process that is destructive of *Lm*. The establishment documents the test results and the

disposition of the product. Based upon your review, you determine that the establishment is in compliance with 9 CFR 430.4(b)(3).

DETERMINING COMPLIANCE

Gather Information

IPP should use the GAD thought process to verify compliance with Alternatives 1, 2, or 3. Alternative 2 is based on the same requirements as Alternative 1 except that the establishment can choose to use only a post-lethality treatment (Choice 1) **or** an antimicrobial agent or process (Choice 2). When verifying compliance with Alternative 1 and Alternative 2 requirements, IPP should seek answers to the following questions:

1. Is the post-lethality treatment (which may be an antimicrobial agent) incorporated in a HACCP plan?
2. Does the establishment have scientific documentation supporting the effectiveness of its post-lethality treatment in accordance with 9 CFR 417.5(a)(2)?
3. Does the establishment have validation data for the post-lethality treatment in accordance with 9 CFR 417.4?
4. Is the establishment implementing the post-lethality treatment as described in the HACCP plan?
5. Has the establishment incorporated the use of the antimicrobial agent or process to suppress or limit the growth of *Lm* in its HACCP plan, its Sanitation SOPs, or a prerequisite program?
6. Is the establishment using the antimicrobial agent or process as described in its HACCP plan, its Sanitation SOPs, or a prerequisite program, and can it scientifically support how the antimicrobial agent or process is being used?
7. Has the establishment incorporated the use of the antimicrobial agent or process to suppress or limit the growth of *Lm* in its HACCP plan, its Sanitation SOPs, or a prerequisite program?
8. Is the establishment using the antimicrobial agent or process as described in its HACCP plan, its Sanitation SOPs, or a prerequisite program?

When verifying compliance with Alternative 2, Choice 2, or Alternative 3 requirements, IPP should seek answers to these questions regarding the establishment's sanitation procedures.

1. Has the establishment incorporated sanitation measures in a HACCP plan, SSOP, or other prerequisite program?
2. Is the establishment's food contact surface testing used to verify the on-going effectiveness of its sanitation procedures?
3. Does testing of food contact surfaces in the post-lethality processing environment ensure that the surfaces are sanitary and free of *Lm* or of an indicator organism?

4. Did the establishment identify the conditions under which it will implement hold-and-test procedures following a positive test of a food contact surface for *Lm* or an indicator organism?
5. Did the establishment state the frequency with which testing will be done?
6. Did the establishment identify the size and location of the sites that will be sampled?
NOTE: establishments should identify all possible FCS sites (*AskFSIS QA dated 2-17-12*)
7. Did the establishment include an explanation of why the testing frequency is sufficient to ensure that effective control of *Lm*, or an indicator organism, is maintained?

If an establishment produces a RTE deli product or a hot dog product under Alternative 3, IPP should verify that the establishment:

1. Effectively implemented corrective actions (with respect to sanitation after an initial positive result on a food contact surface in the post-lethality processing environment) by follow-up testing that includes targeted testing of the specific site on the food contact surface area and other sites as necessary to ensure effectiveness of the corrective actions.
2. Holds product lots that may have become contaminated by contact with the food contact surface when the establishment obtains a second positive test for *Lm* or an indicator organism during follow-up testing until the problem is corrected as indicated by negative follow-up test results.
3. Sample and test product lots for *Lm* or an indicator organism using a sampling method and frequency that will provide a level of statistical confidence that ensures that each lot is not adulterated with *Lm*.
4. Documents testing results.
5. Reworks held product using a process that is destructive to *Lm*.

Assess Information

To answer these questions, IPP should:

- Review the HACCP plan,
- Review validation data (supporting documentation) for the post-lethality treatment,
- Review HACCP records,
- Review the Sanitation SOP and/or prerequisite programs associated with the use of the antimicrobial agent or process (as necessary), and
- Review Sanitation SOP and/or prerequisite program records (as necessary).

Determine Compliance

IPP must determine regulatory compliance after all available information pertaining to the *Listeria* Control Alternative selected has been gathered and assessed. There is no noncompliance if the establishment has met all regulatory requirements. If the establishment has not met all regulatory requirements, the noncompliance should be documented on an NR under the appropriate PHIS task as described in FSIS Directive 5000.1 Rev. 5, citing the

appropriate sections of 9 CFR 430.4(b), Part 417 for HACCP and prerequisite programs, and/or Part 416 for sanitation. IPP should verify that the establishment has taken effective corrective and preventive actions to bring itself into compliance with 9 CFR 430. Such actions may include a reassessment of the HACCP plan and the establishment's choice of another alternative.

Alternative 1 Noncompliance Examples:

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

Alternative 2 Noncompliance Examples

1. The establishment is testing food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Lm* or of an indicator organism, but does not have a post-lethality treatment to reduce or eliminate *Lm* included in a HACCP plan OR an antimicrobial agent or process to suppress or limit the growth of *Lm* incorporated into a HACCP plan, SSOP, or a prerequisite program. (Cite 430.4(b)(2), 417.2, 417.5(a)(1) & (2))
2. The written sanitation procedures the establishment is using to meet the requirements of Choice 2 only addresses the testing of non-food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Lm* or of an indicator organism. (Cite 430.4(b)(2), 416, 417.5(a)(1) & (2))
3. The written sanitation procedures the establishment is using to meet the requirements of Choice 2 do not identify the conditions under which or at what point hold-and-test procedures following a positive test of a food-contact surface for *Lm* or an indicator organism will be initiated. (Cite 430.4(b)(2), 417.5(a)(1) & (2))
4. The written sanitation procedures the establishment is using to meet the requirements of Choice 2 do not identify the size of the sites to be sampled or explain why the testing frequency selected is sufficient to ensure that effective control of *Lm* or an indicator organism is maintained. (Cite 430.4(b)(2), 417.5(a)(1) & (2))

Alternative 3 Noncompliance Examples

1. The establishment does not have sanitation measures incorporated in its HACCP, Sanitation SOP, or other prerequisite program. (*Cite 430.4(b)(3), 417.5(a)(1) & (2)*)
2. An establishment that produces deli and hot dog products does not conduct follow-up testing of target sites on the FCS area that is the most likely source of contamination after an initial positive test for *Lm*, or its indicator organisms, to verify the effectiveness of its sanitation corrective actions. (*Cite 430.4(b)(3), 417.5(a)(1) & (2)*)
3. An establishment that produces deli and hot dog products does not hold-and-test lots of product for *Lm*, or an indicator organism, that may have become contaminated by contact with the food contact surface when it obtains a second positive test for *Lm*, or an indicator organism, during its follow-up testing. (*Cite 430.4(b)(3), 417.5(a)(1) & (2)*)

Documentation and Enforcement

If noncompliance with the *Lm* regulations is found, IPP are to issue an NR under the appropriate HACCP or SSOP task as described in FSIS Directive 5000.1, citing 9 CFR 430.4(b)(1), (2), or (1) and the appropriate sections of 9 CFR 417 or 416 if applicable. IPP are to verify that the establishment has taken effective corrective actions to bring itself into compliance with 9 CFR Part 430. Such actions may include, but are not limited to, a reassessment of the HACCP plan and the establishment's choosing of another alternative or determining that the decisions it made in the hazard analysis regarding the use of a prerequisite program remain valid.

If an establishment is producing post-lethality exposed products and has failed to meet any of the requirements of 9 CFR 430, IPP should contact the District Office through supervisory channels. A NOIE may be issued if the establishment HACCP system and/or SSOP is inadequate due to failure to meet the 430 regulations.

ATTACHMENT 1: CONTROL REQUIREMENTS for *Listeria MONOCYTOGENES*

Requirements	→ Increasing Risk Levels and Frequency of FSTs Verification Testing →				
	ALTERNATIVE 1	ALTERNATIVE 2		ALTERNATIVE 3	
	Post-lethality Treatment AND Antimicrobial agent or Process	Post-lethality Treatment OR Antimicrobial agent or Process	Choice 1: Post-lethality Treatment	Choice 2: Antimicrobial Agent or Process	Sanitation and Testing Program
Validate effectiveness of post-lethality treatment (PLT). Must be included as a CCP in the establishment's HACCP Plan and should show at least a 1-log reduction in <i>Lm</i> prior to distribution of the product into commerce	X	X			
Document effectiveness of antimicrobial agent or process: Must be included as part of the establishment's HACCP, Sanitation SOP, or Pre-requisite Program and should demonstrate no more than 2-logs growth of <i>Lm</i> over the estimated shelf life.	X		X		
Sanitation Program Requirements			X	X	X
Testing food contact surfaces (FCS) in the post-lethality processing environment for <i>Lm</i> or an indicator organism.			X	X	X
State testing frequency.			X	X	X
Identify size and location of sites to be sampled.			X	X	X
Explain why testing frequency is sufficient to control <i>Lm</i> or an indicator organism.			X	X	X
Identify conditions for Hold-and-Test, when FCS (+) for <i>Lm</i> or an indicator organism.			X	X	X
Additional Sanitation Program Requirements					
Effective after 1 st FCS (+) for <i>Lm</i> or an indicator organism. Includes testing of targeted FCS as most likely source and additional testing of the surrounding area.					X
If follow-up testing yields 2 nd FCS (+), hold products that may be contaminated until problem is corrected as shown by FCS (-) in follow-up testing.					X
Hold and test product lots using a sampling plan that provides statistical confidence that the lots are not contaminated with <i>Lm</i> or an indicator organism. Release, rework or condemn products based on results. Document results and product disposition.					X
Establishments in all three alternatives must maintain sanitation in accordance with 9 CFR 416.	X	X	X	X	X

***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 for *L. monocytogenes*) 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

30 Sampling Ready-to-Eat (RTE) Product

FSIS's microbiological testing program is designed to **verify that the establishment's food safety system is effective**, and that FSIS performance standards and regulations are met. FSIS tests RTE products for pathogens because of the potential public health impact of a breakdown in the establishment's food safety system.

There are **6 general steps** in sampling RTE product:

1. Determine which product to sample and schedule the sample
2. Notify establishment management
3. Collect the sample
4. Document the sample
5. Pack and ship the sample and form
6. Respond to the results

RTEPROD_RAND: For this sample program, **IPP will randomly select any RTE product** produced at the time of collection, regardless of whether the product has been exposed post-lethality; and make every effort to randomly sample all the RTE products produced at the establishment by rotating through the products over time (i.e., through subsequent sample requests).

RTEPROD_RISK: For this sample program, IPP are to select a post-lethality-exposed product based on the highest risk level.

IPP will collect the sample from the current day's production after the establishment has applied all interventions *except* any microbiological testing intervention. If the establishment intends to test the product for *Lm* or *Salmonella*, IPP are not to wait for the establishment to receive the test results.

For both RTEPROD_RAND and RTEPROD_RISK samples, IPP are to collect a two-pound sample of product in an **intact package**.

31 HACCP System and Recall Verification

Introduction

The HACCP system, referenced in 9 CFR 417.4, is defined in 9 CFR 417.1 as “the HACCP plan in operation, including the HACCP plan itself”. The HACCP plan in operation includes the:

- Hazard analysis;
- HACCP plan;
- Supporting documentation including prerequisite programs used to make decisions in the hazard analysis; and
- HACCP records generated on an ongoing basis.

In using the regulatory thought process to determine if wholesome, unadulterated products are being produced, IPP are actually verifying the overall effectiveness of the establishment's HACCP system. Verifying whether individual product units are wholesome is less important than determining the overall effectiveness of the establishment's comprehensive HACCP system.

HACCP Regulatory Process

The diagram in module 13 (HACCP Regulatory Process) shows the HACCP regulatory process, which includes the following four components:

- **Inspection Methodology**
 - Performing HACCP inspection tasks
 - Verifying specific HACCP regulatory requirements by performing the HACCP inspection task
- **Decision-making (GAD)**
 - Gathering information, making observations, reviewing documentation, assessing the gathered information, arriving at a supportable compliance determination
- **Documentation**
 - Entering HACCP inspection task results (observations and determinations) in PHIS
 - Documenting noncompliance on a Noncompliance Record (NR)
 - Associating noncompliance from the same cause
- **Enforcement**
 - Following the Rules of Practice (ROP)
 - Providing the establishment with due process

FSIS Responsibilities

FSIS responsibilities for verifying an establishment's food safety system are outlined in FSIS Directives 5000.1 and 5000.6. IPP are responsible for understanding and properly performing in PHIS the HACCP inspection tasks described in these Directives.

INSPECTION METHODOLOGY

To verify that establishments are complying with 9 CFR Part 417, IPP perform two HACCP inspection tasks: The Hazard Analysis Verification (HAV) task and the HACCP Verification Task. The HAV Task directs IPP to review the establishment's hazard analysis, prerequisite programs, and other supporting documentation for one HACCP plan. The HACCP Verification Task focuses on verifying the implementation of the establishment's HACCP plans, prerequisite programs, and other supporting programs. Both of the HACCP verification tasks, which can be performed as a routine or directed task, has two verification components:

- Recordkeeping (RK)
- Review and Observation (RO)

IPP may use either component or a combination of the components to verify regulatory compliance.

DECISION-MAKING (GAD)

IPP should use the regulatory GAD (Gather, Assess, and Determine) thought process to perform the HACCP inspection tasks. IPP are to gather all available information to help them determine regulatory compliance. This may include:

- Reviewing hazard analyses, HACCP plans, prerequisite programs, supporting documentation, and ongoing monitoring records HACCP plans, SSOPs, prerequisite programs, and other supporting programs or procedures.
- Observing establishment employees performing or implementing HACCP, SSOP, or prerequisite program or other supporting program procedures, and occasionally taking measurements as specified in HACCP system documents.

After reviewing the gathered information, IPP are to assess the significance and meaning of information gathered by:

- Comparing the information gathered to HACCP regulatory requirements.
- Considering how each piece of information, either taken separately or with other findings, supports that the HACCP system is functioning as intended.
- Considering the information in the context of past findings to identify any patterns or trends (e.g., Is this an isolated or recurring problem? Are conditions getting worse? Is the establishment responding effectively and in a timely manner to problems?)

HACCP system noncompliance is a failure to meet any of the regulatory requirements outlined in 9 CFR Part 417. If a HACCP system noncompliance is identified, the establishment is

expected to take immediate and further planned actions to come back into compliance. Before IPP determine whether or not they should document the failure to meet the HACCP regulatory requirements as a noncompliance, they should consider the following four questions:

1. Did the establishment identify the failure to meet regulatory requirements or deviations from a critical limit?
2. If product is involved, has the establishment ensured product safety?
3. Has the establishment taken immediate and further planned actions to correct the failure to meet regulatory requirements, or has it taken corrective actions to address the deviation in accordance with 9 CFR 417.3?
4. Is a trend developing (i.e., has the establishment failed to carry out the actions in 1 through 3 above for similar situations)?

Note: When answering these questions, it may be necessary for the IPP to gather additional information (e.g., ongoing verification records).

There is no noncompliance if the answer to questions 1, 2, and 3 is “yes” and question 4 is “no” because the establishment identified and addressed the situation. IPP would verify and document compliance with the applicable regulations in PHIS because the establishment’s response included the further planned actions and preventive measures for the noncompliance or deviation. The ability to track developing trends would not be adversely affected by not issuing an NR.

If the answer to questions 1, 2, or 3 is “no” or question 4 is “yes,” a noncompliance exists. IPP would document the noncompliance in PHIS and generate an NR. IPP should discuss with their supervisor any concerns whether the information supports a particular compliance determination.

HACCP System Compliance

The purpose of the HACCP verification task is more than to just identify isolated instances of noncompliance. IPP must also consider what their positive, negative, or inconclusive findings indicate about the overall effectiveness of the establishment’s HACCP system. It is important that each piece of information be considered in the context of the HACCP system and the potential for product adulteration. The following questions will help IPP to consider the significance of each finding for the HACCP system:

- **Is this piece of information part of a pattern?** For example, is the establishment missing a measurement for a prerequisite program an isolated incident or has the establishment regularly failed to implement its prerequisite programs?
- **Is there other information to indicate that the HACCP system is working or is not working?** For example, if an establishment’s prerequisite program specifies product will be received with supplier certificates of analysis (COA) and periodically tested but the establishment failed to receive a COA for a particular product, how did they respond on whether or not to use the product?

- **Does the information seem to agree with the other available information about the food safety system?** For example, an establishment uses a prerequisite program to prevent a hazard in incoming products, and the records appear to show that a particular hazard is being prevented. However, the establishment's testing of finished product for the particular hazard finds positive results.
- **Do these results support each other or is there an apparent contradiction?** For example, an establishment that uses a prerequisite program to prevent *E. coli* O157:H7 in incoming beef has COAs and verification test results on incoming trim that indicate the hazard is not reasonably likely to occur, but the establishment gets a positive test result on a finished product lot. The finished product test result calls into question the effectiveness of the prerequisite program as means of supporting the decision that *E. coli* O157:H7 is not reasonably likely to occur.

Inadequate HACCP System Determination

By considering the preceding questions, IPP can determine whether the information supports a finding of HACCP system regulatory compliance:

- Has adulterated product been produced or shipped?
- Is the HACCP system effectively controlling the relevant food safety hazards?
- Has the establishment failed to meet one or more HACCP regulatory requirements?

If noncompliance is found, IPP need to determine if it indicates an inadequate HACCP system.

Depending on the problems identified, the establishment may need to reassess the hazard analysis and HACCP plan. For example, if an establishment has not identified *E. coli* O157:H7 as a food safety hazard reasonably likely to occur, tests outside the HACCP plan or SSOP, and gets a positive result, a reassessment of its HACCP plan and hazard analysis would then be required by 9 CFR 417.4(a)(3). The establishment must support the decisions made during the reassessment as specified in 417.5(a)(1) & (2).

If the establishment did not reassess its HACCP plan and hazard analysis as required by 417.3(b)(4) and 417.4(a)(3)(i) or does not have supporting documentation required by 417.5(a)(1) & (2), IPP cannot determine that the HACCP system meets the requirements of 417.2. In this case, and the HACCP system may be determined to be inadequate as described in 417.6. Consider the following questions to determine if there is an inadequate HACCP system:

Does the HACCP plan meet the regulatory requirements of Part 417?

If an establishment did not implement all or some of its HACCP plan or did not meet regulatory requirements, IPP would be unable to determine whether or not the establishment was producing unadulterated product in compliance with 9 CFR Part 417. For example, the HACCP system is inadequate if an establishment does not maintain any records associated with its HACCP plan, does not monitor critical limits at any CCP, or did not reassess or modify its HACCP plan when necessary.

2. Was adulterated product produced or shipped?

The HACCP system is inadequate if it did not prevent the production and distribution of adulterated product. For example, if an establishment failed to meet a critical limit for a CCP and did not take corrective actions per 9 CFR 417.3 but performed a pre-shipment review, the HACCP system is inadequate.

3. Is there a trend in establishment noncompliance?

Trends in the regulations cited on NRs are a key factor in determining if an establishment's HACCP system is inadequate. Two or more NRs citing the same regulations and recurring noncompliance descriptions addressing similar causes may be a trend that indicates the HACCP system is inadequate.

No specific number of incidents constitutes a trend because of the variabilities in processing environments and HACCP plans. IPP should closely review the noncompliance descriptions contained in Block 10 of the NR form and not rely solely on the number of linked NRs to indicate a possible trend in noncompliance. Careful analysis of the regulations cited and written descriptions of noncompliance is necessary when determining if a trend indicates that the HACCP system may be inadequate.

Action to Take If an Inadequate System Exists

After determining that an inadequate HACCP system exists, IPP would take action and notify the District Office via supervisory channels. If adulterated product was produced and shipped in commerce, IPP would take an immediate withholding action according to the Rules of Practice.

DOCUMENTATION

Completing a Noncompliance Record

When documenting noncompliance on an NR, identify each noncompliance. Be specific and thorough, and include the time and location. Explain that establishment management received notification, and state any regulatory control actions taken. Please consult FSIS Directive 5000.1 and the PHIS User Guide for further information about completing the NR.

Throughout this course, you have learned that noncompliance is documented when it is observed, and the same causes of noncompliance are associated when they are identified. Documenting and associating noncompliance is not only useful in identifying trends, it also enables the Agency to provide establishments with due process and to take enforcement action when necessary.

If IPP document multiple or recurring noncompliance, they could request (through their chain of command) that the DO issue a Notice of Intended Enforcement Action (NOIE) to the establishment per §500.4. A request for an NOIE should come as no surprise. In reaching this conclusion, IPP should have been discussing the noncompliance trend with the establishment during weekly meetings and keeping the FLS or IIC apprised of what was happening.

ENFORCEMENT

Rules of Practice

The Rules of Practice (ROP) in 9 CFR 500 provide establishments with due process. They also describe how and under what circumstances the Agency progresses with further enforcement actions. Enforcement action may be necessary to prevent adulterated product from being produced and shipped. In accordance with the Rules of Practice, enforcement action could be one of three types.

1. **Regulatory Control Action** - The retention of product, rejection of equipment or facilities, slowing or stopping of lines, or refusal to allow the processing of specifically identified product.
2. **Withholding Action** - The refusal to allow the marks of inspection to be applied to products. A withholding action may affect all product in the establishment or product produced by a particular process.
3. **Suspension** - An interruption in the assignment of program employees to all or part of an establishment.

Withholding actions affect whether the mark of inspection may be applied, while suspensions affect whether inspection verification activities will be performed.

Regulatory Control Actions

FSIS may take a regulatory control action (RCA) for insanitary conditions or practices, product adulteration or misbranding, conditions that preclude FSIS from determining that product is not adulterated or not misbranded, or inhumane handling or slaughtering of livestock.

An RCA allows IPP to prevent the movement of the affected product or use of the equipment or facility involved until the noncompliance has been corrected. IPP are not required to give the establishment prior notification that they are about to execute a RCA. IPP will take the RCA (e.g., retaining product, rejecting the equipment or room with a tag) and then complete an NR. RCAs should remain in effect until the establishment has brought itself back into regulatory compliance.

If there is SPS or SSOP noncompliance with direct product contamination or adulteration, IPP will verify that the establishment addressed the noncompliance by meeting the requirements of either Part 416 or Part 417, including corrective actions. An NR will be written, citing the appropriate SSOP or HACCP regulations. The establishment may need to re-evaluate the effectiveness of its procedures in its HACCP plan or SSOP and modify them if they are no longer effective in preventing contamination or adulteration of product.

If the direct product contamination poses a food safety hazard, IPP will verify that the establishment effectively implemented corrective actions that meet the requirements of §417.3(b). These corrective actions should include a reassessment to determine whether the unforeseen hazard should be incorporated into a HACCP plan. Regulatory control actions are not frequently used for HACCP regulatory noncompliance unless control is necessary to prevent shipment of contaminated or adulterated product.

Examples of common regulatory control actions related to slaughter include stopping a line or retaining a carcass as a result of a slaughter food safety standard finding.

Withholding Action - Without Prior Notice

It may be necessary for IPP to take immediate enforcement actions without giving the establishment prior notice to prevent an imminent threat to public health. For example, IPP would need to take an immediate withholding action if an establishment produced and shipped adulterated product. In this situation, the immediate withholding action would be taken and then the District Office and supervisor would be notified as soon as possible. Refer to the ROP module for additional information.

Withholding and Suspension Actions - With Prior Notification

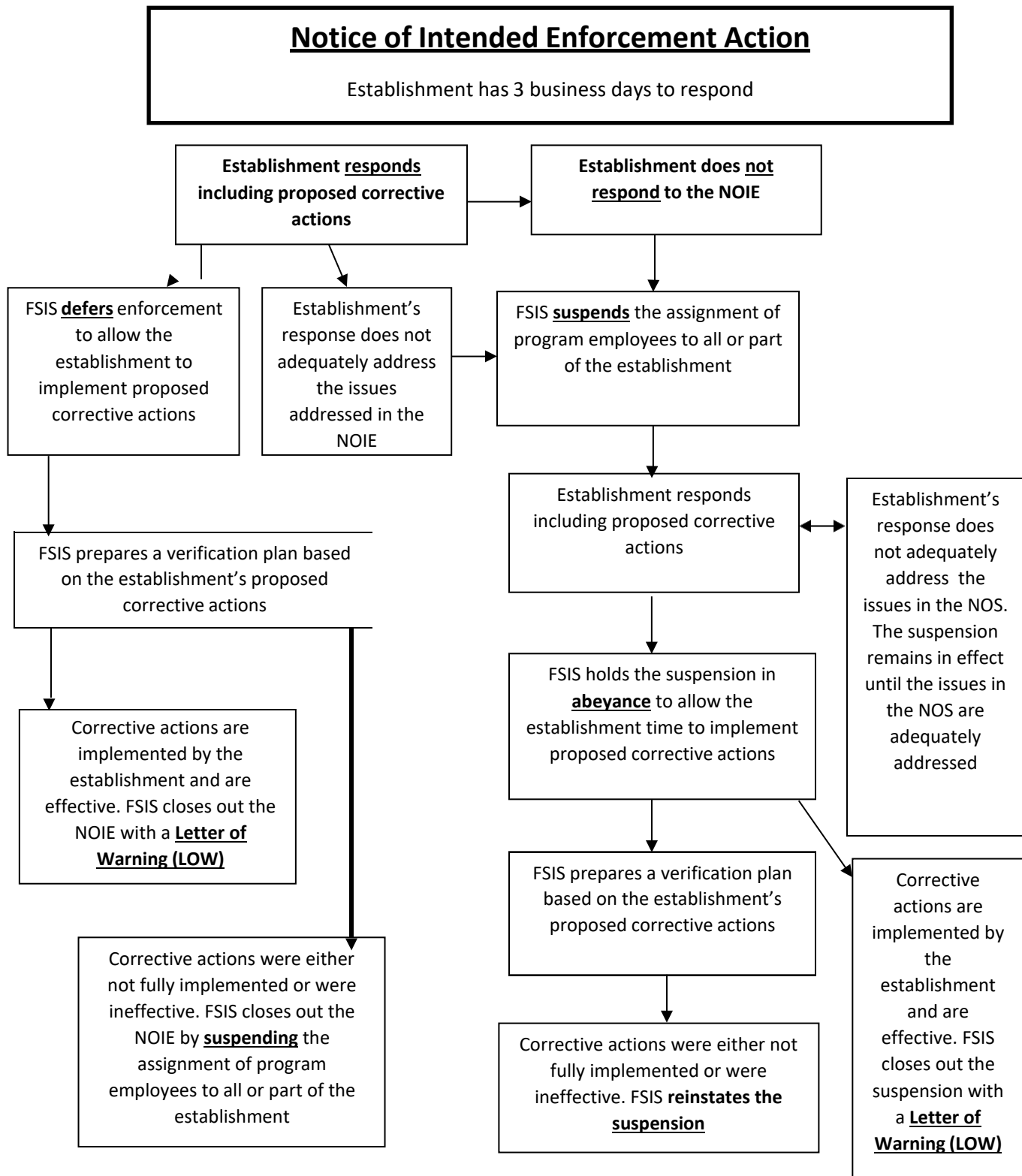
Some withholding and suspension actions require prior notification according to the ROP. The most common withholding or suspension actions related to HACCP noncompliance are those in which the HACCP system is inadequate due to multiple or recurring noncompliance. Withholding or suspending inspection for this cause requires prior notification to the establishment. The prior notice is in the form of a written Notice of Intended Enforcement Action (NOIE). Remember that a suspension may only be issued by a District Manager or higher FSIS official.

District Office Notification

After determining that an inadequate HACCP system may exist, IPP should notify the District Office and request that a Notice of Intended Enforcement (NOIE) be issued to the establishment. The DO will provide direction about any further actions that may need to be taken. The DO may assign an EIAO to evaluate the establishment's HACCP system.

District Office Determines Enforcement Action

After evaluating all of the facts of the case, the District Office will determine the appropriate enforcement action based upon the ROP.



Verification Plan

When FSIS defers an enforcement action or holds a suspension in abeyance, the establishment is allowed time to implement proposed corrective actions. A verification plan (VP) is developed by the EIAO with input from the in-plant inspection team, FLS, and DO. A VP captures all of the corrective actions the establishment stated they would do and provides a systematic means for FSIS to verify that an establishment is effectively implementing the proffered corrective measures.

A Verification Plan:

- Describes the verification activities to be performed by inspection personnel based on the establishment's corrective measures;
- Lists the procedures and frequency for each verification activity; and
- Identifies the regulatory citation for each verification activity.

IPP schedule and perform the directed verification activities identified in the VP, which typically lasts for 90 days and is updated every 30 days. On a weekly basis, the in-plant team reports the results of the activities conducted under the VP, via e-mail to the District Office. The in-plant inspection team has the flexibility to increase the frequency of the verification activities based on its findings. Any failure to meet the conditions of the proposed corrective measures would support FSIS imposing further enforcement actions.

RECALLS

Recalls are initiated when there is evidence of adulterated or misbranded product in commerce (e.g., a positive pathogen sample result is obtained for product the establishment already has shipped). FSIS Directive 8080.1, Rev. 7, "Recall of Meat and Poultry Products," details all verification requirements for recalls.

NOTE: Product is "in commerce" if it is out of the producing establishment's direct control and is in distribution (e.g., in a warehouse, distribution center, retail facility, restaurant, or other institution).

Establishment Recall Requirements

On May 8, 2012, FSIS published the final rule "Requirements for Official Establishments to Notify FSIS of Adulterated or Misbranded Product, Prepare and Maintain Written Recall Procedures, and Document Certain Hazard Analysis and Critical Control Points System Plan Reassessments" (77 FR 26929). The rule requires official establishments to:

1. Notify the local FSIS DO within 24 hours of learning or determining that an adulterated or misbranded meat or poultry product received by or originating from the official establishment has entered commerce (9 CFR 418.2). The 24-hour period begins once an establishment believes that a product in commerce is adulterated or misbranded under the FMIA or PPIA (e.g., final results of a laboratory analysis show that raw ground beef contains *E. coli* O157:H7 or product contains an allergen that is not declared on the product label).
2. Prepare and maintain written procedures for the recall of all meat and poultry products produced and shipped by the establishment (9 CFR 418.3).

3. Prepare written recall procedures as required by 9 CFR 418.3 before being granted Federal inspection (9 CFR 304.3(a) and 381.22(a)).

NOTE: There may be situations in which laboratory results are not available, but epidemiological evidence indicates there may be a probability of harm from consuming the product. Under these circumstances, official establishments should consider the strength of the epidemiological evidence to determine whether there is reason to believe that the product is adulterated or misbranded.

When notifying the DO that an adulterated or misbranded meat or poultry product was received by or originated from the official establishment, establishment officials should provide the type, amount, origin, and destination of the adulterated or misbranded product.

The DO is to notify the Recall Management and Technical Analysis Division (RMTAD) as soon as possible after notification. If establishments contact other FSIS personnel, those employees are to contact RMTAD promptly through supervisory channels.

The DO and possibly the RMTAD evaluate each situation on a case-by-case basis (see FSIS Directive 8080.1, Rev. 7, "Recall of Meat and Poultry Products"). The RMTAD coordinate any recall activities and are to be notified immediately if product has left the establishment's control. The RMTAD is also notified so that a press release can be issued and recall effectiveness checks can be performed.

More or less product may be determined to be "affected product" when all factors are considered (e.g., whether some or all products produced under the same or a substantially similar HACCP plan have been affected, what pathogens are involved, whether there have been any other incidents of contamination in the establishment associated with the pathogen, and whether there have been persistent and recurring noncompliance in the establishment).

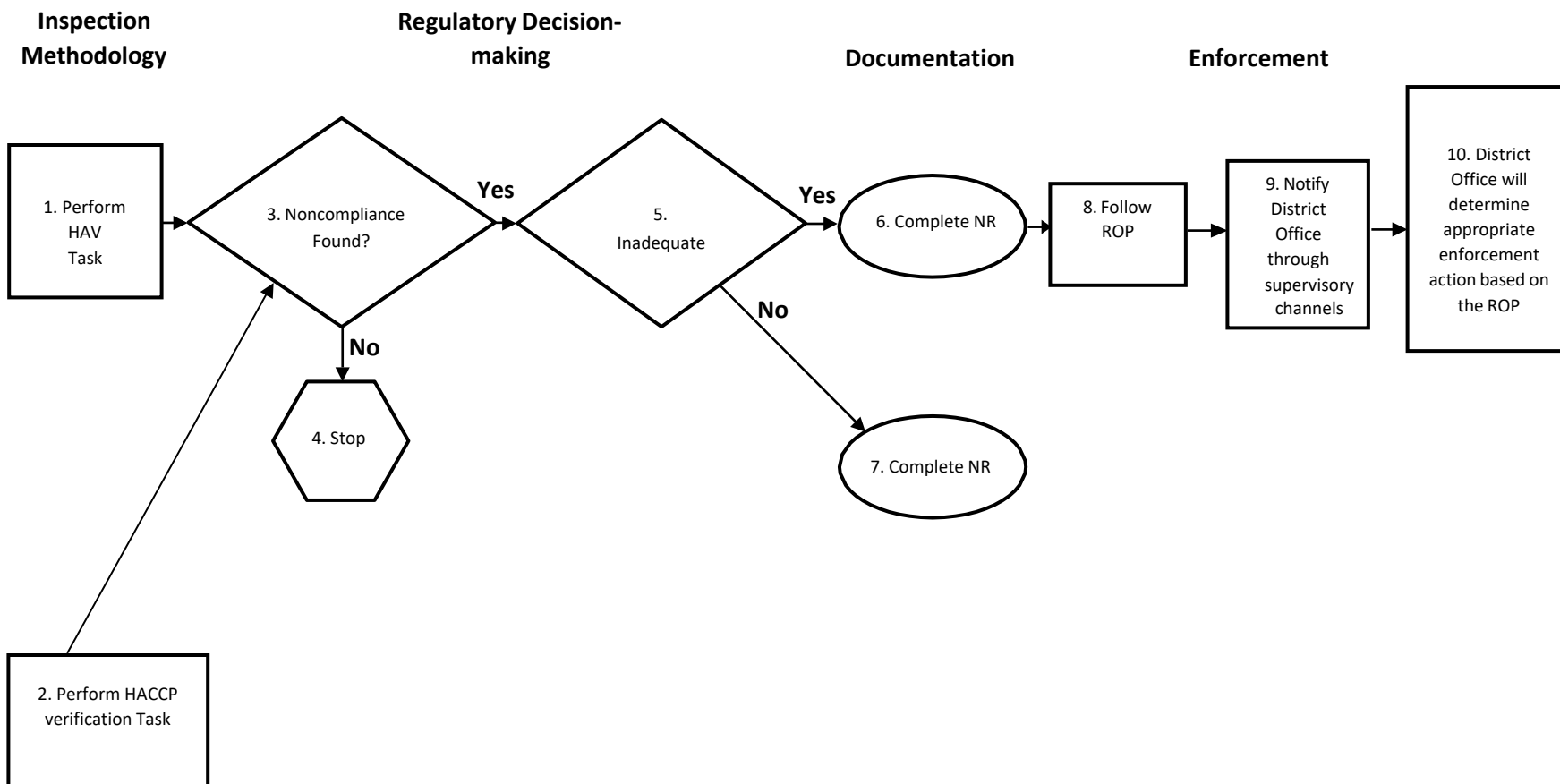
The establishment is expected to perform a voluntary recall of any unsafe product in commerce. If the establishment does not voluntarily recall product, the DO will coordinate actions to detain or seize affected product.

Meat and poultry establishments must have written procedures for the recall of any meat or poultry product produced and shipped by the official establishment. FSIS Directive 5000.8, Verifying Compliance with Requirements for Written Recall Procedures, dated 12/18/2013, outlines the details of how to verify the requirements of 9 CFR 418.3.

FSIS Verification

At least once a year, IPP are to perform a directed Other Inspection Requirements task to verify that establishments have written recall procedures. If IPP determine that the establishment has written recall procedures, they are to document in PHIS that they performed the task, and that the establishment complies with 9 CFR 418.3. If IPP determine that the establishment does not have written recall procedures, they are to document the noncompliance in PHIS on a noncompliance record, citing 9 CFR 418.3.

HACCP Regulatory Process



HACCP Systems and Recall Verification: Workshop

Refer to the module and to FSIS PHIS 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 you are to use when verifying regulatory compliance?

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. Could the conditions you observed lead to contaminated product?
- d. Is there a food safety hazard associated with the contamination you observed? Why or why not?
- e. You take official control of the blenders by placing a U.S. Rejected 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? Why or why not?

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? Why or why not?

- 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?
NOTE: Remember the 4 questions from the HACCP Regulatory Process presentation. If the system is working, you may not document some noncompliance.
- c. What regulations need to be considered?
- d. Is there a noncompliance? Why or why not?
- 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?
- g. Is there an indication of an inadequate system? Why or why not?
- h. 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 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		7a. NAME OF CCP(S) or PREREQUISITE PROGRAM DOCUMENTATION	
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			
<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:			
This document serves as written notification that your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.			
13. SIGNATURE OF PLANT MANAGEMENT		14. DATE	
15. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE		16. DATE	

32 Export Certification

The certifying official (CO) is any FSIS official who signs the completed export certificate, verifies the information on the export certificate comparing to the information on the signed export application and the country requirements in the FSIS Export Library. The CO may not be directly associated with the production or inspection of exported product. IPP perform a physical check of containers, labels and product. After checking the Export Library and the product, if you believe that products listed on the application are not eligible for export to the country listed on the application, first discuss your concerns with the exporter. Then, write a memorandum of interview (MOI) detailing your discussions and whether your concerns were addressed adequately. Give a copy of the completed MOI to the exporter and file a copy in the inspection file.

Means of stamping

The USDA stamp is an accountable item that must be held under control. The stamp is applied to the container. Establishments may also use computer-generated stickers. Stickers must be the exact size and impression as the export stamp, must be printed with authorization, must be based on assigned export number, and the establishment must identify number of stickers produced prior to applying. They must give all unused stickers to the inspector upon completion. Establishments may also perform direct inkjet printing of the export mark to the carton or container. You are to verify that the inkjet mark is equal in size and an exact impression of the FSIS rubber export stamp, they should not be printed on the cartons or containers until authorized by you, they should only be applied in the quantity needed for application to the consignment, and the establishment should notify you in advance of the quantity of cartons or containers to be printed. Applying the export mark to the cartons or to the containers should be done under the supervision of a designated, responsible plant employee.

A unique identifier (UI) is an alternate export mark that may be used for export consignments instead of using the standard USDA export mark that contains the export certificate number. The UI may be any combination of numbers or letters. IPP are not to certify export consignments marked with a UI unless the importing country allows containers to be marked with a UI. The applicant should link the UI to the corresponding export certificate by including the following statement in the remarks section of the export certificate or on FSIS Form 9060-5B (remarks continuation page); "The products covered by this certificate are marked with the Unique Identifier X#X#X#X#X#XX#X#."

Pre-stamping

Under some conditions, establishments can pre-stamp the product. Pre-stamping occurs when the establishment stamps the boxes and completes the export certificate when you are not present.

FSIS Form 9060-5 (Export Certificate of Wholesomeness) are accountable items and should be maintained secured. Keep a record of the issued and voided certificate numbers at the establishment. When completed, the CO reviews the certificate. The country requirements show if the importing country needs additional certificates, usually hyperlinked in the Export Library. Before signing the certificate, the CO should check the certificate for corrections, check for attachments and ensure that the exporting firm has lined-out any unused space. If IPP have questions about the information on the application, the export certificate, or other supplemental

documents, do not to sign the certificate until you seek clarification. If IPP still have concerns about signing the export certificate after reviewing the completed export documents and performing product re-inspection or export verification activities, discuss the concerns with establishment management, and document their concerns and discussion with establishment management in an MOI if the concerns cannot be resolved. Provide a copy of the MOI to establishment management and retain a copy for the government file. Document any regulatory non-compliances by issuing an NR and notify the supervisor of your concerns, the establishment's plan to address the concerns, and do not sign the export certificate.

A replacement certificate is to be issued for one of the following reasons:

- Original certificate did not contain required information;
- It contained incorrect information, importer, exporter, consignee, or consignor has changed, but is within the same country that appears on the certificate.

If the certificate is lost, IPP are not to issue a replacement certificate unless the exporter provides a letter of assurance to the CO stating the certificate will be returned if found, and the replacement certificate only restates the information contained on the original certificate; or, if the country of destination has changed. The exporter may split or consolidate a shipment with stamped pallet or conveyance. The Remarks section for a replacement certificate must contain the statement "This certificate replaces certificate number _____(original certificate number). The export mark covered by the certificate shows certificate number _____(new certificate number)."

Export Verification/Quality System Acceptance (EV/QSA)

Establishments which want to participate in this program first contact the Agricultural Marketing Service (AMS), who approves by auditing and notifies FSIS OPPD and IECPPDS, then notifies the appropriate DO. You will need to check the country requirements in the Export Library to verify the receiving country participates in EV/QSA. IPP check that the product codes are approved for export, check if the country requires a Statement of Verification (SOV) for the exported product, check that the applicant supplied a copy of the SOV with the completed export application, completed additional certificates, and completed export certification when presenting for IPP signature. Check if supporting documents such as lab sampling results are available. Not all countries will require all these steps. The exporting facility must obtain the SOV confirming that the EV/QSA program met the country requirements and that the products are eligible for export before the FSIS certifying official signs the completed export certificate. Establishments that need to obtain an SOV for export must contact AMS directly. If there is improper execution of the EV/QSA, notify AMS with the following information: establishment name, address, product type, product code, quantity of product, date of production, lot number, and shift, date and nature of observation, name of country for which product is intended, export certificate number, any other information to verify claim, and name of IPP documenting concerns. If any of the problems with the EV/QSA requirements are also regulatory non-compliances, take the appropriate enforcement actions and issue an NR.

Reimbursable export activities include: becoming familiar with requirements in the Export Library, conducting and documenting inspection or certification activities required by an EV/QSA program, conducting and documenting any other additional inspection or certification activities, reviewing foreign country label requirements, certifications requiring a PHV signature, and approval and issuance of all replacement export certificates.

Record export activities in PHIS. Each day IPP issue an export certificate at official establishments, they are to schedule and document **one** domestic Export Certification task in PHIS. Regardless of the number of export certificates issued or the number of IPP that issue certificates on a given day, IPP are only to record the task as performed **once each day, per shift** and not for each inspector or export certificate they issue.

33 Food Defense

Food defense is the protection of food products from intentional contamination or adulteration intended to cause public health harm or economic disruption.

The Significant Incident Preparedness & Response Staff (SIPRS) is responsible for managing all food defense activities for the Agency. SIPRS works with government agencies at all levels, industry, and other organizations to develop and implement strategies to prevent, protect against, mitigate, respond to, and recover from intentional contamination of the food supply.

FOOD DEFENSE TERMINOLOGY

Food Security – When all people at all times have both physical and economic access to enough food for an active, healthy life. Food security includes both physical and economic access to food that meets people's dietary needs and food preferences. Therefore, the concept of food security certainly includes but encompasses much more than the idea of food defense.

Food Safety – Means guarding against unintentional contamination of food. HACCP plans and Sanitation SOPs, which are developed based on what can be predicted to happen if we do not put safety measures at critical points, are used to guard against unintentional contamination.

Food Defense – is the protection of food products from intentional contamination or adulteration intended to cause public health harm or economic disruption. Food Defense is an integral part of FSIS's mission in protecting public health. The mission of the FSIS Food Defense Program is to protect the U.S. food supply from dynamic and evolving threats.

Food Defense Practices – Policies, procedures, or countermeasures to mitigate vulnerability to intentional contamination.

Critical Infrastructure – The Patriot Act of 2001 defined critical infrastructure as systems and assets, whether physical or virtual, so vital to the United States that the incapacity or destruction of such systems and assets would have a debilitating impact on security, national economic security, national public health or safety, or any combination of those matters. The Food and Agriculture Sector is one of 16 critical infrastructures identified by the Patriot Act.

Supply Chain – Continuous process, including every step involved in food production and food reaching the consumer; often referred to as “farm-to-table” or “farm-to-fork.”

FOOD DEFENSE VULNERABILITIES AND FOOD DEFENSE PRACTICES

A **vulnerability** can be any part of the food production or storage system where a protective measure should be implemented to protect a product from intentional adulteration, but such a measure is found to be missing or not in place.

Food defense vulnerabilities are weaknesses within the food production process that make it easy to intentionally contaminate product.

An establishment can put **food defense practices** (also called mitigation strategies) into place to reduce the likelihood that intentional contamination will occur. **Food defense is not a one-size-fits-all approach!** Food defense practices that are implemented to protect products within a large establishment may not be effective or needed in a small or very small establishment. This should be considered when inspection program personnel (IPP) conduct their food defense activities.

FOOD DEFENSE IN FSIS-REGULATED ESTABLISHMENTS

Food defense is voluntary for FSIS-regulated establishments.

A **functional food defense plan** is an approach to identify and mitigate vulnerabilities; it can help an establishment prevent, protect against, respond to, and recover from an intentional contamination incident. A food defense plan is functional when it meets all four of the following criteria:

1. Developed – The plan is documented and signed.
2. Implemented – Food defense practices identified in the plan are actually implemented.
3. Tested – Food defense measures are monitored and validated to ensure they are working.
4. Reviewed and maintained – The plan is reviewed at least annually and revised as needed.

Note: An establishment must be **implementing** the elements of its food defense plan in order for FSIS to consider it “functional.”

IPP are responsible for maintaining the functional food defense plan status for an establishment in the Establishment Profile in PHIS. This status should be updated per the frequency identified in Directive 5300.1, *Managing the Establishment Profile in the Public Health Information System*, or when IPP become aware of a change in the establishment’s functional food defense plan status.

NATIONAL TERRORISM ADVISORY SYSTEM

The **National Terrorism Advisory System (NTAS)** is a system managed by the Department of Homeland Security (DHS) to communicate information about terrorist threats by providing information to the American public. Under the NTAS system, DHS coordinates with other federal entities to issue formal alerts when the Federal government receives information about a specific or credible terrorist threat.

If there is specific and credible information about a terrorist threat against the U.S., DHS will share the NTAS alert with the American public when circumstances are justified. These alerts include a clear statement that there is an “elevated threat” or “imminent threat.”

- **Elevated threat:** If there is credible threat information, but only general information about timing and target such that it is reasonable to recommend implementation of protective measures to thwart or mitigate against an attack.
- **Imminent:** There is a belief that the threat is credible, specific, and impending in the very near term.

The NTAS alerts are based on the nature of the threat including the geographic region, mode of transportation, or critical infrastructure potentially affected by the threat. The alerts also provide

a concise summary of the potential threat, information about actions being taken to protect public safety, and recommended steps that individuals, communities, businesses, and governments can take.

Performing Food Defense Tasks in PHIS

IPP in meat and poultry establishments are to perform the Food Defense task as assigned in PHIS. PHIS will automatically generate one routine Food Defense task per quarter to the establishment Task List. This task has a priority 3 in the establishment Task List, including a start/end date window of three months. Only one questionnaire is to be completed per establishment. The task is to only be performed on one shift in multi-shift establishments. The supervisor should determine which shift performs the task. The shift that does not complete the task should mark the task as not performed with a justification of 'Task assigned to another inspector.'

IPP perform the Food Defense task to identify vulnerabilities within establishments that may lead to intentional contamination of FSIS-regulated products.

In the case of a NTAS alert identifying an elevated or imminent threat to food or agriculture, the inspector-in-charge (IIC) will receive specific instructions through supervisory channels on other measures to take. If additional Food Defense tasks are necessary, IPP will schedule them as directed task in PHIS. Other measures may include sampling of specific products and deploying inspectors to establishments producing the products to ensure that FSIS has an on-site presence.

SUMMARY

Defending the food supply against intentional contamination is a critical function. IPP, both in and outside of establishments, serve as the Agency's eyes and ears to help identify vulnerabilities that may lead to intentional contamination. IPP are responsible for three activities related to food defense:

- Updating the functional food defense plan status in the PHIS establishment profile and ensuring it is accurate;
- Performing food defense tasks;
- Submitting a food defense MOI when food defense vulnerability is observed and discuss with establishment management.

Implementation of Food Defense tasks serves to protect the public, which is essential to our mission, and ensures the security of our food, a vital component of homeland security.

Report any suspicious activities in establishments to your District Manager through supervisory channels or call the **FSIS 24-hour emergency hotline** at **1-866-395-9761**.

34 Non-Food Safety Consumer Protection (NFSCP)

The Non-Food Safety Consumer Protection (NFSCP) requirements are verified by **Other Consumer Protection** tasks to determine that establishments are complying with regulatory requirements designed to protect the consumer in ways other than ensuring food safety.

FSIS Directive 7000.1 provides general instructions for how IPP are to perform specific verification tasks related to non-food safety requirements. The PHIS system will assign other consumer protection tasks to establishment task lists based on the product information recorded in the establishment profile. As with other tasks, IPP are to schedule the tasks on the dates most appropriate for performing the particular verification task.

Perform the appropriate verification procedures by:

- Observing establishment product formulation;
- Verifying the accuracy of labeling;
- Observing processing procedures;
- Reviewing establishment records;
- Examining product;
- Checking product identification, condition and temperature;
- Performing a variety of other in-plant measurements, testing and calculations; or
- Observing slaughter practices.

PHIS - Introduction to the Public Health Information System

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 exportcertification 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

References

1. FSIS Directive 5300.1, Rev. 1, *Managing the Establishment Profile in the Public Health Information System (PHIS)*, Dated 10-19-16
2. PHIS Quick Reference Guide

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
- 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	
<u>Month</u>	<u>Profile Information Focus Area</u>
January	Establishment Contacts
February	HACCP Systems Information for Raw-Intact product categories
March	HACCP Systems Information for Raw-Non-Intact product categories
April	HACCP Systems Information for Thermally Processed-Commercially Sterile, Not Heat Treated-Shelf Stable, and Heat Treated Shelf Stable product categories
May	HACCP Systems Information 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	General Profile Information
July	Product Information for Raw-Intact product categories
August	Product Information for Raw-Non-Intact product categories
September	Product Information for Thermally Processed-Commercially Sterile, Not Heat Treated-Shelf Stable, and Heat Treated Shelf Stable product categories
October	Product Information 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	Slaughter Information
December	General Profile Information

- 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.

PHIS 2 – Task List / Task Calendar

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 that 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.

There are two types of tasks: 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 inspection 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 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 of 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 Work Day, 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	Not Open Task Color Blue on the calendar	<ul style="list-style-type: none"> Task has been added to inspector's task calendar Verification component option has NOT been selected in PHIS
	Open (in-progress) Task Color Yellow on the calendar	<ul style="list-style-type: none"> Verification component option has been selected in PHIS IPP have begun to enter results

	Status in PHIS	Definition
Inspection Task	Completed Task Color Green on the calendar	<ul style="list-style-type: none"> All verification has been performed and all 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
	Not Performed Task Color Red on the calendar "if scheduled"	<ul style="list-style-type: none"> 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

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.

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 time-saving 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.

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.

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.

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

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 gender, 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.

PHIS 4 - Sample Management

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.

References:

FSIS Directive 13,000.2, Rev. 1, *Performing Sampling Tasks in Official Establishments using the Public Health Information System* 7-25-2014

FSIS Directive 10,800.1, *Procedures for Residue Sampling, Testing and Other Responsibilities for the National Residue Program* 7/12/2007

PHIS Users Guide on Inside FSIS Intranet PHIS page

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 samples.

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 Rev. 1).
- 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.

PHIS 5 - Animal Disposition Reporting

References

PHIS Users Guide - FSIS Intranet PHIS Resources
 FSIS PHIS Directive 6100.1, *Ante-Mortem Livestock Inspection*
 FSIS PHIS Directive 6100.2, *Post-Mortem Livestock Inspection*
 FSIS PHIS Directive 6100.3, *Ante-Mortem and Post-Mortem Poultry Inspection*
 FSIS PHIS Directive 6170.1, *Ratite Ante-Mortem and Post-Mortem Inspection*
 FSIS Directive 10,800.1, *Procedures for Residue Sampling, Testing and Other Responsibilities for the National Residue Program 7/12/2007*

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 (KIST™) 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.

PHIS 6 - Perform Hazard Analysis Verification (HAV) Task with 2 Noncompliances

Scenario #1

An IPP is conducting a HAV task in a portion control establishment that produces ground beef for HRI use. While reviewing the flow chart he notes the establishment has **no returned product step in its flow chart**, but recalls observing several cases of ground beef being offloaded from a food service truck the day before. At that time, a shipping supervisor had stated **a restaurant was returning these cases of ground beef**. The IPP determines that the establishment's flow chart is not in compliance with 417.2(a)(2).

Scenario # 2

An IPP is reviewing the HACCP plan for a large beef slaughter establishment and finds that it has a CCP for *E. coli* O157:H7 at the steam pasteurization step prior to chilling. The verification procedures specify that maintenance will calibrate the **temperature recording device once a week prior to operations**. She asks the establishment for documentation supporting this frequency of calibrating the temperature recording device, and they produce some technical documents from the manufacturer that states the **temperature recording device should be calibrated daily**. The establishment has no documentation supporting the verification procedure and frequency; therefore, it is not in compliance with 417.5(a)(2).

Inspection Methods (IM) Course On-the-Job Training (OJT) PHIS Checklist

IM Participant Name: _____

IM Session Number: _____

Supervisor Name: _____

District: _____

The objective of this OJT Checklist is to verify that the IM participant practiced navigating through PHIS pages, tabs, tasks entries and applied what they learned during training.

Supervisors should coach the IM participant in the following PHIS tasks. Give them the opportunity to shadow an experienced employee while navigating PHIS pages and entering data into PHIS tasks.

The time dedicated for each task can be adjusted according to staffing needs and supervisor decisions. The Center for Learning (CFL) recommends completing the checklist within the first week after finishing the IM training. PHV participants can complete this during Mentoring. Certification for CSI participants must be provided to CFL within 3 weeks of completing the IM Course in order to achieve successful completion.

Upon completion of the OJT, the IM participant should keep the OJT form for their record. The supervisor should certify completion via sending an email to FSISAgLearn@usda.gov stating that the student has completed the OJT. The email should include the student's name, the class number, the name of the supervisor who mentored the student during the OJT, and the date of completion.

Tasks	Estimated Time in PHIS	Date	Participant Signature	Supervisor Signature**
Update Establishment Profile task*	60 minutes			
SPS task*	60 minutes			
SSOP task*	60 minutes			
HACCP Verification task*	60 minutes			
Create an Inspection Note, prepare an Agenda, and document an Establishment Weekly Meeting on MOI	60 minutes			
Zero Tolerance task*	60 minutes			
NR documentation in PHIS, any task (If no noncompliance found during OJT, provide an alternate noncompliance scenario to document.)	60 minutes			
Schedule any sampling task and enter sample information in PHIS questionnaire	60 minutes			
Document data in Animal Disposition Reporting (ADR)	60 minutes			
Humane Handling or Poultry Good Commercial Practices task* (Include documenting HATS verification time)	60 minutes			

*Includes scheduling task from the task list to the task calendar, and rescheduling one task

Comments**: (explain any task substitutions or items not practical to complete)

Resources: IM Student Materials, PHIS Quick Reference Guide, and IPP Help button

RULES OF PRACTICE ROP	HAZARD ANALYSIS CRITICAL CONTROL POINT HACCP
500.1 Definitions 500.2 Regulatory control action 500.3 Withholding/Suspension WITHOUT prior notification 500.5(a) Notification 500.4 Withholding/Suspension WITH prior notification 500.5(b) Notification 500.6 Withdrawal 500.7 Refusal to grant inspection 500.8 Rescinding labels, marks	417.1 Definitions 417.2 Hazard Analysis and HACCP Plan <ul style="list-style-type: none"> (a) Hazard analysis <ul style="list-style-type: none"> (1) Determine RLTO hazards, identify preventive measures (2) Flow chart (3) Expected food safety hazards (b) HACCP plan <ul style="list-style-type: none"> (1) develop and implement for each process/product, if hazard RLTO (2) requirements for single HACCP Plan (3) requirements for thermally processed (c) Contents of HACCP Plan <ul style="list-style-type: none"> (1) List of food safety hazards (2) List of CCP's (3) List of critical limits (4) List of procedures & frequency (5) Corrective actions (6) Record keeping system (7) List of verification procedures/frequency (d) Signing and dating HACCP plan <ul style="list-style-type: none"> (1) Signed and dated by responsible person (2) Sign and date frequency (e) Failure to Develop and Implement HACCP Plan
SANITATION PERFORMANCE STANDARDS SPS 416.1 General rules 416.2 Establishment grounds and facilities <ul style="list-style-type: none"> (a) Grounds and pest control (b) Construction (c) Light (d) Ventilation (e) Plumbing (f) Sewage disposal (g) Water supply and water, ice, and solution reuse (h) Dressing rooms, lavatories & toilets 416.3 Equipment and utensils <ul style="list-style-type: none"> (a) constructed to facilitate cleaning (b) accessibility for inspection (c) receptacles for storing inedible material 416.4 Sanitary operations <ul style="list-style-type: none"> (a) food contact surface, cleaning & sanitizing (b) non-food contact surface, cleaning & sanitizing (c) cleaning compounds and sanitizers (d) product protected 416.5 Employee Hygiene <ul style="list-style-type: none"> (a) Cleanliness (b) Clothing (c) Disease control 416.6 Tagging equipment, rooms or compartments	417.3 Corrective Actions <ul style="list-style-type: none"> (a) Describe action after deviation <ul style="list-style-type: none"> (1) Cause is identified & eliminated (2) CCP is under control (3) Prevent recurrence (4) No adulterated product shipped (b) Unforeseen hazard <ul style="list-style-type: none"> (1) Segregate, hold product (2) Perform review (3) Actions to ensure product not shipped (4) Reassessment of HACCP plan (c) Document corrective actions 417.4 Validation, Verification, Reassessment <ul style="list-style-type: none"> (a) Every establishment shall validate HACCP plan/s <ul style="list-style-type: none"> (1) Initial validation (2) Ongoing verification to include, (i) calibration (ii) direct observation (iii) review of records (3) Reassessment, (i) at least annually or when change is made, (ii) record reassessment (b) Reassessment of hazard analysis
SANITATION STANDARD OPERATING PROCEDURES SSOP 416.11 General Information 416.12 Development of SSOP's <ul style="list-style-type: none"> (a) describe all procedures (b) signed and dated (c) procedures for pre-op (d) frequency of procedures & responsible individual 416.13 Implementation of SSOP's <ul style="list-style-type: none"> (a) conduct pre-op (b) conduct all other procedures (c) monitors implementation of SSOP procedures 416.14 Maintenance of SSOP's routinely evaluate 416.15 Corrective Actions <ul style="list-style-type: none"> (a) conduct corrective actions, including (b) disposition of contaminated product restore sanitary conditions prevent recurrence 416.16 Record Requirements <ul style="list-style-type: none"> (a) daily records required, responsible individual, initialed and dated (b) records on computers (c) location and retention of records maintained 416.17 Agency Verification review SSOP's, daily records, direct observation of SSOP procedures & direct observation of testing	417.5 Records <ul style="list-style-type: none"> (a) Establishment shall maintain <ul style="list-style-type: none"> (1) Written hazard analysis (2) Written HACCP plan (3) Records of CCP's, temps., corrective actions (b) Made at time event occurs (c) Pre-shipment review (d) Records on computer (e) Record retention (f) Official review 417.6 Inadequate HACCP System <ul style="list-style-type: none"> (a) Plan doesn't meet requirements (b) HACCP tasks not accomplished (c) Fails to take corrective actions (d) No records (e) Adulterated product shipped 417.7 Training <ul style="list-style-type: none"> (a) Trained individual develops/reassesses (b) Course of instruction 417.8 Agency Verification <ul style="list-style-type: none"> (a) Review HACCP plan/s (b) Review CCP records (c) Review adequacy of corrective actions (d) Review critical limits (e) Review other records pertaining to HACCP plan/s (f) Direct observation of CCP (g) Sample collection (h) On-site observation & records review
RECALL 418.2 Notification 418.3 Preparation and maintenance of written procedures 418.4 Records	

Additional Resources

Acronym Listing

AA	Assistant Administrator
ACS	Acidified Calcium Sulfate
ADR	Animal Disposition Reporting
AER	Administrative Enforcement Report
AM	Antemortem Inspection
AMA	Antimicrobial Agent
AMAP	Antimicrobial Agents and Processes
AMP	Antimicrobial Process
AMS	Agricultural Marketing Service
AOAC	Association of Official Analytical Chemists (Now called AOAC International)
APC	Aerobic Plant Count
APHIS	Animal and Plant Health Inspection Service
AMR	Advanced Meat Recovery
ASC	Acidified Sodium Chlorite
ATP	Adenosine Triphosphate
a _w	Water Activity
BITES	Biological Information Transfer Email System
BSE	Bovine Spongiform Encephalopathy
CA	Corrective Actions
CCMS	Consumer Complaint Monitoring System
CCP	Critical Control Point
CDC	Centers for Disease Control and Prevention
CFL	Center for Learning
CFR	Code of Federal Regulations
CFU	Colony Forming Units
CIP	Clean in Place
CL	Critical Limit
COA	Certificate of Analysis
CPS	Coagulase Positive Staph
CSI	Consumer Safety Inspector
CSO	Consumer Safety Officer
DM	District Manager
DDM	Deputy District Manager
DCS	District Case Specialist
DJE	Dual Jurisdiction Establishment
DO	District Office
DRO	District Recall Officer
DVMS	District Veterinary Medical Specialist
EARO	Executive Associate for Regulatory Operations
EIAO	Enforcement Investigations and Analysis Officer
EMC	Emergency Management Committee
EPA	Environmental Protection Agency
EPIA	Egg Products Inspection Act

FCS	Food Contact Surface
FDA	Food and Drug Administration
FDIB	Foodborne Disease Investigation Branch
FFDCA	Federal Food, Drug, and Cosmetic Act
FI	Food Inspector
FIFRA	Federal Insecticide Fungicide and Rodenticide Act
FLS	Frontline Supervisor
FMIA	Federal Meat Inspection Act
FNS	Food and Nutrition Service
FO	Field Operations
FOIA	Freedom of Information Act
FPS	Finished Product Standard
FR	Federal Register
FSA	Food Safety Assessment
FSIS	Food Safety and Inspection Service
GAD	Gather Assess Determine
GMP	Good Manufacturing Practice
GRAS	Generally Recognized as Safe
HA	Hazard Analysis
HACCP	Hazard Analysis and Critical Control Point
HATS	Humane Activities Tracking System
HAV	Hazard Analysis Verification
HCG	Hazards Control Guide
HEP	High Event Period (with regard to STECs)
HH	Humane Handling
HIMP	HACCP-based Inspection Models Project
HMSA	Humane Methods of Slaughter Act
HPP	High Pressure Processing
HRI	Hotels, Restaurants, and Institutions
HUS	Hemolytic Uremic Syndrome
ICMSF	International Commission on the Microbiological Specification for Foods
IIC	Inspector in Charge
IKE	Interactive Knowledge Exchange
IPP	Inspection Program Personnel
IVT	Intensified Verification Testing
KIS	Kidney Inhibition Swab
LIMS	Laboratory Information Management System Direct
Lm	<i>Listeria monocytogenes</i>
LOG	Letter of Guarantee
LOI	Letter of Information
LOW	Letter of Warning
LPDS	Labeling and Program Delivery Staff
LTD	Less Than Daily
MOI	Memorandum of Interview
MOU	Memorandum of Understanding
MPCM	Microbial Pathogen Computer Modeling
MPN	Most Probable Number
MPR	Moisture Protein Ratio

NACMCF	National Advisory Committee on the Microbiological Criteria for Foods
NACMPI	National Advisory Committee on Meat and Poultry Inspection
NFCS	Non Food Contact Surface
NFSCP	Non-Food Safety Consumer Protection
NIST	National Institute of Standards and Technology
NOIE	Notice of Intended Enforcement
NOL	No Objection Letter
NOS	Notice of Suspension
NPDW	National Primary Drinking Water
NR	Noncompliance Record
NRLTO	Not Reasonably Likely to Occur
NRTE	Not Ready to Eat
OCP	Other Consumer Protection
OFO	Office of Field Operations
OIG	Office of Inspector General
OM	Office of Management
OEED	Office of Employee Experience and Development
OPACE	Office of Public Affairs and Consumer Education
OPARM	Office of Planning, Analysis, and Risk Management
OIEA	Office of Investigation, Enforcement, and Audit
OPHS	Office of Public Health Science
OPPD	Office of Policy and Program Development
OSHA	Occupational Safety and Health Administration/Act
PDS	Policy Development Staff
PFGE	Pulsed Field Gel Electrophoresis
PHV	Public Health Veterinarian
PHIS	Public Health Information System
PLE	Post Lethality Exposed
PLT	Post Lethality Treatment
PM	Postmortem Inspection
PMP	Pathogen Modeling Program
PMP	Pest Management Program
PPIA	Poultry Products Inspection Act
PPM	Parts Per Million
PR	Pathogen Reduction
PRP	Pre-Requisite Program
QA	Quality Assurance
QC	Quality Control
QRG	Quick Reference Guide
RCA	Regulatory Control Action
RD	Regional Director (OIEA)
REC	Recall Effectiveness Check
RMIS	Risk Management and Innovation Staff
RLm	Risk Based <i>Listeria monocytogenes</i> Testing
RLTO	Reasonably Likely to Occur
RMA	Resource Management Analyst
RMS	Resource Management Specialist
RMTAD	Recall Management and Technical Analysis Division

ROP	Rules of Practice
RTE	Ready to Eat
RTE/SS	Ready to Eat/Shelf Stable
SCSI	Supervisory Consumer Safety Inspector
SEIAO	Supervisory Enforcement Investigations and Analysis Officer
SIP	<i>Salmonella</i> Initiative Program
SOP	Standard Operating Procedures
SPC	Statistical Process Control or Standard Plate Count
SPHV	Supervisory Public Health Veterinarian
SPS	Sanitation Performance Standards
SRM	Specified Risk Materials
SSOP	Sanitation Standard Operating Procedures
STEC	Shiga toxin-producing <i>E. coli</i>
STEPS	System Tracking <i>E. coli</i> Positive Suppliers
SVMO	Supervisory Veterinary Medical Officer
TA	Talmadge-Aiken Act
TCOE	Training as a Condition of Employment
TDT	Thermal Death Time
TPC	Total Plate Count
TSP	Trisodium Phosphate
TT	Time Temperature
USC	United States Code
USDA	United States Department of Agriculture
vCJD	Variant Creutzfeldt-Jakob disease
VMO	Veterinary Medical Officer
VP	Verification Plan

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Handwritten Note-taking Pages 2 of 8

Handwritten Note-taking Pages 3 of 8

Handwritten Note-taking Pages 4 of 8

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