Food Safety and Inspection Service

U.S. DEPARTMENT OF AGRICULTURE

Inspection Methods Hybrid (IMH)

Class Workbook
Part 1 of 3

Revised January 2025

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

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USDA

United States Department of Agriculture

Food Safety and Inspection Service

1400 Independence Avenue, SW.
Washington, D.C. 20250

TO: Field Operations Attending Training

FROM: Soumaya Tohamy, Ph.D
Assistant Administrator
Office of Employee Experience and Development

SUBJECT: Food Safety and Inspection Service (FSIS) Training Classes

Congratulations on being selected to attend FSIS training. This is an opportunity to gain significant knowledge about the skills and abilities needed to perform your job duties.

Please use these opportunities to learn as much as you can from the training and to actively participate by asking questions and engaging in class activities.

You represent FSIS and your conduct must reflect a high degree of professionalism. Improper conduct and unprofessional behavior will not be tolerated. Individuals exhibiting unprofessional behavior may be removed from class and returned to their duty station.

Although FSIS does not have a formal dress code, the goal is to project a positive professional image at all times. Shorts, flip flops, short skirts, crop tops, tank tops, clothing with a message that may be offensive to others, are not neat, clean, and free from holes or tears, are examples of inappropriate clothing in an FSIS worksite.

Finally, your feedback is very important. Please take the time to complete the evaluation forms and let us know what worked well and what could be improved.

Thank you for maintaining a positive and professional learning environment.

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How to use the IMH workbook

The IMH class workbook is printed into **three parts**. **Part one** and **two** contain a summary of the topics that will be discussed in class. **Part three** contains all corresponding workshops, scenario modules, and Public Health Information System (PHIS) contents.

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WELCOME TO THE INSPECTION METHODS HYBRID TRAINING COURSE

Class hours:

- **In-person**: Class hours are from 7:30am to 4:30pm local time zone, lunch break (1 hour) at approximately 11:30am to 12:30pm local time.

- **Online**: 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, call 1-833-ASK-OEED (1-833-275-6333) during class hours, or email CFLHelpDesk@usda.gov .

Joining online class through FSIS Training Site:
You may join the MS Teams webinar up to 15 minutes prior to the start of the class using the corresponding class link posted on the training website https://fsistraining.fsis.usda.gov/ . To login to the training website, your District Office or State program provides you the username and password. Connect to the training website daily to access the class information, slides, notes, workshops, and other references. To listen to the presentations, we recommend that you use the computer audio. However, if you are unable to listen to the computer audio, you can join the audio by phone.

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. To ask a question verbally, use the raise hand button, and a trainer will allow you to unmute to speak. Alternatively, you can type your questions in the chat.

Attendance:
Attendance will be taken each day, multiple times a day. Students are expected to be present, seated, and ready to begin class at the announced start times.

*Note: Trainers do not approve or disapprove leave requests. If you are unable to attend class, please notify your supervisor and have them to contact trainers via email. Unexcused absences will be followed up by the trainers with the District or State offices to inquire the reason for your absence which will alert your supervisor that you are Absent Without Leave (AWOL).

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 FSIS Directive 4338.1 for details).
- Test will be proctored at the testing location.
- Online test is taken using the training laptop provided to you or using your issued government laptop.
- 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 this Student Workbook is allowed during the test. Handwritten notes and highlights are allowed on the provided pages.
- Additional pages, sticky notes, paper clips, or anything else added to the workbook is **NOT** allowed during online testing. The exception is for small section tabs.
- Paper, pens, pencils, or writing devices are **NOT** allowed in the testing area.
- Talking or interacting with other participants is **NOT** 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 online link to complete the online registration form.

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

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

IM Electronic Notebook:

Each course module has a set of detailed notes. You can download the electronic notebook files (located in IM Resources) to your computer at: https://fsistraining.fsis.usda.gov/mod/folder/view.php?id=522 . Or on the FSIS website under Inspection Methods Course Materials at: https://www.fsis.usda.gov/inspection/inspection-training-videos/inspection-mission-training .

These electronic notebook files are more detailed than what is available in this condensed workbook. They provide more information, examples, and references and can be helpful during training.

Online Learning Tips:

- Understand online learning practices and expectations
- Eliminate distractions
- Create a regular study space, stay organized
- Actively participate, join discussions, ask questions
- Stay motivated, keep yourself accountable
- Treat this 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

Approximate Daily Agenda Outline:

In- person:

Time (Local Time)	Activity

7:30am - 8:00am	Morning briefing
8:30am - 11:30am	Class instruction (2 10-min breaks)
11:30am - 12:30pm	Lunch break
12:30pm - 4:00pm	Class instruction (2 10-min breaks)
4:00pm - 4:30pm	Evening briefing

online class:

Time (Eastern Time)	Activity
9:00am - 9:30am	Morning briefing
9:30am - 1:00pm	Class instruction (2 10-min breaks)
1:00pm - 2:00pm	Lunch break
2:00pm - 5:30pm	Class instruction (2 10-min breaks)
5:30pm - 6:00pm	Evening briefing

Approximate Agenda by Day

Day	Modules
1	Intro, 1 – 5 Statutes, Rules of Practice, Reg. Process, Systems Thinking, Professionalism
2	6 – 8: Food Microbiology/SRM, SPS, SSOP
3	8 SSOP (cont.), Sanitation Scenarios, 9 – 10: Noncompliance, HACCP Process Categories
4	11 – 14: HACCP 7 Principles, HACCP Reg. Process, Food Ingredients, HACCP Verification
5	14 – 15: HACCP Verification (cont.) HAV task,
6	16 – 19: Review Est. Data, Workshop #1, HACCP Sys. and Recall, Sanitary Dressing, Slaughter FS Standard,
7	19 – 21: Slaughter FS Standard (cont.), *Salmonella*/*Campy.*, Raw Beef Sampling, HAV scenario,
8	22 – 25: Process Control, HH/GCP, RTE/SS, Lethality/Stabilization,
9	26 - 29: Haz/Control Workshop, RTE Sanitation, *Lm* regulation Workshop #2, LM Regulations, RTE Sampling,
10	Workshop #3, 30 - 32: Export Certification, Food Defense, NFSCP, Resources
11	PHIS 0-5 and 34: Intro, Establishment Profile, Task List/Calendar, Documentation, Sampling, ADR and Food Safety Systems Thinking
12	PHIS Simulations 1 – 3, Case Study #2
13	PHIS Simulations 4 – 6, Case Study #1
14	PHIS Simulations 7 – 16, E-Testing Instructions
15	IM Test – no class

INSPECTION METHODS TRAINING AS A CONDITION OF EMPLOYMENT (TCOE)

Satisfactory completion of the Inspection Methods training is a condition of your employment for newly hired or promoted Consumer Safety Inspectors (CSI), according to FSIS Directive 4338.1, Training as a Condition of Employment. Newly hired Public Health Veterinarians must satisfactorily complete the PHV Intern training program, part of which entails completion of the Inspection Methods training.

This means that you must complete and pass the training. The consequences of failing this training program include the following:

- If you are a new hire with FSIS, you will be terminated from Federal Employment.
- If you are not a new hire, you will either be removed from Federal service or returned to a position similar to that which you previously held, if available.

The Inspection Methods training will provide you with the skills and knowledge needed to accomplish inspection verification duties. This training is based on FSIS Directive 5000.1 and consists of such subject areas as: PHIS, Rules of Practice, Sanitation, HACCP, Microbiological Sampling, Pathogen Reduction and Process Familiarization. The coursework is instructor-led and also includes practical learning through workshops, individual activities, and group activities. Participation in these learning activities is expected of all students.

There is a written exam in Inspection Methods. This exam is the tool used to measure your successful completion of the training. For successful completion you must score a 70%. The CFL will determine your final exam results and will notify your District Office of your results after the conclusion of the course.

CSIs will be contacted concerning the scheduling of a retesting opportunity. Logistical information regarding the retesting procedures will be provided to you at that time.

You must also adhere to Employee Conduct and Responsibilities while attending the training, as stated in FSIS Directive 4338.1. Regular attendance is expected of all students, and any anticipated absences must be cleared with the instructor prior to the absence. Emergency absences **must be** reported as soon as possible. If any problems arise concerning attendance, cheating on a test, or any other conduct issue, the CFL will contact the Employee Relations Branch.

If you have any further questions, refer to the Training Information Packet you received from Human Resources during your selection process. If you are unclear whether you are expected to meet the training as a condition of employment requirements contact your District Office.

Revised 9/19/2012.

01 STATUTES (ACTS)

Objectives

1. Identify and define where FSIS derives its authority.
2. Relate subject matter in the Federal Meat Inspection Act (FMIA), Egg Products Inspection Act (EPIA) and the Poultry Products Inspection Act (PPIA) to food safety.
3. Describe how the FMIA, EPIA, and PPIA legally support the Sanitation Performance Standards (SPS), Standard Sanitation Operating Procedures (SSOP), and Hazard Analysis Critical Control Points (HACCP) regulations.
4. Explain the relationship between the Statutes, Regulations, Directives, and Notices.

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

References:

Food Safety Acts:
https://www.fsis.usda.gov/policy/food-safety-acts

Title 9 Code of Federal Regulations, Chapter III, Parts 300-599:
https://www.ecfr.gov/current/title-9/chapter-III

FSIS Directives and Notices:
https://www.fsis.usda.gov/policy/directives-notices

02 RULES OF PRACTICE

Objectives

1. Define key terms.
2. Identify circumstances where prior notice of enforcement action is not required.
3. Identify circumstances where prior notice of enforcement action is required.
4. Describe the appeals process.

- 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). A withholding action can be taken with or without prior notification of the establishment.

- **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. Suspension actions can be taken with or without prior notification being given to the establishment and can only be taken at the district office level or higher (District Manager 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. This notice is called the Notice of Intended Enforcement (NOIE). 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 9 CFR 416.13 through 416.16.

    - The establishment has not maintained sanitary conditions as prescribed in FSIS regulations 9 CFR 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 not corrected.

    - 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 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.
- FSIS enforces a **30 calendar day 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.

03 REGULATORY PROCESS OVERVIEW

Objective:

1. Identify the four components of the regulatory process.

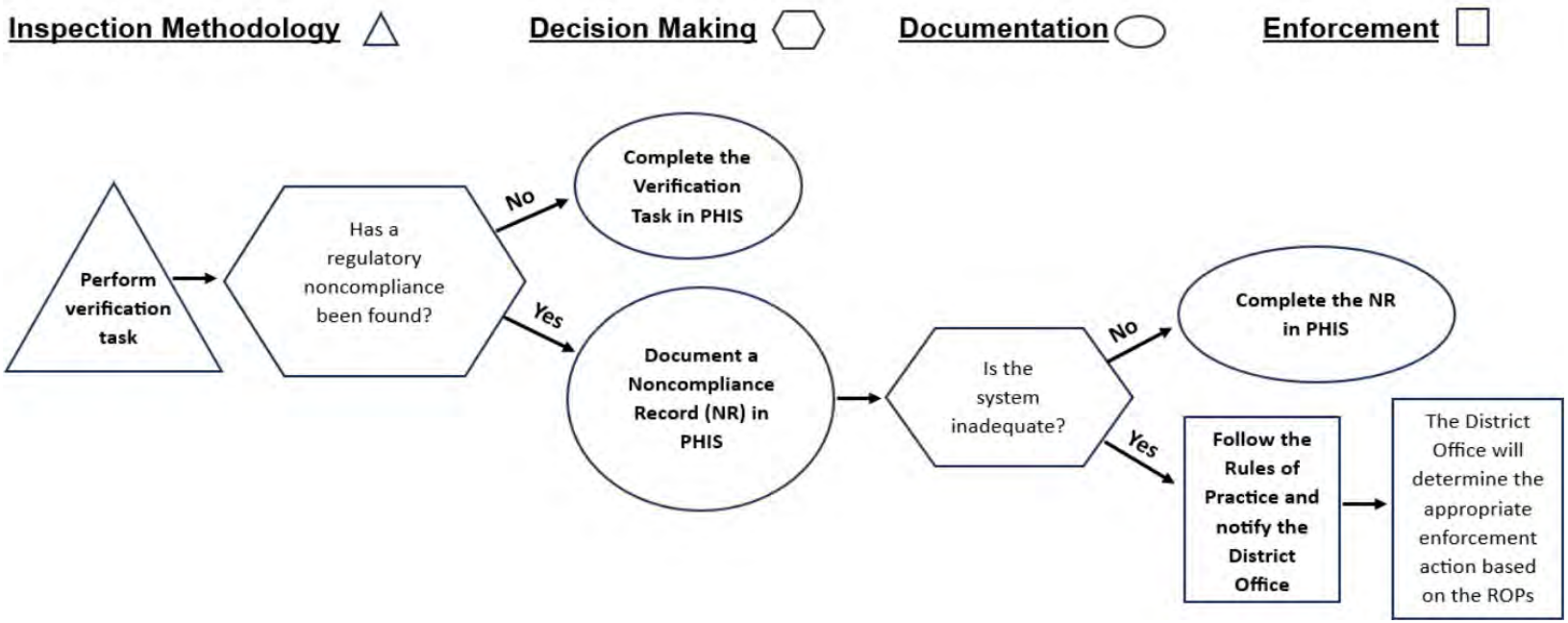
An establishment's food safety system consists of several different parts, including the HACCP plan, a Sanitation SOP, and other programs, like sanitary dressing procedures. These programs ensure that the product the establishment produces is wholesome and not adulterated. Inspection Program Personnel (IPP) allow products to be labeled with the marks of inspection when they have verified the regulatory requirements and determine no product was adulterated.

Regulatory Process

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 the Public Health Information System (PHIS)
  - Documenting noncompliance on a Noncompliance Record (NR)
- **Enforcement**
  - Following the Rules of Practice (ROP)
  - Providing the establishment with due process

HACCP Regulatory Process



04 FOOD SAFETY SYSTEM FUNDAMENTALS

Objectives:

1. Define what a System is and give examples.

2. List two basic components of a food safety system and describe their relationship to each other.

3. Describe "systems thinking" and its application to food safety systems and assessing inspection findings.

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.

- FSIS Regulatory System
- Food Safety System

Food Safety System

Purpose:

> To produce safe food

Evidence of Failure:

> Deficiencies/noncompliances that evidence increased risk of producing unsafe food, reoccurring deficiencies or trends, the production of unsafe food, or 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 an unsafe food
- May impact another processor's system
- Catastrophic lack/loss of control with food safety hazard AND illness/death

Examples of Possible Failures of a Food safety System:

- The temperature of the oven is too low
- The product is not left in the oven long enough
- The product is too thick causing the heat not to reach the center of the meat

Note: The consequences of these failures would be that the meat product was not cooked to the appropriate temperature, which allowed microorganisms to grow in the product, causing illness, injury, or death

Hazard Analysis

Purpose: To identify any food safety hazards that are reasonably likely to occur and identify preventative measures to control those hazards

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 programs** 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. The purpose of prerequisite programs is to reduce the likelihood of certain hazards occurring in the food safety system.

Prerequisite Program Examples:

- Pest control
- Facilities & grounds
- Air system /Ventilation
- Water quality
- Chemical control
- Production equipment
- Cross contamination prevention
- Allergen control
- Personal hygiene
- Specifications
- Traceability/Recall
- Training
- Cleaning and sanitation
- Receiving, storage, shipping
- Supplier control
- GMP

Food Safety System Basic Components

HACCP Plan:

- Controls food safety hazards that are reasonably likely to occur
- Product and process specific

Prerequisite Programs:

- 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

- Each system is a unique assemblage or combination of things or parts forming a complex or unitary whole.
    - 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 – "Systems Thinking"

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.

05 PROFESSIONALISM AND GOVERNMENT ETHICS

Objectives:
To demonstrate mastery of Professionalism and Government Ethics Essentials the trainee will:

1. Define “professionalism”- what does it look like.

2. Define how professionalism relates to, and impacts, food safety and biosecurity.

3. Identify appropriate and inappropriate behavior and explain how they affect employees, industry officials, consumers, and others.

4. Define the Agency’s expectations and the role each employee has in supporting the Agency in achieving its public health mission.

5. Identify the 14 Principles of Ethical Conduct in public service and your annual responsibility to complete the ethics training.

Introduction

We will be talking about professionalism at all levels of our workforce, which is critical to support FSIS in achieving our vision of becoming the premier public health agency and improving our working environments.

Like all professionals, we have a set of tools that we use in our work – the acts, directives, notices, regulations, due process, and professionalism. During Inspection Methods training you will learn more about these tools and how they can be used for making sound and supportable decisions and providing high quality customer service. This module will focus on the professionalism and how conduct perceived as “unprofessional” adversely affects our integrity, consumer confidence, and our ability to carry out our public health mission.

What is the definition of professionalism?

If we look at the dictionary definition of professionalism, according to dictionary.com, it states that “Professionalism most commonly means the state or practice of doing one’s job with skill, competence, ethics, and courtesy.” Professionalism is something that we learn and can and should strive to improve upon as we grow in our careers.

Why is professionalism important?

Practicing “unprofessional conduct and behavior” puts you and the public at risk relative to food safety and biosecurity because it detracts from inspection responsibilities and our ability to enforce food safety standards effectively. Displaying professionalism means maintaining high standards of skill, competence, ethics, and courtesy, as well as consistently following Agency policy and making sound, supportable decisions as you carry out your inspection responsibilities.

Public service is a public trust position and as a federal employee, you represent the agency in the eyes of the public. A popular saying about trust is that “trust equals consistency over time.” Which means that to maintain the high level of trust that the public has in our agency, we should strive to be consistent in how we enforce regulations each in every day.

Examples of unethical conduct

- *Working in an establishment where immediate family members are employed*
- *Accepting gifts or engaging in business or financial dealings with regulated establishments or their employees*
- *Engaging in outside employment or activities, including speaking, or negotiating for employment, that conflict with official Government duties and responsibilities*
- *Making unauthorized commitments or promises that involve binding the government*
- *Using public official for private gain*
- *Receiving anything of value given with the intent to influence the performance of official duties*

What are the possible consequences of unprofessional behavior?

The consequences of “unprofessional conduct and behavior” put you and the public at risk relative to food safety and biosecurity because it detracts from Inspection responsibilities and our authority to enforce food safety standards effectively. If you do decide to display unprofessional or unethical behavior, while in the performance of official duties, the following are possible consequences of those actions:

- Caution or Warning
- Official Letter of Reprimand
- Suspension without Pay
- Demotion
- Removal
- Non-pay Absence Status

Ethics And The Hatch Act

Another important ethical policy to keep in mind is the HATCH Act. The HATCH act was put into place to allow you to participate in the political process to the fullest extent possible, while maintaining an efficient and impartial workforce. The purpose of the HATCH Act is "...to ensure that federal programs are administered in a nonpartisan fashion, to protect federal employees from political coercion in the workplace, and to ensure that federal employees are advanced based on merit and not based on political affiliation.”

What can you do to ensure professionalism in the workplace?

- Consistently follow agency policy to carry out your responsibilities.
- Use the 14 Principles of Ethical Conduct
- Maintain high levels of skill, competence, ethics, and courtesy
- If you ever have any questions regarding the permissibility of a specific action, you should first email or call your ethics advisor at Ethics-FoodSafety@usda.gov

The 14 Principles Of Ethical Conduct

To ensure that every citizen can have complete confidence in the integrity of the Federal Government, each Federal employee shall respect and adhere to the14 fundamental principles of ethical conduct. These principles can be found in Part 1 of Executive Order 12674 of April 12, 1989. They are as follows:

1. Public service is a public trust, requiring employees to place loyalty to the Constitution, the laws, and ethical principles above private gain.
2. Employees shall not hold financial interests that conflict with the conscientious performance of duty.
3. Employees shall not engage in financial transactions using nonpublic Government information or allow the improper use of such information to further any private interest.
4. An employee shall not, except pursuant to such reasonable exceptions as are provided by regulation, solicit, or accept any gift or other item of monetary value from any person or entity seeking official action from, doing business with, or conducting activities regulated by the employee's agency, or whose interests may be substantially affected by the performance or nonperformance of the employee's duties.
5. Employees shall put forth honest effort in the performance of their duties.
6. Employees shall make no unauthorized commitments or promises of any kind purporting to bind the Government.
7. Employees shall not use public office for private gain.
8. Employees shall act impartially and not give preferential treatment to any private organization or individual.
9. Employees shall protect and conserve Federal property and shall not use it for other than authorized activities.
10. Employees shall not engage in outside employment or activities, including seeking or negotiating for employment, that conflict with official Government duties and responsibilities.
11. Employees shall disclose waste, fraud, abuse, and corruption to appropriate authorities.
12. Employees shall satisfy in good faith their obligations as citizens, including all just financial obligations, especially those such as Federal, State, or local taxes--that are imposed by law.
13. Employees shall adhere to all laws and regulations.
14. Employees shall endeavor to avoid any actions creating the appearance that they are violating the law, or the ethical standards promulgated pursuant to this order.

See E1 for Professionalism Workshop

References

FSIS Directive 4735.3 - Employee Responsibilities and Conduct

FSIS Directive 4735.9 - Office of Field Operations Assignment Restrictions and Rules on Gifts from Regulated Industry

Social Media and Email FAQs.pdf (osc.gov)

Form USDA OE-101 Request For Approval of Outside Activity

Office of Ethics | USDA

Additional Resources for Hatch Act

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 effect 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.

Objectives:

1. Identify the 4 types of microbes.
2. List important pathogens of concern.
3. Describe the typical bacterial growth patterns and factors affecting bacterial growth.
4. Describe sources of microbes in the establishment.
5. Explain basic methods of controlling microbial contamination in meat and poultry establishments.
6. Identify specified risk materials 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 product. For example:

- **Pathogenic** microbes cause illness or disease.
- **Spoilage** microbes cause food products to smell, taste or look weird, but may not have an effect on the safety of the product.
- **Fermentation** microbes help produce a safe food product.

What are the 4 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.

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.

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.

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.* Bacterial spores are unable to reproduce; however, once conditions again become favorable for growth the spores reactivate and become vegetative (reproducing) cells again.

How do bacteria grow?

We 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 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 will 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 aw) 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 aw requirements, molds have the lowest, and yeasts are intermediate. It is important to note that aw 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.

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.

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.

How are microbes controlled?

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.** This includes reducing the contamination or cross-contamination from live animals, processing procedures and equipment, employees, and the environment. Cross-contamination refers to the transfer of microbes from a contaminated source to a previously clean or sanitized surface. Recognizing that bacteria will be present on meat and poultry products is important to keep the overall number of bacteria very low to minimize concern about bacterial pathogens as well as spoilage organisms. The second involves **making the environment for microbes as inhospitable as possible to reduce their numbers and minimize their 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. In addition, temperature, acidity, salting and drying, or some combination of these, can be used to restrict the growth of pathogens.

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.

Variety of control measures

- **Product handling**

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.

Drying, adding salt, and lowering the water activity (aw) 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.

Maintaining adequate **temperature controls** are important on all classes of food products.

Packaging and processing steps such as reducing the oxygen level through **vacuum packaging** 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.

- **Temperature controls**

Maintaining products under refrigeration, or in a frozen condition, is one of the most important ways to inhibit microbial growth. Refrigeration temperatures between 40-45°F slows the growth of spoilage and pathogenic bacteria. Cooking product to temperatures adequate enough to eliminate pathogens of concern is another way to control microbes. Temperatures above 165°F are capable of destroying or inactivating some bacterial cells. Bacteria, toxins, and spores can be very heat resistant though, and inactivation of toxins and spores requires thermal processing under very high temperatures under pressure, as found in canning operations. 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.

- **Environmental controls**

Both pathogenic and spoilage microbes can be found throughout the slaughter and processing environment. This emphasizes the need for the effective control these organisms. 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. 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.

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.

- **Foodborne Parasites**

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. Protozoan parasites are visible only through a microscope. Many adult parasitic worms are visible without a microscope; however, a microscope is necessary for detecting eggs and pre-adult forms of some worms. Identification of the adult forms of certain parasitic worms can also require microscopy.

The respective lifecycle of different parasites also varies. While some parasites use a permanent host, others go through a series of developmental phases using different animals or human hosts. 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.

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).

- **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).

Mad Cow Disease, also known as Bovine Spongiform Encephalopathy (BSE), is the brain disease that affects cattle. The human version of BSE, known as 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
(see FSIS Directive 6100.4 - Verification Instructions Related to Specified Risk Materials in Cattle of all Ages) 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

Objectives:

1. Identify the directive that provides instructions for the SPS Verification Task.
2. List the two activities used to identify compliance.
3. Describe the documents that are required by the SPS regulations.
4. Describe the appropriate enforcement actions that should be taken when the SPS regulations are not met.
5. Given scenarios, determine SPS compliance or noncompliance.
6. Identify when it is appropriate to cite 9 CFR 416.1.

Purpose:

Proper and effective sanitation is vital to every step of the food manufacturing (making) process. This section will focus on helping 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 or not. 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

Custom Exempt 9 CFR 303.1(a)(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.

Sanitation Requirements:

- 9 CFR 416.1 - 416.5 *You can find the complete regulations in the Supplemental Content in part 2 of the workbook*.
- FSIS Directive 5000.1- Verifying an Establishment's Food Safety System addresses the Sanitation Performance Standards (SPS) regulations and the SPS Verification task.

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.

9 CFR 416.1 is only 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:

There are 11 Sanitation Performance Standards in the regulations that IPP will verify establishment compliance with the following regulations:

- 416.2(a) Grounds and Pest Control
- 416.2(b) Construction
- 416.2(c) Lighting
- 416.2(d) Ventilation
- 416.2(e) Plumbing
- 416.2(f) Sewage
- 416.2(g) Water Supply, Water, Ice, Solution Reuse
- 416.2(h) Dressing Rooms, Lavatories, and Toilets
- 416.3 Equipment
- 416.4 Sanitary Operations
- 416.5 Employee Hygiene
- 416.6 Tagging Insanitary equipment, utensils, rooms, or compartments

Official Premises:

The official premises are designated by the establishment during the grant of inspection application process. IPP must conduct all inspection activities within the physical boundaries designated as the official premises of the establishment.

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 may also 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., documentation describing the safe and correct use of chemicals that are in the establishment

Under SPS, an establishment is NOT required to maintain daily records. There is no regulatory recordkeeping requirement in the SPS regulations. The SPS regulations require the establishments to continuously maintain some documents on file (water potability certificate, safety data sheets for chemicals, sewage disposal letter for private sewage system and information on pesticides used).

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
- Assess the establishment's answers to those questions

How to determine compliance or noncompliance?

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 IPP determine that the establishment is not meeting the SPS requirements, IPP must document the noncompliance on a Noncompliance Record (NR). If IPP determine that the SPS noncompliance is due to the establishment's repeated failure to maintain sanitary conditions, IPP should consult with their FLS or IIC to determine if 9 CFR 416.1 should be added to the NR.

NOTE: You are to notify your supervisor when repetitive noncompliances or systemic problems are documented.

Use professional knowledge and good judgement (GAD)

1. **G**ather information
2. **A**ssess each situation
3. **D**etermine if an insanitary condition has occurred

See E2a, E2b, E2c, E2d, for SPS Workshops

08 SANITATION STANDARD OPERATING PROCEDURES (SSOP)

Objectives:

1. Identify the directives that provide instructions for the SSOP Tasks.
2. List the two activities (components) used to verify compliance.
3. Describe the tasks that are used when verifying compliance with the SSOP regulations.
4. Describe the appropriate enforcement actions that IPP should take when food contact surfaces are contaminated or when product is contaminated.
5. Given scenarios, determine SSOP compliance & noncompliance.

The purpose of SSOPs is to have procedures in place that prevent the contamination of product and food contact surfaces. IPP will develop their knowledge of the SSOP regulations (9 CFR 416.11 - 416.16). *You can find the complete regulations in the Supplemental Content in part 2 of the workbook*. SSOPs provide an essential foundation for a HACCP food safety system.

IPP will learn how to perform the (4) SSOP Verification Tasks using the GAD process specified by inspection verification questions related to specific SSOP regulations. IPP will also understand their regulatory responsibilities (9 CFR 416.17).

Please see supplemental part for SSOP regulations 9 CFR 416.11 – 17.

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.

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

1. Implementation and monitoring
2. Maintenance
3. Corrective actions
4. Recordkeeping

How IPP Verify SSOP Regulatory Requirements:
The following table lists the four tasks used to verify compliance with Sanitation SOP requirements. IPP will verify compliance by:

1. **Reviewing** establishment **records.**

2. **Directly observing** the establishment employees performing procedures in their SSOPs and by **taking hands on measurements and comparing their results with the establishment's results.**

SSOP Inspection Tasks

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.

While performing each SSOP task, IPP will verify compliance with:

- Basic Design (416.12)
- Implementation & Monitoring (416.13)
- Maintenance (416.14)
- Corrective Actions (416.15)
- Recordkeeping (416.16)

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 9 CFR 416.12.

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 to meet the requirements of 9 CFR 416.13 & 416.15.

    a. 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 9 CFR 416.16 and maintenance requirements of 9 CFR 416.14.

    a. 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 9 CFR 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 flashlight (to check dark areas or inside pipes/equipment).
- 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.
- Been trained in lockout/tagout safety procedures (Pre-Op SSOP).

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

Pre-Op Sanitation SOP Review and Observation Task
Note: IPP not trained in lockout/tagout methodology (FSIS Directive 4791.11) **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 the Pre-Op Sanitation SOP Review and Observation verification task.

- Using sound professional judgment, IPP will use a **risk-based approach** to gather information to assist them in selecting equipment or areas for pre-op sanitation verification and deciding the extent of their pre-op sanitation verification. IPP are to focus on those areas and equipment that present the highest risk to public health.

  The following factors would indicate higher risk to public health:

  - Equipment that will contact exposed product.
  - Equipment that will contact RTE product post-lethality.
  - Equipment that is difficult to clean.
  - Equipment that FSIS has not verified recently.
  - Equipment/areas with a history of noncompliance.
  - Testing results suggesting that specific pieces of equipment may present a risk to public health.

- 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 U.S. Reject tag (i.e. regulatory control action) that will not be removed from the food contact surface until the establishment has restored sanitary conditions;

    - **Notify** the establishment, and

    - **Document** the noncompliance on an NR.

- The establishment has the responsibility to restore sanitary conditions (clean the contaminated food contact surface) in accordance with 9 CFR 416.13 and document the restoration of sanitary conditions under 9 CFR 416.16(a). In this instance the regulatory requirements of 9 CFR 416.15 do not apply. **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 review the written Operational SSOPs.

- 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.

- 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.

- When possible, IPP should also observe the establishment conducting its monitoring activities.

- If IPP observe contaminated direct food contact surfaces or contaminated product during operations, there is a Sanitation SOP noncompliance, whether there is a procedure written in the establishment's Sanitation SOP to cover that situation or not. **When IPP observe a noncompliance**, they are to:

    - **Reject** the affected equipment or **Retain** the affected product by placing a reject tag (i.e. regulatory control action) that will not be removed from the food contact surface or product, until the establishment has restored sanitary conditions and ensured appropriate product disposition.

    - **Notify** the establishment, and

    - **Document** the noncompliance on an NR.

- When IPP or establishment personnel find that the Sanitation SOPs have failed to prevent direct contamination of products, IPP are to review Sanitation SOP records and, when possible, observe establishment employees implementing corrective actions to verify that establishment corrective actions meet all the requirements of 9 CFR 416.15.

- When IPP have completed their assessment of operational sanitation in one or more areas of the establishment, they should compare their findings with the establishment's findings. If the records are not complete at the time, IPP might ask the establishment if they have 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.

Evaluating Trends for Systemic Problems
After IPP document a noncompliance, they are to consider whether the noncompliance is associated with previous noncompliances or other findings that did not result in a noncompliance. These associated findings may indicate systemic problems in the establishment's food safety system. Trends that indicate systemic problems may not involve any NRs, such as repeated positive test results from either FSIS or establishment testing. When IPP determine that an NR is associated with previous NRs or other findings, they are to record the association in the Inspection Notes features of PHIS and notify the FLS through the supervisory chain. IPP are to discuss any identified associated findings at the next weekly meeting and document the discussion on an MOI.

Noncompliance Example
You are a CSI assigned to an Egg Products establishment that produces Fully Cooked-Not Shelf Stable Whole Egg products and Raw Non-Intact Egg Yolks. You log into PHIS that morning and see that you have a routine task assigned: Pre-Operational Sanitation Verification.

You review the task and see that the following should be inspected, before a tanker is filled, for cleanliness and adequate sanitizing:

-The interior of the tanker
-The inlet caps
-The dome gaskets
-The air vents
-The dismantled outlet valves
-The "O" rings

After the establishment has informed the CSI that they are ready for FSIS inspection, you find egg yolk residue in the interior of the tanker from the tanker's previous load.

1) ***Is there an insanitary condition?***
   Yes, the pre-op sanitation procedures in the Sanitation SOPs are to address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils prior to use.
2) ***If so, is it effecting product or food contact surfaces?***
   Yes. The interiors of tankers are considered food contact surfaces.

3) ***Is this a noncompliance?***

Yes. When IPP determine that there is noncompliance with the pre-op Sanitation SOP regulatory requirements, they are to document the noncompliance on an NR in PHIS in accordance with the instructions in FSIS Directive 5000.1. The description of the noncompliance is to clearly explain how the IPP's findings support the determination that the establishment did not meet regulatory requirements and include the problem, time of occurrence, and location. When IPP observe pre-op Sanitation SOP noncompliance that does not result in contamination of food contact surfaces (e.g. failure to initial records), they are not to take a regulatory control action.

If so, which regulation(s)?

9 CFR 416.13(a).

9 CFR 416, sections 416.11 through 416.17, Sanitation SOPs, requires establishments to implement procedures sufficient to prevent direct contamination or adulteration of products while under the control of the establishment.

Should you take a regulatory control action?

Yes. When IPP observe contamination of direct food contact surfaces during pre-op sanitation verification, they are to reject the affected equipment. Finding contamination during pre-op sanitation will not affect any product. IPP are to remove the USDA reject tag only after the establishment has restored sanitary conditions.

IPP should refer to FSIS Directive 5000.4 Performing The Pre-Operational Sanitation Standard Operating Procedures Verification Task.

See E3a, E3b, E3c for SSOP Workshops

09 NONCOMPLIANCE

Objectives

1. Define the term “noncompliance.”
2. Identify the information that must be recorded on the NR when IPP are documenting a trend in noncompliance.
3. State the purpose of associating NRs.
4. Identify the requirement for associating NRs.
5. Identify the activity inspectors must perform before an NR can be completed.

Noncompliance is defined as an establishment’s **failure to meet a regulatory requirement**.

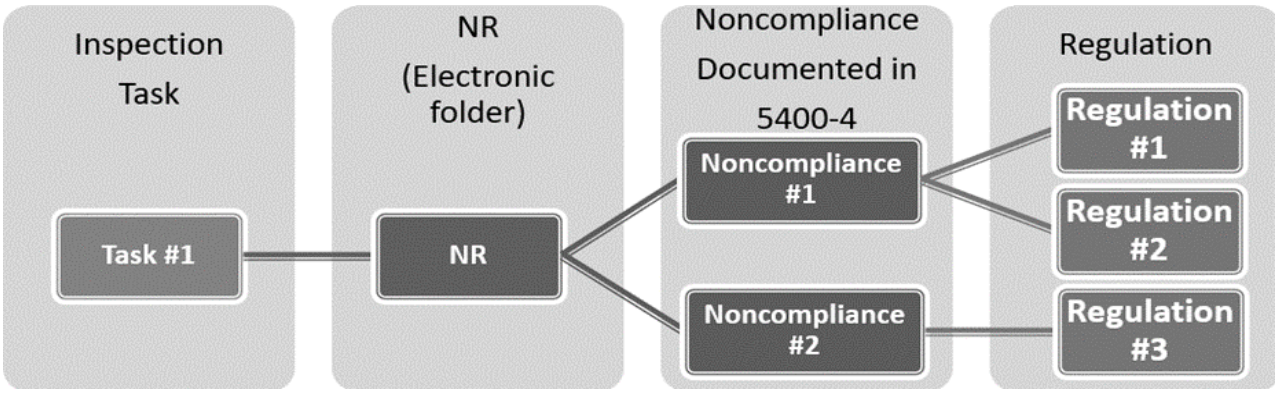
When IPP find regulatory noncompliance, they are to:

- 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	• A noncompliance has been documented in PHIS
	Finalized	• The noncompliance is ready to deliver to establishment management
NONCOMPLIANCE RECORD (NR)	Open	• An NR has been created in PHIS
	Completed	• 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 **6W's (While, When, What, Where, Who, and Why)** and then document the details for each one of the W's.

The 6 Ws method
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 a brief summary of the 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(s) 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 ¼ 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** two or more NRs when they indicate an ongoing trend of related noncompliances. This may also include NRs documented during a Food Safety Assessment (FSA) performed by an enforcement, investigations and analysis officer (EIAO). 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 noncompliances 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** (Block10) of the NR.

When IPP determine that an NR is associated with one or more previous NRs or other findings that did not result in noncompliance, they are to record the association in the inspection notes feature of PHIS and describe the reason for the association.

At the weekly meeting, IPP are to:

- Discuss associations between current and past noncompliances and explain why the associated NRs indicate a trend of noncompliance.

- Document the discussion of noncompliance trends and NR associations in a Memorandum of Interview (MOI).

- IPP should continue associating noncompliance that are similar and discussing associations and trends of noncompliance at weekly meetings until the issues are resolved or they determine that additional enforcement action is necessary to bring the establishment into compliance with the regulations.

- Always keep your supervisor informed.

See E5 for Noncompliance Record Association Workshop

10 HACCP PROCESSING CATEGORIES

Objectives:

1. Distinguish between the different HACCP processing categories.
2. Identify common hazards for all raw products.
3. Identify common hazards for other product categories.
4. Identify the raw product processing categories.
5. Identify common meat and poultry slaughter steps.
6. Identify common processing steps for intact and non-intact raw product.
7. Explain the food safety significance of non-intact product.
8. Identify common lethality for ready-to-eat product.
9. Identify amenable fish species.

The HACCP (Hazard Analysis Critical Control Point) regulations set out nine 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** hazards 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 "+"			
		Salmonella	STEC, including *E. coli* O157:H7	*Campylobacter*	SRM
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. Antibiotic residues at violative levels in tissues are of particular concern. Antibiotic residues are most often found in "Bob" veal calves and cull dairy cows due to their higher likelihood of illness.

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 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 9” 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, sesame, 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 subprimal cuts 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 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. Both the thermal process (high temperature/pressure) and special seal define the production in this category.

Not Heat Treated - Shelf Stable Processing Category

This processing 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 processing category applies to products that receive 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 processing category applies to establishments that further process products by primarily using 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. For example***, Listeria monocytogenes*** could be introduced through recontamination.

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 processing category applies to further processed products that are not ready-to-eat products (NRTE) processed products that are refrigerated or frozen throughout the product's shelf life. They are produced using the criteria of one of two following heat processing steps:

1. **The heat processing step is not adequate to achieve food safety.** For example, products may be partially cooked or heated to set batter on a raw product.

2. The heat processing step is adequate to achieve food safety. However, product is further processed, assembled, or packaged in a way that results in the cooked product contacting product or ingredients that are not ready-to-eat. In this case, the final product is in a form that is inedible without additional preparation 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. Hazards and controls will vary based on the product and how it is processed.

Products with Secondary Inhibitors - Not Shelf Stable Processing Category

This processing 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 products don't fit into any of the other 8 categories. This category includes country ham, semi-dry fermented sausage, and salt pork.

Inspection of Fish of the Order Siluriformes

Background

This inspection 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 species.

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).

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. Products labelled as "catfish" must be of the family Ictaluridae.

Inspection of Egg Products

On October 29, 2020, FSIS published a final rule to modernize egg products inspection: Egg Products Inspection Regulations (85 FR 68640). The rule has staggered effective dates. Most provisions became effective on December 28, 2020. Provisions related to the implementation of Sanitation SOPs had become effective on October 29, 2021, while provisions related to the implementation of HACCP systems will become effective on October 31, 2022. Plants that produce egg substitutes or freeze-dried egg products will be regulated by FSIS on October 30, 2023.

TABLE 1: PHIS Product Category List (Egg Products Plants)			
HACCP Processing Category	Finished Product Category	Product Group Category	Production Volumes Categories (by Product Groups)
Raw Non-Intact	Raw non-intact egg products	Unpasteurized (bulk or packaged)	- Whole eggs or Yolks (<2% added ingredients) - Egg Yolk (with or without ingredients) - Whole eggs with added yolks (with >2% salt or sugar) - Egg whites (w/wo added ingredients) - Egg products (blends of whole egg, egg whites, and/or yolks w/wo added ingredients) - Spray-dried egg whites (w/wo added ingredients) - Pan-dried egg whites
Fully Cooked – Not Shelf Stable	RTE fully cooked egg products	Pasteurized (bulk or packaged)	- Whole eggs or yolks (<2% added ingredients)
	RTE egg product fully cooked w/o subsequent exposure to environment		- Egg Yolk (with or without added ingredients) - Egg products (blends of whole egg, egg whites, and/or yolks) - Whole eggs with added yolks (w >2% added salt or sugar) - Whole egg or yolks (w/ >2% salt or sugar) - Egg whites (w/wo added ingredients)
Heat Treated – Shelf Stable	RTE dried egg products	Pasteurized Dried Egg Products	- Whole eggs or yolks (w/wo added ingredients) - Egg yolk (with or without added ingredients) - Egg products (blends of whole egg, egg whites, and/or yolks - Whole eggs w/ added Yolks (w >2% salt or sugar) - Spray-Dried Egg Whites (w/wo added ingredients) - Whole Eggs or Yolks (<2% added ingredients) - Pan Dried Egg Whites

See E6 for Common Hazards for Raw Product Workshop

11 HACCP SEVEN PRINCIPLES

Objectives

1. Identify the HACCP Seven Principles

2. Define HACCP

3. Define the following terms:

    a. Hazard Analysis
    b. Prerequisite Program
    c. Critical Control Point
    d. Critical Limit
    e. Monitoring
    f. Verification

4. Explain the purpose of monitoring

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

What is HACCP?

The National Advisory Committee on Microbiological Criteria for Food (NACMCF) working group created guidelines and redefined the seven basic principles of HACCP as an effective and rational means of assuring food safety from harvest to consumption. The working group published the HACCP principles and application guideline document in August 1997. This paper is not a regulatory document. However, it was used by FSIS when the HACCP regulation was developed and then published in the Federal Register. As regulators, you will be responsible for verifying compliance with the HACCP regulation. The HACCP guideline with the seven principles is not an enforceable document; however, it is helpful for inspection personnel to be familiar with the basis for the development of the HACCP plan is under Title 9 Code of Federal Regulation (CFR) Part 417.

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 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.

- Four processes are involved in the verification of the establishment's HACCP system.
  - Validation
  - Ongoing verification
  - Reassessment
  - Government verification

See E7 HACCP 7 Principles Workshop

12 HACCP REGULATORY PROCESS

Objectives:

1. Define the term “HACCP system”.
2. Identify the components of a “HACCP plan in operation”.
3. Describe the four components that are part of the HACCP regulatory process.
4. Identify the two HACCP inspection tasks that IPP perform to verify the HACCP regulatory requirements.
5. Describe the two verification components used when performing HACCP inspection tasks.

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, and 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 noncompliances or other related findings
    - Descriptions for determining why the events are associated, and other noncompliance history to determine whether the findings indicate a trend of ongoing noncompliance or systemic problems with the establishment's food safety system.
- 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
    - IPP gather information by looking at establishment records.
    - These records might include the hazard analysis, prerequisite programs, HACCP plans, or HACCP records.
- A **review and observation component**
    - Directly observe establishment HACCP procedures
    - Take independent measurements and compare IPP use either component or a combination of the components to verify regulatory compliance.

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.

- Reviewing establishment hazard analyzes, HACCP plans, prerequisite programs, and other supporting documentation.
- Reviewing establishment records documenting the implementation of HACCP plans, prerequisite programs and other supporting programs or procedures.
- Observing establishment employees implementing each HACCP plan, prerequisite program or other supporting program or procedure.
- Observing product and occasionally taking measurements as specified in the HACCP plans, prerequisite programs, or other supporting programs or procedures.

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

- Comparing the information gathered to HACCP regulatory requirements.
- Considering what each piece of information, either taken separately or with other findings.
- Considering the information in the context of past findings to identify any patterns or trends.

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

- Has the establishment already identified the failure to meet regulatory requirements or deviation from a critical limit?
- If product is involved, has the establishment ensured product safety?
- 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?
- Is a trend developing?

HACCP Noncompliance Scenario

You are a CSI assigned to an Egg Products establishment that produces Fully Cooked-Not Shelf Stable Whole Egg products and Raw Non-Intact Egg Yolks You log into PHIS that morning and see that you have a routine task assigned: a Fully Cooked-Not Shelf Stable Verification task. You review the HACCP Plan and note they use the FSIS Food Safety Guideline for Egg Products as support for CCP1 at the tempering step, which states that egg products defrosted at ambient temperatures at greater than 40*F must be held for 24 hours or less. You then review the records for the tempering of the frozen whole eggs. You see that the establishment has tempered the eggs for 52 hours at a room temperature of 42°.

- **Is this a noncompliance?**
  Yes.

- **What do you do?**
  You will issue an NR because the plant did not comply with a regulatory requirement, and you notify the plant orally of the finding. You consider all relevant factors when determining the amount of affected product. Factors you consider include such items as the plant's lot identification procedures, receiving records, and production records, as well as the average amount of product produced per shift or per production line. If necessary, consult with your supervisor for assistance in determining the amount of affected product.

- **What regulation(s) would you cite?**
  9 CFR 417.2(c)3 - List the critical limits that must be met at each of the critical control points. Critical limits shall, at a minimum, be designed to ensure that applicable targets or performance standards established by FSIS, and any other requirement set forth in this chapter pertaining to the specific process or product, are met.

See E8 HACCP Regulatory Process Workshop

13 FOOD INGREDIENTS OF PUBLIC HEALTH CONCERN

Objectives:

1. List the “Big 9” food allergens.
2. Distinguish between a food allergy and a food intolerance.
3. List examples of food ingredients to which some individuals are intolerant.
4. Describe establishment responsibilities for controlling ingredients of public health concern.
5. Identify situations that may lead to cross-contact with a food allergen.
6. Identify situations that may result in mislabeling of a product containing an ingredient of public health concern.
7. Distinguish between labeling requirements for ingredients of public health concern and voluntary labeling declarations.
8. Describe when an establishment can include factual statements about the processing environment on a finished product label.
9. Perform and document the “Big 9” Formulation Verification task.
10. Identify additional labeling concerns that require a directed General Labeling task and documentation of general labeling noncompliance.

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 may occur in an allergic individual.

The FDA has identified nine foods ("**Big 9**") 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**
- **Sesame**

NOTE: Attachment 1 in FSIS Directive 7230.1 provides a comprehensive list of ingredients and products that may be derived from the "Big 9" 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 resembling 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, and inflammation and damage to the lining of the small intestine.

- **Nitrate and nitrites** are different nitrogenous 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 formulation and that 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 pose 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: When reviewing an establishment's hazard analysis and supporting documentation regarding the use of highly refined edible oils, be aware that highly refined edible oils (e.g., soybean oil, peanut oil, sesame 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. However, 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.

Avoiding cross-contact between products containing a food allergen and those that do not is critically important. Cross-contact could result from inadequate control or inappropriate use of ingredients of public health concern.

Situations that may allow for cross-contact to occur include the establishment failing to:

- Check ingredient containers for damage at receiving to prevent allergen contamination within the establishment.

- Implement a program to ensure proper identification and control of allergenic ingredients, allergen containing products, and allergen containers through receiving, weighing, formulation, and packaging.

- Ensure effective sanitation measures are in place to address the potential for cross- contact when producing multiple products with different formulations.

- Implement adequate sanitation procedures for cleaning of utensils and equipment used in formulating and processing both products containing an allergen and products without allergens.

- Train employees on the appropriate use of ingredients and the need to be especially careful when working with allergens.

- Appropriately identify/store products to be reworked that contain an allergen.

- Manufacture a product in accordance with the intended product formulation.

In addition to inadequate controls to prevent cross-contact, accidental application of inaccurate labels to properly formulated products could pose a threat to consumers sensitive to any ingredients in the formulation. **Examples of how inaccurate labeling of a product can occur include the establishment failing to:**

- Declare ingredients listed in the product formula on the product label by common or usual name.

- Change labels when changing over from one product formulation to another.

- Review the labels on incoming non-meat/non-poultry ingredient mixes at receiving for changes.

- Discard obsolete labels after a change in product formulation.

- Review newly printed labels to ensure accuracy.

- Control labels for products with similar appearance but different ingredients to ensure application of the correct label (e.g., storing mixed bundles of labels for similar products with different ingredient formulas which could lead to a mix-up of labels).

- Maintain adequate production controls over a product that contains an allergenic ingredient and is intended for rework, allowing it to be reworked into a product not labeled to contain that ingredient.

- Declare an allergen that was indirectly added to the product. An example would be an establishment that is producing product on a food contact surface sprayed with a non-stick coating (a release agent intended to prevent product from adhering to the food contact surface) containing soy lecithin and is not properly declaring the soy lecithin on its finished product label. Note that substances used as release agents on surfaces, including grills, loaf pans, cutters, or other hard surfaces, are generally considered to be processing aids and are not required to be declared in the ingredients statement on the meat or poultry product label. However, if a particular release agent contains a known allergen, such as soy lecithin, official establishments must list the allergenic ingredient in the ingredients statement on the product label. Many cooking sprays (e.g., PAM®) used as release agents will contain soy lecithin as an emulsifier. Some may contain other allergenic ingredients as well.

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 particularly helpful to consumers and is not a substitute for 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 2) no such ingredient is in the product; and 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 9" 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 9" Formulation Verification Task

The "Big 9" Formulation Verification task provides IPP with a method for verifying that establishments are accurately controlling and labeling the nine 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 9" 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 9" 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 FSIS Directive 7230.1 (page 5) to prioritize product selection. Whether or not the establishment produces products containing a "Big 9" 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 9” 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 9” 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 9” 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 9” Formulation Verification task may be performed more frequently as a “for cause” directed task. Before scheduling additional “Big 9” 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 9” Formulation Verification Task

IPP are to document noncompliance on an NR in PHIS under the “Big 9” Formulation Verification task whenever they determine that a meat or poultry product contains a “Big 9” allergen not declared in the ingredients statement on the product label. IPP will cite the relevant 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.

The establishment's food safety system has failed anytime it ships product containing an undeclared allergen in commerce.

NOTE: If IPP identify concerns when performing the "Big 9" 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 9" 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 9" 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 Division (RMTAD). Refer to FSIS Directive 8080.1 for more information on recalls.

14 HACCP VERIFICATION TASK

Objectives:

1. Identify the regulatory requirements verified with the HACCP verification task.

2. Explain how Inspection Program Personnel (IPP) is to perform the HACCP Verification task.

3. Identify issues that represent noncompliance with an establishment's HACCP plan and inadequacy of the HACCP system.

4. Identify the type of issues or concerns that are to be discussed with supervision before determining compliance and completing the HACCP verification task.

Introduction

The HACCP verification task is for verifying that an establishment complies with the requirements of 9 CFR Part 417. There is one HACCP verification task for each of the nine HACCP processing categories.

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

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.

2. **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 group. FSIS does not determine the method used to define specific production; this is an establishment's responsibility. 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.

HACCP Verification Task Example 1*: The Raw Non-Intact HACCP verification task is on the IPP's PHIS task calendar for today. The establishment has one HACCP plan in this processing category for ground beef patties. The IPP knows from previous experience that this establishment defines specific production as each day's production, and that they generally perform pre-shipment review each morning on the previous day's production. The HACCP plan identifies one CCP for chilling the finished patties and the establishment implements a temperature control program for processing rooms and coolers/freezers. The establishment is producing a lot of patties today. The IPP decides to use the review and observation and recordkeeping components to verify the four HACCP regulatory requirements at the CCP and the recordkeeping component for verifying the implementation of the temperature control program. He proceeds to the production floor to begin verifying that all of the HACCP requirements were met for the CCP by reviewing the current day's HACCP records and prerequisite program records. After reviewing these records, he will observe the establishment employee performing the monitoring activity for today's production lot. Since the establishment had not performed all of the verification activities when he reviewed the HACCP records, he knows that he will have to review the HACCP records again to verify the establishment meets the HACCP verification requirement and verify that the establishment conducted the pre-shipment review tomorrow before he can complete the task.*

HACCP Verification Task Example 2: *The IPP has a Heat Treated – Shelf Stable HACCP verification task scheduled in her PHIS task calendar. The establishment has one HACCP plan for salami sticks in this processing category. She knows from previous experience that this establishment defines specific production as each day's production lot. The establishment performs pre-shipment review each day on the production lot that passes the final CCP, drying.*

This may take between 4-5 weeks. She proceeds to the HACCP office and determines that one production lot passed the drying CCP today and the pre-shipment review has been completed. She reads the HACCP plan to be familiar with the CCPs. She uses the recordkeeping component in this case because production is complete. She performed her verification and concluded that all of the HACCP requirements were met for all of the CCPs in the HACCP plan for this specific production, including the pre-shipment review. Then, she proceeds to enter her HACCP verification findings in PHIS and marks the task as completed.

Regulatory Reference

	Regulatory References	**Component**
Monitoring	9 CFR 417.2(c)(4) Monitoring Requirement	Rk R&O
Verification	9 CFR 417.2(c)(7) Verification Requirement 417.4(a)(2)(i)(ii)(iii) Verification Activities	Rk R&O
Recordkeeping	9 CFR 417.2(c)(6) Recordkeeping System	Rk
	9 CFR 417.5(a)(3) HACCP Records	Rk
	9 CFR 417.5(b) Records Authenticity	Rk R&O
	9 CFR 417.5(d) Computerized Records	Rk
	9 CFR 417.5(e)(1) and (2) Record Retention	Rk
	9 CFR 417.5(f) Official Review	Rk
	9 CFR (Prerequisite Program Implementation) 9 CFR 417.5(a)(1) Supporting Documentation	Rk R&O
	9 CFR 417.5(c) Pre-Shipment Review	Rk R&O (on occasion)
Corrective Action	9 CFR 417.3(a) Deviation from a critical limit 9 CFR 417.3(b) Deviation not covered by a specifiedcorrective action/unforeseen hazard	Rk R&O

1. 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).

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.

Monitoring Example 1: *An IPP is performing the Slaughter HACCP verification task and verifying the monitoring requirements for the steam pasteurization CCP. She reviews the establishment's HACCP plan and finds that it specifies monitoring personnel will observe and record the temperature as measured by the steam pasteurization cabinet gauges. The plan states that this monitoring procedure is to be performed hourly. Based upon her review of the plan, she decides the monitoring procedures and frequencies for this CCP are included in the HACCP plan.*

Monitoring Example 2*: An IPP is performing the Fully Cooked – Not Shelf Stable verification task and verifying the monitoring requirement for the metal detector CCP for the cubed breaded chicken product at the packing step. He reviews the HACCP plan, which specifies that monitoring personnel will observe the metal detector is properly functioning by passing the seeded sample through the metal detector and observing that the metal detector detects and rejects the seeded sample. The plan states that this monitoring procedure is to be performed hourly and results recorded. Based upon the IPP review of the plan, he decided the monitoring procedures and frequencies for this CCP are included in the HACCP plan.*

Reviewing HACCP Monitoring Records

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.

Monitoring Example 3*: An IPP is performing the Slaughter HACCP verification task and verifying the monitoring requirements for the steam pasteurization CCP. Reviewing the records, she finds that monitoring personnel have recorded temperatures hourly as per the HACCP plan for this CCP. She determines that the establishment is monitoring at the frequency stated for this CCP and is in compliance. She also verified that the critical limits were met.*

Note: When the establishment has a frequency of hourly listed for the monitoring activity, IPP should ask the establishment what hourly means. Hourly may mean on the clock hour (8:00 am, 9:00 am, etc.) on the average (could be a few minutes before or after the clock hour) or once during the clock hour (could be almost 2 hours between the monitoring activities). Therefore, monitoring records with results a few minutes before or after the clock hour would be acceptable when the frequency is hourly on the average stated in the HACCP plan.

Monitoring Example 4: *An IPP is performing the Heat Treated – Shelf Stable HACCP verification task at a dry sausage establishment and verifying the monitoring requirements for the fermentation CCP, using the recordkeeping component. Reviewing yesterday's records in the HACCP office, she finds that monitoring personnel have recorded the pH for 3 pieces of product from each smokehouse prior to initiating the cook cycle as per the HACCP plan for this CCP. All the recorded pH readings were below the required maximum pH. She determines that the establishment's monitoring frequency for this CCP is in compliance and that the critical limit is met.*

Monitoring Example 5*: An IPP is performing the Slaughter HACCP verification task and verifying the monitoring requirements for the steam pasteurization CCP. She observes the establishment monitoring personnel as they visually observe the temperature gauge on the steam cabinet and document the temperature on the record for the steam pasteurization CCP. From her observation, she determines that the establishment is in compliance with the monitoring procedure because it is performed as described in the HACCP plan.*

Monitoring Example 6*: While performing the Heat Treated – Shelf Stable HACCP verification task at a dry sausage establishment, the IPP decides to perform the review and observation component as part of her verification of the monitoring requirements for the fermentation CCP. The HACCP plan states that the pH of three pieces from each smokehouse will be measured at the completion of the fermentation cycle. The IPP observes the establishment monitoring personnel as they prepare each sample and use the pH meter to determine the pH for the three pieces of product from one smokehouse and document the results on the Fermentation records. From her observation, she determines that the establishment is in compliance with the monitoring requirement because the monitoring activity is performed as described 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.

Monitoring Example 7: *Continuing with the Slaughter HACCP verification task, from example 5 above, the IPP proceeds to the temperature gauges on the steam pasteurization cabinet and observes the temperature reading. She then compares her temperature reading with the temperature reading that was recorded by the establishment monitoring personnel. She determines that the establishment is in compliance because her temperature reading is within the critical limits and compares with the temperature reading that was recorded by establishment monitoring personnel.*

Monitoring Example 8: *An IPP is performing the Fully Cooked-Not Shelf Stable HACCP verification task at a hot dog operation, she proceeds to the smokehouse and takes 3 temperature readings, with the handheld thermometer provided by the establishment, as described in the HACCP plan. She then compares her temperature readings with the three temperature readings that were recorded by the smokehouse operator. She determines that the establishment is in compliance because her temperature readings are within the critical limits and her readings compare with the temperature readings recorded by establishment monitoring personnel.*

Noncompliance Examples with the Monitoring Requirement (but not limited to)

- The HACCP plan does not include a written monitoring procedure to ensure that product meets the critical limit at each CCP.
- The establishment is not conducting the monitoring procedures as written in the HACCP plan.
- The establishment did not implement the monitoring procedures at the frequencies specified in the HACCP plan.
- The IPP takes a measurement at a CCP and finds that the critical limit is not met.
- IPP observe a deviation from the critical limit that was not detected by the establishment monitoring procedure.

Monitoring Noncompliance Example 1: *The HACCP plan specifies that monitoring personnel will select three samples from different locations of each batch of product, blend/emulsify the sample, and measure the pH. While performing verification for the monitoring requirement, the IPP observes that the monitor took one sample. The establishment is not conducting the monitoring procedures as specified in the HACCP plan.*

Monitoring Noncompliance Example 2: *The HACCP plan specifies that the concentration of the organic acid beef carcass rinse will be monitored hourly by establishment personnel and recorded in the Pathogen Reduction Logbook. The IPP reviews the logbook and finds that the monitoring checks were recorded every 2 hours. Upon further inquiry, she determines that the monitoring checks were actually being performed every 2 hours. The establishment is not performing the monitoring procedures at the frequencies specified in the HACCP plan.*

Monitoring Noncompliance Example 3*: The HACCP plan specifies that the temperature inside the post lethality steam tunnel will be maintained at a minimum of 180ºF at the center of the tunnel. The IPP observes the temperature gauge on the side of the equipment and finds that it reads 177ºF. The critical limit for the CCP is not met.*

Monitoring Noncompliance Example 4: *An IPP is performing the poultry Slaughter HACCP verification task and verifying the establishment compliance with the monitoring requirements. The IPP proceeds to the establishment's management office and reviews the HACCP plan. The IPP finds that the establishment incorporated a chilling procedure into its HACCP plan and specifies that trisodium phosphate (TSP) will be used as a prechill antimicrobial spray, chlorine will be added to the chiller water and the post chill carcasses internal temperature will be measure. The critical limits values for those 3 CCPs consecutively are 9% concentration, 20 ppm concentration, and less than 40 F. All critical limits will be monitored hourly. The IPP*

reviews all the 3 CCPs monitoring records and finds that the monitoring checks for the chlorine concentration were not recorded in the past 3 hours. The IPP determines that the establishment is not performing the monitoring procedures at the frequencies specified in the HACCP plan.

2. 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) and 417.4(a)(2)(i), (ii) and (iii).

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.

Review Verification Records

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

Thought Process

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

Review the HACCP Plan

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

Verification Example 1*: An IPP is performing the Slaughter HACCP verification task in a poultry slaughter operation and verifying the establishment verification requirements for the chilling CCP. He reviews the establishment's HACCP plan and finds that it specifies verification personnel will review the temperature records and observe the monitoring procedures at this CCP once per shift. It also specifies that maintenance personnel will verify the accuracy of the temperature recording charts once per shift by taking an independent temperature check. Based upon his review of the HACCP plan, he determines that the establishment is in compliance with 417.2(c)(7) and 417.4(a)(2)(i)(ii)(iii).*

Verification Example 2: *An IPP is performing the Heat Treated – Shelf Stable HACCP verification task in a beef jerky operation. She reviews the establishment's HACCP plan and finds that it specifies quality control personnel will review the water activity records and observe the monitoring procedures at this CCP once per shift. It also specifies that quality control*

personnel will verify the accuracy of the water activity measuring equipment once per shift by performing a calibration check procedure. Based upon her review of the HACCP plan, she determines that the establishment is in compliance with 417.2(c)(7) and 417.4(a)(2)(i)(ii)(iii).

Verification Example 3: *An IPP is performing the Slaughter HACCP verification task in a very small sheep and goat slaughter operation and verifying the establishment verification requirements for the contamination (feces/ingesta/milk) CCP. She reviews the establishment's HACCP plan and finds that it does not provide for direct observation of monitoring procedures. She determines that the establishment only has one employee working on the slaughter floor and it would be impossible for direct observation of monitoring to take place. There is no noncompliance in this instance.*

Verification Example 4: *An IPP is performing the Raw-Intact HACCP verification task in a poultry cut-up operation and verifying the verification requirements for the finished product storage CCP. He reviews the establishment's HACCP plan and finds one of the verification procedures specifies the HACCP Coordinator will observe maintenance personnel perform the monitoring check once per shift. He reviews several recent room temperature logs and observe that the HACCP Coordinator has recorded results for the verification procedure for each shift. He determines that this requirement is in compliance because the verification procedures are being performed at the frequency specified in the HACCP plan.*

Verification Example 5: *An IPP is performing the Heat Treated – Shelf Stable HACCP verification task in a dry sausage operation and verifying the establishment's verification activities for the addition of an antimicrobial agent at the formulation CCP, using the recordkeeping component. He reviews the establishment's HACCP plan and finds that one of the verification procedures specifies the HACCP Coordinator will observe production personnel weighing and adding the antimicrobial agent to a batch of sausage once per shift. He reviews several recent formulation logs and observe that the HACCP Coordinator has recorded results for the verification procedure for each shift. The IPP determine that this requirement is in compliance because this verification procedure is being performed at the frequency specified in the HACCP plan. He realizes that this is just one of the verification activities.*

Assess Information

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

Observe Product Sampling

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

Verification Example 6: *Continuing with the Raw-Intact HACCP verification task at the poultry cut-up establishment, the IPP reviews of the establishment's HACCP plan revealed that the other verification procedure specified is that the HACCP Coordinator will check the accuracy of the finished product storage temperature monitoring equipment daily and adjust as necessary. He proceeds to the HACCP office, and observe the thermometers being checked for accuracy, and results being recorded on the thermometer calibration log. He determines that this*

requirement is in compliance because the verification procedure is being carried out as written in the HACCP plan.

Verification Example 7: *As part of the Heat Treated –Shelf Stable HACCP verification task, the IPP decides to observe the direct observation verification procedure. She notices that the HACCP Coordinator is in the packaging area, and watches while he observes the packaging personnel performing the monitoring check at the post lethality treatment CCP and records the result. The IPP determine that the direct observation verification procedure requirements are met.*

Verification Example 8: *An IPP is performing the Raw Non-Intact HACCP verification task in a raw ground beef operation and verifying the establishment verification requirements for the finished ground beef temperature CCP. She reviews the establishment's HACCP plan and finds one of the verification procedures specifies the establishment will conduct finished product testing for E. coli O157:H7 daily. She observes the HACCP Coordinator take the samples from the finished ground beef. She observes the production lot control procedures. She reviews several days' records in the laboratory-testing log and finds negative test results were recorded for each day. She determines that the establishment is in compliance because the verification procedures are being performed as described, and at the frequency stated.*

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 frequency set out in the HACCP plan?
- Directly observe any corrective actions that need to be taken.

Noncompliance Examples with the Verification Requirement (but not limited to)

The following are examples of noncompliance with the verification requirement (9 CFR 417.4(a)(2):

- The HACCP plan does not include written verification procedures and frequencies for calibration of any process monitoring instruments used to monitor the CCPs (also noncompliance with 9 CFR 417.2(c)(7)).

- The HACCP plan does not include written verification procedures and frequencies for direct observation of monitoring activities (also noncompliance with 9 CFR 417.2(c)(7)).

- The HACCP plan does not include written verification procedures and frequencies for review of records (also noncompliance with 9 CFR 417.2(c)(7)).

- Establishment employees do not implement the verification procedures at the frequencies specified in the HACCP plan.

- The HACCP plan does not include written description of additional verification procedures (if any) and frequencies the establishment uses to verify the effective implementation of the HACCP plan (e.g. microbiological sampling) (also noncompliance with 9 CFR 417.2(c)(7)).

- Establishment employees do not implement the verification procedures as written in the HACCP plan.

- The establishment verification employee does not actually observe the monitoring employee performing the monitoring procedure during the direct observation verification procedure.

- The verification results indicate that the establishment is not implementing the HACCP plan as written, and the establishment has not corrected the situation.

Verification Noncompliance Example 1: *The HACCP plan, which has one CCP at the product storage area, specifies that the verification procedure is that the QC supervisor will calibrate thermometers daily and that the QC supervisor will review the finished product room temperature logs daily. The IPP observes that there is no direct observation verification procedure listed for this HACCP plan. She recalls that the regulations require that all three verifications must be listed in the HACCP plan when they are applicable. One verification procedure, the direct observation, is missing.* ***The HACCP plan does not, at a minimum, list records review verification procedures; direct observation verification procedures; or calibration of process instruments verification procedures.***

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

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

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

Verification Noncompliance Example 5: *The HACCP plan specifies that one of the verification procedures for the product temperature CCP is that the QC supervisor will verify the accuracy and calibrate, if needed all handheld thermometers daily. The IPP observes that the QC supervisor verifies the accuracy of only about half of the thermometers. When the IPP asks, he is provided the explanation that "we have learned that checking every other thermometer is sufficient."* ***The establishment is not performing the process monitoring verification procedures as specified in the HACCP plan.***

Verification Noncompliance Example 6*: The HACCP plan specifies that one of the verification procedures is that finished product will be sampled and tested for Listeria monocytogenes once per day. When the IPP reviews the microbiology testing records, he observes that there are only results for two samples a week. When he asks about these results, he is told that the financial department required QC to cut back on the number of samples sent to outside labs.* ***The establishment is not performing one or more of the verification procedures listed in the HACCP plan at the frequencies specified in the HACCP plan.***

Noncompliance with the verification requirement is documented in PHIS as part of the HACCP verification task. If IPP find a verification noncompliance, they are to consider whether the noncompliance may have resulted in adulterated product entering commerce. For example, if the verification results show that establishment employees have not been implementing the monitoring procedure correctly, is there sufficient information to determine whether the product met the critical limit? If the establishment cannot demonstrate that the product met the critical limit, IPP are to take a regulatory control action on any affected product to prevent it from entering commerce. If adulterated product may have entered commerce, IPP are to contact their supervisor immediately to discuss the issue.

IPP document the HACCP verification task results in PHIS including any noncompliance.

3. Recordkeeping

Methodology

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).

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

- Verify compliance with 9 CFR 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.

Recordkeeping Example 1:

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 Thermometer Calibration log	HACCP Coordinator will review the Product Temperature Log and observe QC personnel performing monitoring once per shift.	Corrective actions shall meet all requirements of Part 417.3(a)

The establishment's HACCP plan identifies the "Product Temperature Log" as the record that the establishment uses to document product temperatures taken at the chilling step. The establishment is in compliance with 9 CFR 417.2(c)(6) because it has a recordkeeping system for documenting the monitoring activities at the CCP.

Recordkeeping Example 2*: The IPP is verifying the recordkeeping requirement while performing the Fully Cooked-Not Shelf Stable HACCP verification task at an egg roll operation. The IPP reviews the HACCP plan to verify that it provides for a recordkeeping system that documents the monitoring of critical control points and the IPP finds the following records listed for the cooking CCP: Egg Roll Temperature Record and Oil Temperature Chart. The IPP also reviews some Egg Roll Temperature Records and observes that monitoring personnel have recorded the time, product identification, temperatures, and initials. The record is dated to correspond with the day of the monitoring. Based upon the IPP review, the IPP determines that the establishment is in compliance with this part of the recordkeeping requirements of 417.2(c)(6) at this CCP.*

Recordkeeping Example 3: *An IPP is performing the HACCP verification task to verify the establishment recordkeeping requirements for the only CCP, product storage. He reviewed the establishment's HACCP plan and found that it lists the records used to document the monitoring of the critical control points, including the room temperature log, calibration log, and the corrective action log. He also found the monitoring procedure specifies that maintenance personnel observe the product storage area thermometer every two hours, and record results on the room temperature log. He reviewed the room temperature logs and observed that the maintenance personnel have recorded actual temperatures and times on the form and initialed each result. Based upon his review, he determined that the establishment is in compliance with this part of the recordkeeping requirements of 417.2(c)(6) at this CCP.*

Noncompliance Example 1*: An IPP is reviewing the HACCP monitoring log for the stabilization CCP in a sliced turkey bologna establishment and finds that monitoring personnel are placing a check mark on Chilling Log instead of the actual thermometer reading as specified in the*

HACCP plan. The monitoring personnel are not recording actual values as required in 417.2(c)(6).

***Noncompliance Example 2**: An IPP is reviewing the HACCP plan for a very small swine slaughter establishment, and he notices that there is a CCP for finished product storage, but the plan does not provide for any records for documenting the monitoring of cooler temperatures. The HACCP plan does not provide for a recordkeeping system that documents the monitoring of the CCP.*

HACCP Records Requirement

The regulatory requirement for HACCP records is 9 CFR 417.5(a)(3).

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

***Recordkeeping Example 4**: An IPP is performing the Slaughter HACCP verification task in a pork slaughter operation and as part of the task, he is verifying all requirements for all CCPs for a specific production. As part of his review, he examines all HACCP records produced. While verifying the recordkeeping requirement in 417.5(a)(3) for the pre-evisceration carcass rinse CCP. He reviews the HACCP records for this CCP and finds that the monitoring and verification personnel have made the following entries:*

Antimicrobial Intervention Log

Date	*Lot No.*	*Time*	*Solution Conc.*	*Pressure*	*Corrective Actions*	*Monitored by*	*Verified by **
2-1-2024	*1*	*0730*	*2.2%*	*30psi*	*-*	*TDM*	*PP*
**direct observation verification-results as per HACCP plan*							

*Based upon his records review, he determines that the establishment is in compliance with **this part** of the recordkeeping requirements of 417.5(a)(3).*

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

***Recordkeeping Example 5**: An IPP is performing the Raw Non-Intact HACCP verification task in a raw pork sausage operation and as part of the task, he is verifying all requirements for all CCPs for a specific production. As part of his review, he examines all HACCP records produced. He observes that each of the records includes actual values, the production code, and the product name, where applicable, and that each record includes the date. Based on his review, he decides that the establishment is in compliance with **this part** of the recordkeeping requirement.*

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

***Recordkeeping Example 6:** The IPP is performing the Heat Treated-Not Fully Cooked-Not Shelf Stable HACCP verification task in a smoked bacon operation and is verifying the recordkeeping requirement 417.5(a)(3) at the cooling CCP. The IPP selects the process-*

monitoring calibration records to review and finds that the establishment personnel have made the following entries:

Thermometer Calibration Log Calibrate to 32º F in slush ice water.

Date	*Time*	*Area*	*Thermometer ID*	*Personal Thermometer Reading*	*Adjustment Required*	*Initials*	*Comments*
2-1-2024	*0800*	*Belly Chilling*	*2A*	*32*	*No*	*TDM*	

Based upon her records review, she determines that the establishment is in compliance with ***this part*** *of the recordkeeping requirements for the cooling CCP. She would then proceed to verify the other recordkeeping requirements.*

Noncompliance Examples with the HACCP Records Requirement (but not limited to)

- Establishment monitoring records do not document all monitoring activities or do not include actual times, temperatures, or other quantifiable values.
- Establishment verification records do not document all verification activities or do not include the results of verification procedures.
- Establishment corrective action records do not document all corrective actions performed by the establishment.
- Establishment HACCP records (including pre-shipment review) do not include product names, product codes, or other identifying information sufficient to demonstrate which specific production is covered by a particular record.

Noncompliance Example 3: *An IPP is reviewing the monitoring records for the poultry TSP antimicrobial spray CCP and he finds there is no record of a monitoring procedure being performed in the last 3 hours. The HACCP plan specifies that monitoring at this CCP will take place on an hourly basis. He asks the establishment about these missing records. They provide a signed statement from the monitor stating that the monitoring took place, and that the results were within critical limits, but that the monitor neglected to write this on the record at the time it was done. The IPP concludes that the monitoring took place, but it was not recorded.* ***The records do not have the monitoring results recorded.***

Noncompliance Example 4*: An IPP is reviewing the poultry chiller CCP monitoring records and finds that the temperatures have been recorded on the monitoring log, but no times are recorded. Upon further investigation, she was provided evidence that the monitoring checks were performed at the proper times.* ***The records do not include the actual times that monitoring is performed.***

Noncompliance Example 5: *An IPP is reviewing the monitoring records for the carcass wash CCP in a poultry establishment, and he finds that the chlorine monitoring results are recorded simply as "O.K." instead of the actual value in ppm as described in the HACCP plan.* ***The records do not include the actual values as required.***

Noncompliance Example 6: *An IPP is reviewing the HACCP records for the finished product storage CCP in a small sheep slaughter operation, and she notices that the product temperature log does not record the lot number or product ID as is specified in the HACCP plan.* ***The monitoring entries do not include the product identification or code.***

Noncompliance Example 7: *An IPP is reviewing the verification records for the fermentation CCP in a large semi-dry sausage operation, and he notices that the verification results are being recorded once per day. The HACCP plan lists the frequency of this verification as twice per shift. The establishment provides other written evidence that the verification procedures were performed.* ***The verification procedures and results are not being recorded.***

Noncompliance Example 8: *An IPP is reviewing the corrective actions for the fecal CCP in a poultry slaughter operation, and he notices the establishment monitoring procedure at 0700 had a fecal finding and the following procedure at 0710 also had a fecal finding. He looks at the corrective action log and finds no record of any corrective actions. He requests more information, and the establishment provides satisfactory evidence that the corrective actions were performed but not recorded****. The corrective actions taken in response to a deviation from a critical limit are not recorded.***

Noncompliance Example 9*: An IPP is reviewing the chilling records for the stabilization CCP in a turkey bologna operation, and she finds that the calibration for the temperature-recording device had not been documented for the shift. The HACCP plan specifies that the calibration will be performed and recorded prior to the startup of every shift. She requests more information, and the establishment provides her with evidence that the calibration was performed.* ***The results of calibration of process monitoring instruments are not recorded.***

Records Authenticity

The regulatory requirement for record authenticity is 9 CFR 417.5(b).

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.

Recordkeeping Example 7*: The IPP is performing the Heat Treated-Not Fully Cooked-Not Shelf Stable HACCP verification task in a smoked pork chop operation and is verifying the recordkeeping requirements for the cooling (stabilization) CCP. While reviewing the establishment's HACCP plan, he sees that the verification procedure states that QC personnel will observe the monitor conduct the monitoring activities twice per shift. He looks at the chilling record being completed on the shift and QC has made one direct observation entry. The entry includes the time that the direct observation was performed; the monitoring was being conducted as per the HACCP plan, and initials of the verifier. The monitoring entries on the form included product ID, time, actual temperatures, initials, and date the data was recorded. He notices that the verifier is in the area, so he remains in the area and observes that the QC employee performs the second monitoring direct observation verification and records the results at the time of the verification. He determines that this part of the recordkeeping requirement is in compliance because the entries are made at the time the event occurs, each entry includes the time, the form includes the date, and each entry is initialed.*

Noncompliance Examples with HACCP Record Authenticity (but not limited to)

- Establishment employees do not make entries in HACCP records at the time that specific events occur.
  Note: Some establishments may choose to record HACCP results on "scratch paper" or a "note pad" and then transfer the results to a clean record at a later time (significantly after

the event occurred which is allowed, but the original paper has to be maintained as part of the record).

- Establishment records do not clearly state the date and time when each entry was made
- Establishment employees do not sign or initial their entries in HACCP records.

Noncompliance Example 10: *The HACCP plan has a monitoring procedure for checking temperature of incoming trimmings by checking 2 combos from each truck with a long-stem thermometer. An IPP observes this record:*

Incoming trimmings log			Critical limit = 38 F or lower			Date: 2-8-24	
Truck ID	Truck condition	Combo ID	Source	Tracking #	Temp	Time	Monitor initials
138	A	-981	Bexel	380001	34	4:56 am	JP
138	A	-982	Bexel	380002	34	5:05 am	JP
8526	B	-020	Donfort	380003	36	7:20 am	GM
8526	B	-021	Donfort	380004	✓		

He observes the next truck unloaded. The establishment employee "GM" performs the monitoring procedure on the combo bins and does not enter the results on the form until much later in the day. He determines that there is a recordkeeping noncompliance. ***One entry on the record does not contain the time the event occurred or the temperature. The records do not include the signature or initials of the person performing the activity. Results are not being recorded when the events occur.***

IPP document the HACCP verification task results in PHIS including any noncompliance.

Computerized Records

The regulatory requirement for computerized records is 9 CFR 417.5(d).

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

Recordkeeping Example 8: *An establishment enters all HACCP activity results into hand-held computer devices. Network access is for QA employees only. Each employee has a unique login name and password that is kept secure. Passwords are changed periodically. Once an entry is made, it is saved as read-only, and cannot be changed.*

Noncompliance Example 11: *The establishment uses a computer-based system to monitor and record the temperatures in all processing rooms, coolers, and chillers. The IPP requests information about the controls that the establishment has in place to ensure the integrity of the record. The establishment manager provides him with a record showing that all of the establishment's employees can access the records without any restriction. The IPP asks the*

establishment manager if the establishment has any controls in place to ensure that record integrity is not compromised and the establishment manager replies, "No one will do anything to the records that will never happen".

The establishment does not have controls in place to ensure the integrity of the electronic records.

Noncompliance Example 12: *The establishment uses a computer-based system to monitor and record the temperatures in all processing rooms, coolers, and chillers. The IPP observes that on a warm day a processing room employee adjusts the computer settings so that the alarm will not keep going off. The IPP observes that the passwords are prominently posted near the computer station. The establishment has controls to ensure the integrity of the electronic records but is not following those controls. The passwords are not kept secure.*

Record Retention

The regulatory requirements for record retention and off-site storage of records are 9 CFR 417.5(e)(1) and (2).

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

Recordkeeping Example 9: *On January 10, 2024, at 1:30 pm, the IPP performed the Heat Treated-Not Fully Cooked-Not Shelf Stable HACCP verification task in a small bacon processing establishment. The establishment has 2 critical control points: CCP 1 to monitor the critical limit of the amount of sodium nitrite added to the formulation, and CCP 2 for the storage temperature of final product. As part of the procedure, the IPP verified the establishment's compliance with the records maintenance requirements. She asked the establishment to provide her with CCP 1 and CCP 2 monitoring, verification, and corrective action records for February 6th of 2023 and November 10th of 2023. The establishment provided her with November's records and informed her that February's records are stored off-site. February's records were provided to the IPP on January 11th at 8.00 am.*

Noncompliance examples with Records Retention and Availability (but not limited to)

- HACCP records are not kept on-site for 6 months
- HACCP records are not maintained for the required amount of time
- A HACCP record stored off-site cannot be retrieved within 24 hours of the CSI request.

Noncompliance Example 13: *In October, the IPP asks the establishment to provide a sample of the fecal CCP monitoring log records from last January. They give him a folder that contains February's records. He asks the establishment about January's records, and they tell him they had to clean out the files because they were getting too full. The establishment cannot produce January's records****. The establishment is not maintaining records for the required length of time.***

Noncompliance Example 14*: In October, the IPP is reviewing the establishment HACCP records for the Lm sampling component of the post-lethality treatment CCP in a large deli product establishment. She suspects the establishment is not maintaining testing records on-site. She discusses this with her frontline supervisor and then she asks the establishment for the records from May. They tell the IPP that they can give her the records for the past month, but*

they will have to retrieve any other month's records from the corporate headquarters 500 miles away. ***The records are not being maintained on-site for 6 months.***

Noncompliance Example 15*: An IPP is newly assigned to a large deli product establishment and is performing records maintenance verification as part of the Fully Cooked-Not shelf Stable HACCP verification task. He wonders about whether the establishment is able to retrieve records stored off-site and discusses this with his supervisor. He decides to ask the establishment to provide a sample of records from 7 months in the past. Management tells him that after 6 months they store them at corporate headquarters. He requests that the establishment retrieve 2 days of records from corporate headquarters. He receives the records 5 days later****.* ***The establishment cannot retrieve the records within 24 hours when stored off-site.***

Official Review Records

The regulatory requirement for making establishment records available to IPP upon request for official review is 9 CFR 417.5(f).

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

Recordkeeping Example 10*: A relief IPP assigned to a large poultry slaughter establishment is verifying the establishment's compliance with making records available for official review as part of the Slaughter HACCP verification task. He asks the establishment manager to provide him with the HACCP plan, hazard analysis and support documentation records. The establishment manager informs the IPP that they keep all HACCP records in a lock cabinet in his office. The establishment manager opens the locked cabinet and gives the IPP access to the records.* ***The IPP determines that the establishment is in compliance with 9 CFR 417.5(f) of the*** *recordkeeping requirements.*

Noncompliance Example 16*: An IPP is assigned to 2nd shift in a large smoked pork chop processing establishment. While he was performing the Heat Treated-Not Fully Cooked-Not Shelf Stable HACCP verification task, he needed to access the establishment monitoring records to verify the monitoring requirement for the cooling (stabilization) CCP. The IPP asked the smokehouse supervisor to provide him with the monitoring records. The smokehouse supervisor informed him that all of the monitoring records were locked in the HACCP manager's office. The manager is available only during the day shift.* ***This is noncompliance with 417.5(f) because the records are not available for official review.***

Noncompliance Example 17*: An IPP was performing the Slaughter HACCP verification task. As part of her verification activities, she needed to review the HACCP plan. The establishment uses a computer-based system to electronically store the HACCP plan, hazard analysis, support documentation and all HACCP system records. When the IPP asked the establishment owner to provide her with access to the records, he stated that "we have very high-security computer systems the only person who can access the system is Mr. John Hunt who is sick today".* ***This is a noncompliance with 417.5(f) because the records are not available for official review.***

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).

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.

Methodology

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

RLTO: 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.

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.

Prerequisite Program Example 1*: An IPP is reviewing the hazard analysis in a raw ground beef patty operation during the performance of the Raw Non-Intact HACCP verification task. She observes that at the receiving step the establishment has identified that there is a physical food safety hazard, "foreign material," but determined that it was not reasonably likely to occur, on the basis that "establishment records show that there has been no incidence of foreign materials in products received in the establishment." She decides to request the supporting*

documentation for this decision. The establishment provides a copy of a procedure for physical examination of raw materials at receiving.

Prerequisite Program Example 2: *An IPP is reviewing the hazard analysis in a raw ground beef patty operation during the performance of the Raw Non-Intact HACCP verification task. He observes at the raw material storage step that the establishment is implementing a temperature control prerequisite program to maintain the internal product temperature below 42°F to support that the hazard of pathogen growth is not reasonably likely to occur. He decides to request the supporting documentation for this decision. The establishment provides a copy of the procedures for measuring product temperature and recording results.*

Prerequisite Program Example 3*: An IPP is reviewing the hazard analysis in a poultry slaughter operation during the performance of the slaughter HACCP verification task. She observes at the carcass chilling step that the establishment is implementing a carcass chilling prerequisite program to support that the hazard of pathogen growth is not reasonably likely to occur. She decides to request the supporting documentation for this decision. The establishment provides a copy of the chilling procedures and all related records.*

Prerequisite Program Example 1a: *Continuing with the example 1 above, the IPP requests completed raw material examination records for the trimmings that were used in the specific production she has selected. She reviews the records and finds there are no entries that would represent a foreign material hazard. She determines that the establishment in compliance with 9 CFR 417.5(a)(1) because it is implementing the program in a manner that supports the hazard analysis decision and the records generated from the program show that the relevant hazard is not reasonably likely to occur on an ongoing basis.*

Prerequisite Program Example 2a*: Continuing with example 2 above, the IPP knows that a specific production is an 8-hour shift's production and the temperature control procedure states that the internal temperature of product will be measured at the grinding step three times a day. He decides to review internal product temperature record that is on a table next to the grinder for the day's shift. He notices that the establishment employee did not record a time for the second temperature measurement as specified in the written program. The temperature result is 39°F. He realizes that this minor failure to follow the program would not represent a failure to support the hazard analysis because the temperature result is less than 42°F.*

Prerequisite Program Example 2b: *Continuing with example 2a above, the IPP is in the production room and notices that an establishment employee is going to take the last product temperature of the shift at the grinding step. He stops to observe the employee taking the measurement. The establishment employee measures the product temperature as written in the program and documents the result. The IPP decides to observe the temperature result that the employee recorded. The product temperature result is 40°F and the time of the measurement is recorded. Based on these observations, he determines that the establishment in compliance with 9 CFR 417.5(a)(1) because it is implementing the program in a manner that supports the hazard analysis decision and the records generated from the program show that relevant hazard is not reasonably likely to occur on an ongoing basis.*

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).

Noncompliance Examples with the Supporting Documentation Requirement When Using a Prerequisite Program or Other Supporting Program (but not limited to)

- The establishment employees are not implementing the procedures in the prerequisite program sufficiently to continue to support that the relevant hazard is not reasonably likely to occur.
- The prerequisite program records indicate consistent or repeated failures to implement the procedures that are used to support the decision in the hazard analysis that the relevant hazard is not reasonably likely to occur.
- The prerequisite program records do not demonstrate that the program continues to support the decision in the hazard analysis that the relevant hazard is not reasonably likely to occur.

Noncompliance Example 1*: An IPP is performing a Slaughter HACCP verification task in an establishment that slaughters 30 months of age and older cattle. While performing the task, he observes spinal cord on a carcass that passed through the establishment's spinal cord removal step. The establishment has a prerequisite program for SRMs removal to support their decision in the Hazard analysis that SRMs are not reasonably likely to occur, the program states that all spinal cords must be removed at the spinal cord removal step, you had a meeting with the establishment's manager yesterday about their less than perfect implementation of the SRMs removal prerequisite program multiple times over the last few weeks.* ***The finding would represent noncompliance with 9 CFR 310.22(c) and (e) because the establishment has failed to implement its procedures for removal of SRMs. This finding would call into question the establishment's decision SRM is not reasonably likely to occur.*** *The IPP decided to discuss this noncompliance with his supervisor to identify further enforcement actions.*

Noncompliance Example 2: *An IPP is performing the Slaughter HACCP verification task to verify that an establishment is in compliance with 9 CFR 417.5(a)(1). She reviews the hazard analysis and finds that the establishment implements a prerequisite program for the specified risk materials to support that the hazard of SRM is not reasonably likely to occur. The prerequisite program states that all of the specified risk materials will be removed from the carcasses at different SRM removal stations. This procedure is implemented throughout the processing steps to ensure the absence of all of the SRM from edible products before boxing.*

The establishment will have 5 SRM removal stations.

- *Station one (located in the kill floor next to the head inspection area): the establishment's trained employee will remove the palatine and the lingual tonsils from the head and the tongue.*

- *Station two (located in the auger room): the establishment's trained employee will remove the brain by a suction apparatus and dispose the skull in the marked SRM containers.*

- *Station three (located in the kill floor after the viscera inspection): The entire intestine including the distal ileum will be condemned and disposed in the marked SRM containers.*

- *Station four (located on the kill floor before the final trim rail): the spinal cord will be removed entirely by specified marked tools (orange handle).*

- *Station five (located in the boning room): the vertebral column will be removed by specified marked tools (orange handle) and disposed of in the marked SRM containers.*

All SRM will be destroyed through denaturing with a formula consisting of one part FD&C No. 3 green coloring, 40 part water, 40 parts liquid detergent, and 40 parts oil of citronella.

The establishment employees who are assigned to the SRM stations will be trained on the SRM removal procedure (the procedure is attached to the prerequisite program file).

The establishment will maintain daily records to document the implementation and the monitoring of the procedures for the removal, segregation, disposition of the SRM, and any corrective actions taken.

The QC supervisors will monitor the effectiveness of the SRM removal at all of the SRM removal stations twice per day (per station), and log the monitoring time, and sign. This information will be documented on the prerequisite program record Form A.

The establishment will maintain daily records to document the absence of SRM from the edible products. This will be done by the QC supervisor who will randomly check 20 hanging carcasses in the cooler and open, examine 4 boxes of finished products. This check will be done twice per day. The first check should be done before 11.30 am, and the second check should be done after 11.30 am and before 2.30 pm. This information will be documented on the prerequisite program record Form B.

If the QC supervisor observes any errors in implementing the program or observes any identifiable SRM on edible product, all corrective action steps should be followed (a copy of the corrective action steps is attached to the prerequisite program file).

Prerequisite program form A					
Date	*Station #*	*Time*	*finding*	*Corrective actions*	*signature*
01-01-2024	*1*	*6 am*	*No finding*	*N/A*	*JOHN SMITH*
01-01-2024	*1*	*11.30 am*			
01-01-2024	*2*	*6.30 am*			
01-01-2024	*2*	*12.30 pm*			
01-01-2024	*3*	*7.00 am*	*No finding*		*JOHN SMITH*
01-01-2024	*3*	*1.00 pm*			
01-01-2024	*4*	*7.30 am*			
01-01-2024	*4*	*1.30 am*			
01-01-2024	*5*	*8.00 am*			
01-01-2024	*5*	*2.00 pm*	*No finding*		*JOHN SMITH*

Prerequisite program form A					
Date	*Station #*	*Time*	*finding*	*Corrective actions*	*signature*

01-05-2024	*1*	*6 am*	*No finding*	*N/A*	*JOHN SMITH*
01-05-2024	*1*	*11.30 am*			
01-05-2024	*2*	*6.30 am*			
01-05-2024	*2*	*12.30 pm*			
01-05-2024	*3*	*7.00 am*	*No finding*	*N/A*	*JOHN SMITH*
01-05-2024	*3*	*1.00 pm*			
01-05-2024	*4*	*7.30 am*			
01-05-2024	*4*	*1.30 am*			
01-05-2024	*5*	*8.00 am*			
01-05-2024	*5*	*2.00 pm*			

The IPP asked the establishment manager if he has the rest of the prerequisite program records, he replied, "These are all of the records I have." The IPP subsequently went to the kill floor and found that the establishment had 5 SRM stations, but 2 stations did not have any employees on location. ***This finding would call into question the establishment's decision SRM is not reasonably likely to occur. The finding would represent noncompliance with 9 CFR 417.5(a) (1) because the establishment does not have the records specified in the prerequisite program to support that SRM would not be a hazard reasonably likely to occur and 9 CFR 310.22(c)and (e) because the establishment has failed to implement its procedures for removal of SRMs.*** *The IPP decided to discuss this noncompliance with her supervisor to identify further enforcement actions.*

Noncompliance Example 3*: An IPP is reviewing the hazard analysis in a small fully cooked ham operation, during the performance of the Fully Cooked-Not Shelf Stable HACCP verification task. He observes at the raw material storage step that the establishment is implementing a temperature control prerequisite program to maintain the internal product temperature below 42°F to support that the hazard of pathogen growth is not reasonably likely to occur. The IPP asked the establishment manager to provide him with all prerequisite program records for the past 5 days, which includes the day the specific production was produced. While reviewing the records the IPP finds that the temperature results for the last three days are missing. The IPP asked the establishment manager if the temperatures were taken for those days according to the prerequisite program procedures, he replied, "The establishment employee that is responsible for implementing the prerequisite program was out sick and I didn't have another employee to perform this program". The IPP asked the establishment manager to provide him with the records from the last 15 days. After reviewing the records and discussing the issue with the establishment manager, the IPP finds that the establishment did not follow the temperature control program 10 days out of the last 15 days****. The finding would represent noncompliance with 9 CFR 417.5(a) (1) because the establishment does not have the records specified in the prerequisite program to support that the hazard of pathogen growth would not be a hazard reasonably likely to occur. This finding would call into question the establishment's decision that the hazard of pathogen growth is not reasonably likely to occur. The IPP decided to discuss this noncompliance with his supervisor to identify further enforcement actions.***

4. Corrective Actions

Establishment must implement the corrective actions when:

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

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) and 9 CFR Part 417.3(b).

Corrective Action Example 1, Part 1*: Upon arrival at a raw ground beef patty operation establishment on an IPP patrol assignment at 10:30 am, the IPP is notified by the establishment management that there has been a deviation of the metal detection critical limit. He thanks the establishment manager for voluntarily notifying him about this situation. He knows that he must verify that the corrective action requirements are met and realizes he could do this by performing the review and observation component of the Raw Non-intact HACCP verification task. He reviews the establishment's HACCP plan and finds that the monitoring procedure is that the packaging line supervisor will check the metal detector using a seeded sample every two hours to determine that the metal detector is functioning, that results are recorded on the metal detection control log, and that corrective actions are recorded on the corrective action log. He finds that the corrective actions are "all parts of 417.3 will be met." He proceeds to the production area and reviews the metal detection control log, and finds the deviation noted at the 10:04 am monitoring check. The form notes that the equipment failed to detect the seeded sample. He notes that the form states that at the 8:00 check the equipment was operating properly. He observes that the establishment has product identified and segregated. He inspects the amount and the codes of segregated product and compares them to the codes on the monitoring record. He asks the packaging line supervisor about the segregation of product and is informed that all products produced after the 8:00 am check has been identified and segregated. He determines that the establishment has segregated the appropriate affected product.*

Corrective Action Example 1, Part 2*: Continuing with the above example, the IPP continues to observe the establishment's actions in the production area. He observes that production has stopped. Maintenance employees are working on the metal detector, which is then removed from the area. The packaging line supervisor reports to him that the unit is malfunctioning, and that it will not be used until it is repaired. Later, the establishment informs him that the cause of the deviation was that water got into the machine during cleanup. They establish a new SOP for removing the machine from the area during wet cleanup. Based on these observations, he determines that the establishment has identified and eliminated the cause of the deviation.*

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

Corrective Action Example 1, Part 3: *Continuing with the above example, the IPP continues to observe the establishment's actions in the production area. The establishment brings in a replacement unit for the metal detector. The packaging line supervisor checks the replacement unit with the seeded sample, and the equipment responds appropriately. The IPP observes production resume. The packaging line supervisor notifies him that they will perform the monitoring checks at an increased frequency of once per hour for one week. Based on these observations, he determines that the establishment has the CCP under control. He would observe the execution of corrective actions to verify that the establishment prevents product that is injurious to health or otherwise adulterated, as a result of this deviation, from entering commerce.*

Corrective Action Example 1, Part 4*: Continuing with the above example, the IPP returns to the production area. He observes a monitoring check on the metal detector. Next, he observes as the establishment begins to run the segregated product through the metal detector. No metal is detected, and the packaging line supervisor releases the segregated product. Based on these observations, he determines that the establishment has prevented product that is injurious to health or otherwise adulterated, as a result of this deviation, from entering commerce. He would observe the execution of corrective actions to verify that preventive measures are established.*

Corrective Action Example 1, Part 5*: Continuing with the above example, it is now about two weeks since the deviation. The IPP reviews the establishment's HACCP plan and finds that a verification procedure has been added, "make an observation that the machine has been placed in a dry room during cleanup". He goes to the production area. He notices that the original metal detector, the one that malfunctioned, is back in place. He observes that the metal detector appears to be working. He reviews the monitoring records and observes that the monitoring had been done at the increased frequency for one week, as proposed. Later, he observes that the machine is removed to a dry room during cleanup. Based on these observations, he determines that the establishment has established preventive measures.*

CCP	Critical Limit	Monitoring	Verification	Records	Corrective Action
CCP 3 *Cooling*	*Product internal temperature reduced from 130°F to 80°F in less than 1.5 hours and from 80°F to 40°F in less than 5 hours.*	*Product internal temperature will be monitored continuously throughout process using recording chart temperature probes. The two pieces of product that are monitored will be visually selected by QC to represent largest pieces in the lot.*	*Daily, QC Supervisor will review cooling temperature. chart*	*Cooling temperature chart* *Calibration log* *Corrective action log*	*All parts of 417.3 will be met.*

Corrective Action Example 2, Part 1 *- The IPP arrives at an establishment, which produces roast beef and is notified that an internal product temperature deviation occurred at the cooling CCP. The IPP begins the corrective action verification by reviewing the HACCP plan.*

Next, the IPP reviews the cooling temperature chart. The first part of the critical limit was met, but the product took 6 hours to reduce from 80°F to 40°F. The IPP observes that the product has been moved to the storage cooler and is held and segregated by QC.

Note: IPP are to verify that the establishment applies corrective actions to all product affected by the deviation. IPP must consider how the establishment defined the affected product and verify that additional products are not implicated by the deviation hazard. IPP must consider any available information about the establishment process that could indicate whether additional product was affected. These sources of information may include:

- Other establishment HACCP monitoring or verification records,
- SSOP records,
- Establishment testing results, and
- The records of any related prerequisite programs.

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

Corrective Action Example 2, Part 2 *- verifying 417.3(a)(1): Continuing, the IPP observes that maintenance employees are working on the cooling unit. The maintenance supervisor reports that one of the motors burned out and is being replaced. The IPP determines that the establishment has identified and eliminated the cause of the deviation.*

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

Corrective Action Example 2, Part 3 *- verifying 417.3(a) (2): Continuing, the IPP observes that the cooler unit is returned to production. The QC Supervisor reports QC will observe the cooler temperature every hour through a complete cooling cycle, in addition to product temperature. The IPP determines that the CCP is under control.*

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

Corrective Action Example 2, Part 4 *- verifying 417.3(a)(3): Continuing, the QC Supervisor reports that the HACCP plan is being modified to include a verification procedure for checking the cooler temperatures. The IPP reviews the HACCP plan. Verification has been modified to include: "Once per cooling cycle, QC will check cooler temperature." Additionally, the QC Supervisor informs the IPP that a new maintenance SOP has been established, to check cooler unit operation monthly. The IPP determines that the establishment has established preventive measures.*

The IPP would observe the execution of corrective actions to verify that the establishment prevents product that is injurious to health or otherwise adulterated, as a result of this deviation, from entering commerce. Additionally, in reviewing the corrective action records, the IPP should compare the establishment's recorded corrective actions with the requirements of 417.3(a).

Corrective Action Example 2, Part 5 *- verifying 417.3(a)(4): Continuing with example 2, the establishment has held and segregated the affected product, and provided a processing authority with its cooling data points (time/temperature combinations) for the deviation. The processing authority has plotted the data into a pathogen-modeling program and used other scientific literature to determine that there would be no outgrowth of Clostridium botulinum and no more than one log increase in Clostridium perfringens, based on the cooling curve that the product experienced. The report from the processing authority, which indicates that the product is safe for distribution, is attached to the corrective action log. The IPP determines that the establishment has prevented product that is injurious to health or otherwise adulterated, as a result of this deviation, from entering commerce. The IPP determines that the requirements for 417.3(a) have been met. The IPP verifies all the regulatory requirements at all CCPs for that specific production, determines that the establishment has carried out the pre-shipment review for that particular specific production, and records the results in PHIS as a directed Fully Cooked-Not Shelf Stable HACCP verification task.*

Note: Though this procedure would probably be entered as a directed HACCP Verification task, it is possible that the IPP could have already has a routine HACCP verification task in progress on this specific production. In that case, the entry would be made in the in-progress routine HACCP verification task.

Reviewing the Corrective Action Records

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

Corrective Action Example 1, Part 6*: Continuing with example 1, the IPP reviews the establishment's corrective action log for this deviation. He compares the recorded corrective actions with what he has observed, and with the requirements of 417.3(a), and finds that all requirements were met The establishment identified and eliminated the cause of the deviation, the CCP was under control after the corrective action was taken, measures to prevent recurrence were established, and no product that is injurious to health or otherwise adulterated, as a result of the deviation, entered commerce. The IPP observes the record that shows the proposed maintenance repairs were performed. He determines that this requirement is met.*

Corrective Action Example 3, Part 1*: An IPP is performing the Slaughter HACCP verification task in a poultry slaughter establishment. She finds that an event has occurred earlier in the shift, in which the establishment monitoring personnel found metal shavings on the carcasses exiting from the chill system. The establishment decided that the metal would constitute a food safety hazard. The establishment has no CCP for metal contaminants in the chill system. She reviews the corrective action log dated 2-1-2024 and finds the following entry for this incident: All carcasses exiting the chill system held by QA in vats and placed in the cooler. Carcasses were visually examined by production personnel for the presence of metal. Metal shavings were removed from affected carcasses. All carcasses will be deboned and resulting product run through a metal detector system. The HACCP plan will be reassessed by 2-3-2024. Based upon her review of the records, she determines that the recorded actions meet the requirements of 417.3(b).*

Corrective Action Example 3, Part 2: *Continuing from the previous example in which there were metal shavings on the product, the IPP verifies that the establishment segregates and holds the affected product by going to the chiller and the cooler to observe the product. At the chiller, she finds no product exiting the chiller since operations ceased an hour earlier. She finds*

the affected product held by a QA tag and segregated in the cooler. Based upon her observations, she determines that the establishment has adequately held and segregated affected product. She would observe the establishment evaluating the affected product to verify that only acceptable product is released.

Corrective Action Example 3, Part 3: *Continuing from the previous example in which there were metal shavings on the product, the IPP observes the establishment examine and remove the metal contaminants, debone the carcasses, and run the boneless product through a metal detector. Upon completion of the establishment's corrective actions, she inspects several samples of boneless product and finds no trace of metal contamination. Based upon her observations the establishment took necessary measures to ensure that only acceptable product was released.*

Corrective Action Example 4*: During a Raw Non-intact HACCP verification task and while reviewing the establishment's HACCP plan for raw ground beef, the IPP observes a notation that the HACCP plan has been reassessed, and updates made. She further observes that the establishment has added a CCP at receiving that reads, "E. coli O157:H7 in raw beef trimmings". The critical limit is that suppliers must provide certification that products have been subjected to a validated antimicrobial carcass treatment. She decides to investigate further and asks for more information, and any supporting documentation, from establishment management. She learns that this reassessment was conducted as a result of an unforeseen hazard. She is shown a laboratory test result that the establishment conducted on finished product, which came back positive for E. coli O157:H7.*

This is the first positive result for this organism. The corrective action log shows that all corrective actions were met, and product was diverted for cooking. The IPP was shown a record documenting the reassessment, which states that because of the positive result the establishment determined that E. coli O157:H7 was now considered "reasonably likely to occur" and therefore this update was made to the hazard analysis and the HACCP plan was modified. The IPP determines that the establishment has met its requirement to perform reassessment when an unforeseen hazard arises and to determine whether the unforeseen hazard should be incorporated into the HACCP plan. She determines that the establishment is in compliance with 9 CFR 417.3(b) and 417.4(a)(3)(ii).

Noncompliance Examples with the Corrective Action Requirements (but not limited to)

One or more of the following findings is evidence that the establishment does not comply with 9 CFR 417.3(a):

- The establishment does not implement corrective actions as specified in the HACCP plan in response to a deviation from a critical limit.
- The establishment's corrective action does not identify and eliminate the cause of the deviation.
- The establishment's corrective action does not result in the CCP coming back under control.
- The establishment's corrective action does not prevent adulterated product from entering commerce.
- The establishment's corrective action does not prevent recurrence of the deviation.

Noncompliance Examples with the Corrective Action Requirements (but not limited to)

One or more of the following findings is evidence that the establishment does not comply with 9 CFR 417.3(b):

- An unforeseen hazard occurs or there is a deviation not covered by a specified corrective action and the establishment fails to take the corrective actions required by 9 CFR 417.3(b).
- The establishment's corrective action does not segregate and hold all affected product.
- The establishment does not perform a review to determine the acceptability of the affected product.
- The establishment's corrective action does not prevent adulterated product from entering commerce.
- The establishment does not reassess the relevant HACCP plan to determine whether to address the unforeseen hazard

The following are examples of noncompliance with 417.3(a):

Noncompliance Example 1, Part 1*: An IPP is reviewing monitoring records for the TSP CCP in a poultry slaughter operation, and he finds that at 0800 the recorded TSP concentration was below the critical limit of 8%. She proceeds to verify that corrective actions were taken as required in 417.3(a) by reviewing an excerpt from the entries in the corrective action log, which reads as follows:*

"TSP concentration control dial was increased to 9% at 0805. Chlorine in the chiller was increased from 20 to 40 ppm and the post-chill chlorinated rinse cabinets were turned on at 0810."

These actions are consistent with the corrective actions regulations, but she finds no documentation and observes no evidence that the establishment attempted to ***identify the cause of the deviation from the critical limit.***

Noncompliance Example 1, Part 2: *Continuing from the example above, the establishment later documents that the deviation from the critical limit was due to a defect in the electronic apparatus that controls the TSP concentration. She finds no record and no evidence that the establishment took any actions to repair or replace the electronic device.* ***The establishment identified the cause of the deviation from the critical limit but did not take appropriate actions to eliminate the cause.***

Noncompliance Example 1, Part 3: *Continuing the example above, she reviews the corrective action records again and finds that there was no follow-up measurement to verify that the TSP concentration was above the critical limit of 8% after the electronic control was turned up to 9%.* ***The establishment did not implement appropriate measures to ensure the CCP was under control after the actions were taken.***

Noncompliance Example 1, Part 4: *Continuing the example above, if the establishment had not implemented the measures of increasing the chiller chlorination and turning on the chlorinated rinse cabinets, it could be assumed that* ***the establishment did not take measures to ensure that no product injurious to health or otherwise adulterated enters commerce.***

Noncompliance Example 2, Part 1*: An IPP is reviewing monitoring records for the post-packaged pasteurization CCP in a sliced turkey bologna operation, and she finds that at 0800 the recorded pasteurization temperature was below the minimum critical limit of 475ºF. She proceeds to verify that corrective actions were taken as required in 417.3(a) by reviewing an excerpt from the entries in the corrective action log, which reads as follows:*

"The air temperature was increased to 575ºF at 0805". She finds no documentation and observes no evidence that the establishment attempted to ***identify the cause of the deviation from the critical limit.***

Noncompliance Example 2, Part 2*: Continuing with this example, the establishment later documents that the deviation from the critical limit was due to a defect in the electronic device that controls the oven air temperature. The IPP finds no record and no evidence that the establishment took any actions to repair or replace the electronic device.* ***The establishment identified the cause of the deviation from the critical limit but did not take appropriate actions to eliminate the cause.***

Noncompliance Example 2, Part 3*: Continuing with this example, she reviews the corrective action records again and finds that there was no follow-up measurement to verify that the air temperature was above the critical limit of 475ºF after the electronic control was turned up to 575ºF.* ***The establishment did not implement appropriate measures to ensure the CCP was under control after the actions were taken.***

Noncompliance Example 2, Part 4: *Continuing with this example, the establishment had not identified the affected product that went through the process while the temperature was below 475ºF and did not reprocess the affected product after increasing the air temperature to 575ºF.* ***The establishment did not take measures to ensure that no product injurious to health or otherwise adulterated enters commerce.***

The following are examples of noncompliance with 417.3(b):

Noncompliance Example 1, Part 1*: Continuing from our above example in which metal shavings were found on carcasses coming out of the poultry chiller, if the IPP found product in the cooler with metal shavings that the establishment had not held, she would conclude* ***that all affected product was not held.***

Noncompliance Example 1, Part 2*: If the personnel collecting the birds coming out of the chill system had misunderstood which chiller was affected and held product from the wrong chill system, the establishment would have* ***held product, but it would not be the affected product****.*

Noncompliance Example 1, Part 3: *If the establishment did not thoroughly examine the product and pass the deboned product through a metal detector, the establishment* ***did not evaluate the product to determine whether it was acceptable for distribution.***

Noncompliance Example 1, Part 4: *If the establishment found metal in the product after corrective actions were completed and did not hold the product,* ***the establishment did not take necessary action to ensure that no product injurious to health enters commerce****.*

Noncompliance Example 1, Part 5*: If the establishment* ***did not perform a HACCP plan reassessment*** *after the unforeseen hazard event, it would not be in compliance with 9 CFR 417.3(b).*

Noncompliance Example 2: *An IPP is performing the Raw Non-Intact HACCP verification task in a small beef grinding operation and he is verifying the establishment recordkeeping requirements for all CCPs. He reviews a recent corrective action log that documents a large fecal smear observed on the boneless bull meat chucks as they were being prepared for grinding. Currently, the establishment does not have a CCP for visual observation of raw*

materials. Under preventive measures on the corrective action log, "none needed" is recorded. He asks whether they considered this an unforeseen hazard, and whether they performed a reassessment of the hazard analysis and HACCP plan. The QC manager replies, "No, because this was the only time we've observed this." ***A deviation not covered by a specific corrective action, or an unforeseen hazard occurred, and a reassessment was not conducted.***

Noncompliance Example 3*: The establishment's test result for a lot of cooked sliced chicken was positive for Lm. The IPP found that half the product with this lot number was not held by the establishment. The establishment* ***did not hold the affected product****.*

Noncompliance Example 4: *The personnel handling the Lm positive fully cooked sliced ham had misunderstood which operation line was affected and held product from the wrong operation line. The establishment* ***held product, but it was not the affected product.***

Noncompliance Example 5: *The establishment did not destroy or rework a lot of hot dogs that passed over a Lm contaminated food contact surface and the product was not in the cooler. The establishment* ***did not evaluate the product to determine whether it was acceptable for distribution.***

Noncompliance Example 6: *The establishment found the hot dog packaging conveyor belt to be positive for Lm after corrective actions were completed and did not hold the product. The establishment* ***did not take necessary action to ensure that no product injurious to health enters commerce.***

Noncompliance Example 7*: If the establishment* ***did not perform a HACCP plan reassessment*** *after the unforeseen hazard event, it would not be in compliance with 417.3(b).*

Pre-Shipment (before shipping) Review Requirement

The regulatory requirement for pre-shipment review is 9 CFR 417.5(c).

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 recordkeeping 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.**

Pre-shipment Review Compliance Example*: An IPP is performing the Slaughter HACCP verification task in a poultry slaughter establishment and verifying the establishment's compliance with the pre-shipment review requirement. The IPP has already observed that the establishment performs pre-shipment review by looking at and signing and dating each CCP record, and prerequisite program records associated with a shift's production. The establishment has two CCPs (final wash and carcass chilling) and 3 prerequisite programs: chiller chlorine program, antimicrobial online reprocessing program, and a salmonella testing program. The IPP reviews the Sanova antimicrobial rinse CCP log and the chilling CCP log from*

yesterday's shift and finds that all the results were entered, no corrective action was needed, and the establishment's QC supervisor had signed and dated at the bottom of the record. He also reviews the 3 prerequisite program records and finds the same results Based on his observations; he determines that the establishment is in compliance with 9 CFR 417.5(c).

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.

Note: When establishments implement prerequisite programs or other supporting programs to support the decision that the hazard is not likely to occur, the implementation of the program is verified as part of the recordkeeping requirement. The pre-shipment review is also a recordkeeping requirement.

Noncompliance Examples with Pre-Shipment Review Requirement (but not limited to)

- The establishment ships product in commerce without performing a pre-shipment review.
- The establishment transports product to another location prior to pre-shipment review and cannot demonstrate that it maintains control of the product.
- An establishment employee does not sign and date the pre-shipment review.
- An establishment employee does not review the appropriate HACCP records associated with the production covered by the pre-shipment review.

Noncompliance Example 1: *The IPP is performing the Slaughter HACCP verification task on a specific production of turkey carcasses that has left the control of the establishment. She requests the pre-shipment review records for this production, which the establishment is not able to provide****. The establishment shipped the product without conducting a pre-shipment review.*** *The IPP determines that there is noncompliance with 417.5(c) and documents the noncompliance in PHIS.*

Noncompliance Example 2: *An IPP is performing the Slaughter HACCP verification task in a beef slaughter establishment and verifying the establishment's compliance with the pre-shipment review requirement using the review and observation component of the task. The establishment has two CCPs (zero tolerance and final wash), and a prerequisite program for specified risk materials (SRMs). The IPP observed the establishment employee review the CCP records then signed and dated the pre-shipment review record without reviewing the prerequisite program record. The IPP determines that there is noncompliance with 417.5(c)* ***AND*** *417.5(a)(1) and documents the noncompliance in PHIS.*

Systematic Problems with Food Safety System

When IPP document an NR, they are to consider whether the noncompliance is associated with one or more previous NRs or other findings that did not result in noncompliance. If it is determined that the NR is associated with other findings, they are to:

- Assess the significance of their findings and observations in the context of the establishment's food safety system
- Document how the noncompliance is related to previous NRs or findings in the Inspection Notes feature of PHIS
- Work with the FLS to determine how their findings affect the overall food safety system

The noncompliance may be associated with other findings that did not result in a noncompliance but may indicate systemic problems, such as:

- Positive FSIS sampling results
- Corrective actions taken in response to deviations identified by the establishment
- Establishment findings and sampling results
- Changes to the facility or equipment
- Changes in the establishment programs or supporting documentation

IPP are to be aware that trends indicating systemic problems may not involve any NRs, such as repeated positive test results. They are to gather information, assess, and determine (GAD) if there is an underlying issue in the design or implementation of one or more of the establishment's programs.

IPP are to notify the FLS through the supervisory chain when they identify associations between current and past noncompliances or current noncompliances and other related findings that are not documented in an NR.

During weekly meetings, IPP should discuss any associations between current and past noncompliances or other related findings, and they should describe to establishment management why the associated NRs indicate a trend of noncompliance or systemic problems.

See E9a, E9b, E9c, E9d, E9e, E9f, E9g, HACCP Verification Workshops

15 THE HAZARD ANALYSIS VERIFICATION (HAV) TASK

Objectives:

1. Identify the eight steps for performing the HAV task.
2. Describe how IPP use the Meat and Poultry Hazards and Controls Guide while performing the HAV task.
3. Identify the elements of an establishment's HACCP system that are verified while performing the HAV task.
4. Identify issues that represent noncompliance when performing HAV task.
5. Describe the two elements of validation.
6. Identify examples of scientific or technical documentation that establishments use to support their HACCP system.
7. Identify the types of issues or concerns that are to be discussed with a supervisor before determining compliance and completing the HAV task.

Purpose

The purpose of conducting the **Hazard Analysis Verification (HAV) task** is more than simply identifying isolated cases of noncompliance. IPP are to consider what their HAV task findings show about the **overall effectiveness of the establishment's food safety system**. IPP are to conduct the HAV task to verify that an establishment has performed and documented a hazard analysis that meets applicable regulatory requirements and has addressed all relevant food safety hazards associated with the establishment's processes and products, and the intended uses for those products.

The HAV Task is performed quarterly and 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** include the flow chart, hazard analysis, critical control points, critical limits and procedures and frequencies for HACCP monitoring and verification. The following list below summarizes what items IPP are to review when verifying compliance with these foundational elements.

- A flow chart that **matches the actual production processes** in the establishment
- A **hazard analysis that 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 critical limits, and monitoring and verification procedures**

- **Prerequisite programs (or other supporting programs) for hazards that are not reasonably likely to occur (NRLTO)** and **documentation supporting the decision** that a food safety hazard is not reasonably likely to occur (NRLTO) in the process

- Evidence supporting the validity **(validation documents)** of the HACCP system

- **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:*

- *Scientific Journal Articles*
- *Regulations*
- *Pathogen Modeling Program (PMP)*
- *Processing Authority (PA)*
- *Challenge Studies*
- *In-plant data*
- *Agency compliance/guidance documents*
- *Other decision-making documents*

Examples of supporting documents *the establishment can use to support a decision that a hazard is not reasonably to occur:*

- *LOG (Letters of Guarantee)*
- *COA (Certificates of Analysis)*
- *Product temperature controls*
- *Microbial testing programs*

IPP are to review the supporting documents while performing the HAV task.

IPP may find that the **Meat and Poultry Hazards and Control Guide (HCG)** is a useful tool in verifying compliance while performing the HAV Task. The HCG was developed to help IPP evaluate all aspects of an establishment's food safety system. The guide identifies process steps that are commonly used in each processing category, lists common food safety hazards for each process step, and cites some of the controls frequently used by processors to address these hazards.

A more detailed explanation of the 8 steps IPP are to take to verify compliance when conducting this task can be found in the HAV Task Summary Table found in FSIS Directive 5000.6 below.

HAV Task Summary Table

A. Summary of IPP Instructions (Step 1-8) for Performing Hazard Analysis Verification (HAV) Tasks Flow: Refer to applicable sections of this directive for additional information about each step.

Step:	Description:	Verification Questions:	Reg. citation
Step 1	Review flowchart and compare to production process.	• Does the flowchart represent the actual production process?	417.2(a)(2)
Step 2	Review the hazard analysis and consider guidance in the FSIS Meat and Poultry HCG.	• Does the flowchart 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)
Step 3	For each hazard the establishment considers RLTO, verify that the HACCP plan includes one or more CCPs to control it. *If no hazards are reasonably likely to occur, skip to Step 4.*	• 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)
Step 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).	• Does the establishment prevent the hazard by implementing a prerequisite or other supporting program (SSOP, GMP, SOP, etc.)? – *proceed to Step 5.* • Does the establishment support the decision with other documentation besides a prerequisite or other supporting program? – *proceed to Step 6.* • 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? • Do the records and your observations indicate that the program prevents the relevant hazard on an ongoing basis?	417.5(a)(1)

Step 5	Review other supporting documentation.	• 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)
Step 6	Review establishment validation documents, including scientific supporting documents and validation data.	• 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)
Step 7	Verify reassessment requirements. Check most recent signature date for each HACCP plan.	• 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)
Step 8	Document your findings.	• No problems detected – document HAV results in PHIS. • Clear case of noncompliance – document HAV results on 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 results in • PHIS.	

Examples of Noncompliances IPP may find while performing the HAV task and the applicable regulations:

- *The establishment's flow chart does not accurately represent all the steps in the establishment's production process (417.2(a)(2))*
- *The establishment's flow chart does not accurately describe product flow (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 (417.2(c)(2)*
- *The establishment does not have documentation to support the development of CCPs, critical limits, or monitoring and verification procedures (417.5(a)(2))*
- *The establishment does not maintain validation data (417.4(a)(1))*
- *The establishment did not perform a reassessment at least once in the previous calendar year (417.4(a)(3))*

When to talk to your supervisor:

When performing this task IPP should:

- Use the Meat and Poultry Hazards and Control Guide as an aid
- Ask the establishment for additional documents or explanation
- Discuss policy questions with their supervisor and utilize askFSIS for policy questions when needed
- Discuss noncompliance questions with their supervisor
- Notify your supervisor even in clear cases of noncompliance

Supervisors have a key role in supporting IPP in conducting the HAV Task. Supervisors should be actively engaged with askFSIS responses and assist in compliance decisions. Supervisors should respond to scientific and technical questions and/or assist in finding resources to support inspection decisions. As needed, supervisors may include Enforcement Investigations and Analysis Officers (EIAOs) and the District Office.

See E10 HAV Task Workshop

16 REVIEW OF ESTABLISHMENT DATA TASK

Objectives:

1. Explain the purpose of the Review of Establishment Data task
2. Identify the kinds of records that are subject to review during this task
3. Describe how to assess the significance of information gathered during this task
4. Explain how to follow-up on questions or concerns identified
5. Explain how to document the task in PHIS
6. Describe what is done if the establishment management refuses access to records

What Data do IPP Review and Why?

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** 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 and 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 Testing 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 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). The FSA assesses 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 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 in accordance with 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.

17. HACCP SYSTEMS AND RECALL VERIFICATION

Objectives
After completion of this module, the participant will be able to:

1. Explain the regulatory process, including the definition of the four components, and identify key parts of each component.

2. Identify the four questions to consider when determining whether to document noncompliance when there is failure to meet HACCP regulatory requirements.

3. Given a scenario, use the regulatory process to determine whether a food safety system is inadequate.

4. State two instances when a verification plan is prepared.

5. State how to verify the requirements of 9 CFR 418.3 for maintaining written recall procedures.

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. Performing the HACCP Regulatory Process includes the following four components:

- **Inspection Methodology**
  - 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
  - Associating noncompliance or other related findings
  - Descriptions for determining why the events are associated, and other noncompliance history to determine whether the findings indicate a trend of ongoing noncompliance or systemic problems with the establishment's food safety system.
- **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 **Directive 5000.1 and 5000.6**. You are responsible for understanding and properly performing the HACCP inspection tasks in the Public Health Information System (PHIS) as described in these Directives.

Inspection Methodology
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 analyses for one HACCP plan, prerequisite programs, and other supporting documentation. 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. Both of the 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.

Regulatory Decision-Making 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** all available information to help them determine regulatory compliance by:

- Reviewing establishment hazard analyses, HACCP plans, prerequisite programs, and other supporting documentation
- Reviewing establishment records documenting the implementation of HACCP plans, prerequisite programs and other supporting programs or procedures
- Observing establishment employees implementing each HACCP plan, prerequisite program or other supporting program or procedure, and
- Observe product and occasionally take measurements as specified in the establishment HACCP plans, prerequisite programs, or other supporting programs or procedures.

IPP are to **assess** the significance and meaning of information gathered by:

- Comparing the information gathered to HACCP regulatory requirements
- Considering what each piece of information, either taken separately or with other findings, says about how the HACCP system is functioning to ensure that products are not adulterated
- 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?

IPP are to **determine** whether the information supports a finding of regulatory compliance by considering the following questions:

- 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?

HACCP noncompliance is the failure to meet any of the HACCP regulatory requirements of 9 CFR Part 417. If a HACCP noncompliance occurs, the establishment is expected to take immediate and further planned actions or 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 questions:

1. Has the establishment already identified the failure to meet regulatory requirements or deviation from a critical limit?

   Note: A deviation from a critical limit is the failure to meet the applicable value established for the CCP.

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 carried 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., records.

If the answer is "**yes**" to questions **1, 2, and 3** and "**no**" to question **4**, then there is **no noncompliance** because the establishment has already identified and addressed the situation. IPP document compliance with the applicable regulations in PHIS. Because the establishment's response provided the further planned actions and preventive measures for the noncompliance or deviation, not writing an NR does not adversely affect an IPP's ability to track developing trends. However, an establishment's failure to follow through on further planned actions and preventive measures could lead to recurring noncompliances and would warrant NRs in recurring situations.

If the answer is "**no**" to questions **1, or 2, or 3**, **or** "**yes**" to question **4**, then **a noncompliance exists**. IPP document noncompliance in PHIS and generate an NR.

Note: If IPP are uncertain whether the information supports a particular compliance determination, they are to discuss the issue with their supervisor. Once a sound determination has been made, IPP are to document their determination in accordance with FSIS Directive 5000.1.

Noncompliance as it Relates to the HACCP System

While any noncompliance is important and must be properly documented, the purpose of the HACCP verification task is more than just to identify isolated instances of noncompliance. IPP must also consider what their findings, whether positive, negative, or inconclusive, suggest about the overall effectiveness of the establishment's HACCP system. When IPP have concerns about the ability of the establishment's HACCP system to produce safe products, they are to discuss those concerns with their supervisor.

It is important that IPP **consider each piece of information 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, suppose the establishment skipped a measurement for a prerequisite program. Is this an isolated incident or has the establishment regularly failed to implement their prerequisite programs?

- **Is there other information to indicate that the HACCP system is working or is not working?** For example, an establishment's prerequisite program specifies product will be received with supplier certificates of analysis (COA) and periodically tested. If 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, the 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 certificates of analysis and verification test results on incoming trim that appear to indicate that 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.

NOTE: When IPP document an NR, they are to consider whether the noncompliance is associated with one or more previous NRs or other findings that did not result in noncompliance. If it is determined that the NR is associated with other findings, they are to:

- Assess the significance of their findings and observations in the context of the establishment's food safety system
- Document how the noncompliance is related to previous NRs or findings in the Inspection Notes feature of PHIS
- Work with the FLS to determine how their findings affect the overall food safety system

The noncompliance may be associated with other findings that did not result in a noncompliance but may indicate systemic problems, such as:

- Positive FSIS sampling results
- Corrective actions taken in response to deviations identified by the establishment
- Establishment findings and sampling results
- Changes to the facility or equipment
- Changes in the establishment programs or supporting documentation

IPP are to be aware that trends indicating systemic problems may not involve any NRs, such as repeated positive test results. They are to gather information, assess, and determine (GAD) if there is an underlying issue in the design or implementation of one or more of the establishment's programs.

IPP are to notify the FLS through the supervisory chain when they identify associations between current and past noncompliances or current noncompliances and other related findings that are not documented in an NR.

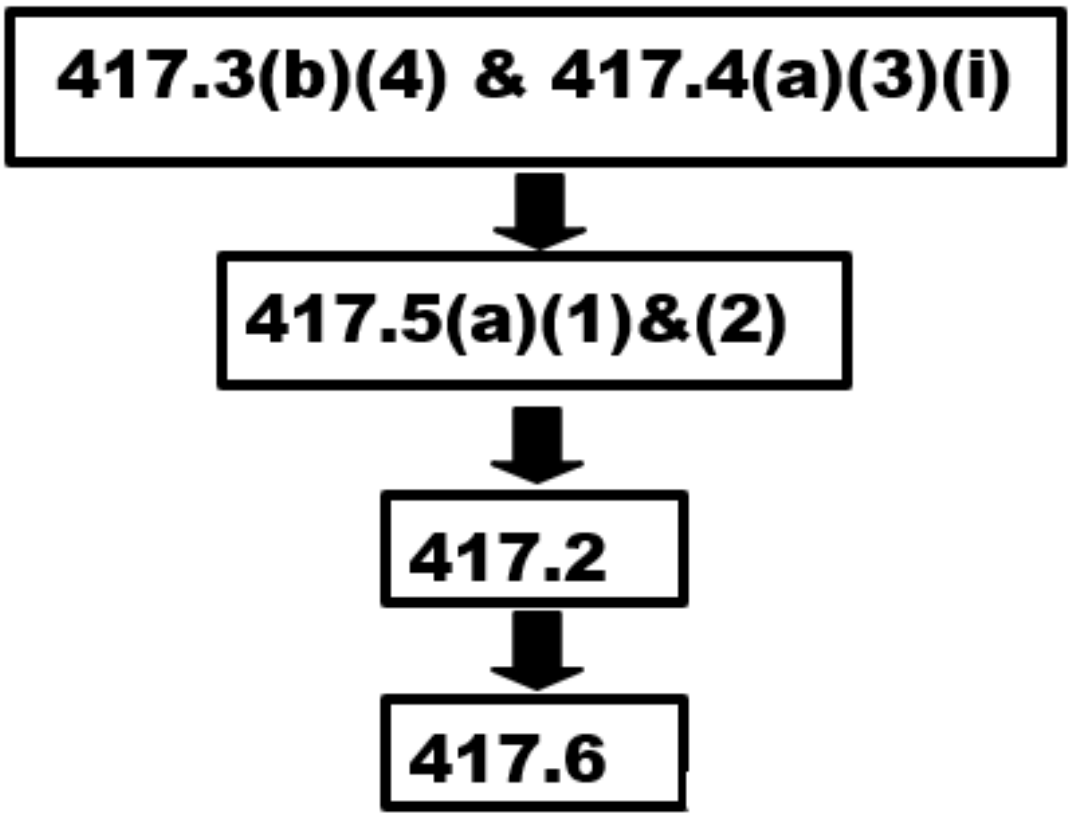
Inadequate System Determination

If noncompliance is found, you need to determine if it indicates an inadequate system in accordance with 9 CFR 417.6.

To determine whether an establishment's HACCP system is adequate, you must consider more than the HACCP plan. Consider all available evidence, including the hazard analysis, supporting documentation, and other parts of the system (SSOP, in-plant testing programs, etc.). 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 in its process, is testing outside the HACCP plan or SSOP, and gets a positive result, then a reassessment of its HACCP plan and hazard analysis is 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), you cannot determine that the HACCP system is meeting the requirements of 417.2, therefore the HACCP system may be determined to be inadequate as described in 417.6.



To determine if there is an inadequate system, you need to answer the following questions:

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

If the establishment is not implementing all or some of its program, it has not met regulatory requirements. For example, if an establishment is not maintaining **any** records associated with its HACCP plan, the establishment is not monitoring critical limits at any CCP, the establishment did not reassess the HACCP plan when required, or the establishment did not modify its HACCP plan when it no longer met the requirements--- then the establishment has not met the regulatory requirements. Therefore, you are unable to determine whether or not the establishment is producing un-adulterated product, and therefore the HACCP system is inadequate. In these cases, the HACCP system would be considered inadequate because it did not meet the regulatory requirements of Part 417.

- If the answer to question **1** is **no**, this may be indicative of an **inadequate system.**

2. Was adulterated product produced or shipped?

If the HACCP system did not prevent the production and distribution of adulterated product, it is an inadequate system. If you determine that the establishment failed to meet a critical limit for a CCP and did not take the corrective actions as per Section 417.3 of the Federal regulations, and the establishment has performed its pre-shipment review, the HACCP system is inadequate.

- If the answer to question **2** is **yes**, this may be indicative of an **inadequate system**.

3. Is there a trend in establishment noncompliance?

You should observe trends in the regulations cited on NRs when determining whether an establishment's HACCP system is inadequate. If two or more NRs have the same regulations cited and if descriptions of noncompliances indicate that similar problems are recurring, there may be a trend indicating the HACCP system is inadequate.

There is no specific number of incidents which determine a trend. Because there will be a variety of processing environments and HACCP plans, FSIS cannot establish that a specific number of the same or similar incidents of noncompliance necessarily support an inadequate system. Therefore, you must thoroughly analyze and document noncompliance trends that may support a determination. When reviewing a possible trend in noncompliance, you must closely review the descriptions of noncompliance contained in Block 10 of the NR form. You should not solely rely on the number of linked noncompliances. Only through careful analysis of the regulations cited and the written descriptions of noncompliance can you determine whether there is a trend indicating that a HACCP system may be inadequate.

- If the answer to question **3** is **yes**, this may be indicative of an **inadequate system**.

Action to Take If an Inadequate System Exists

If you determine that an **inadequate system** exists, then you must take action.

- You would notify the District Office.
- If you determine that adulterated product has been produced and shipped, you will take an immediate withholding action, according to the Rules of Practice.

The main point to remember is to contact the District Office, via supervisory channels, if you believe an inadequate system exists.

Documentation

Completing a Noncompliance Record (NR)

When documenting noncompliance on a Noncompliance Record (NR), do the following.

- Identify each noncompliance.
- Be specific and thorough, including time and location.
- Explain that establishment management has received notification.

- State any regulatory control actions you took.

If you need further information about completing the NR, please consult FSIS PHIS Directive 5000.1 and the PHIS User Guide.

Documenting a Trend

Throughout this course you have learned that when you observe noncompliance, you document noncompliance, and when there is a trend in noncompliance, you associate the noncompliances. Documenting and associating noncompliance are key concepts that must be carried out in your daily duties so that the agency is able to provide establishments with due process and to take enforcement action when necessary.

When you determine that the establishment does not meet one or more regulatory requirements, document your findings on an NR. If the establishment has produced and shipped unsafe food, initiate the appropriate enforcement actions described in 9 CFR 500.3. If you have documented multiple or recurring noncompliances, request that the DO issue an NOIE (Notice of Intended Enforcement Action) to the establishment as per 9 CFR 500.4. If you decide to request an NOIE it should come as no surprise. By the time you have made this decision, you should have been discussing the trend in noncompliance with the establishment during weekly meetings and you should have been keeping your frontline supervisor apprised of what was happening. Everyone (the establishment, your frontline supervisor, and the DO) should be expecting the request for the NOIE.

Enforcement - Follow Rules of Practice

Recall that the Rules of Practice (ROP) in 9 CFR 500 provide establishments with due process. They also describe how the Agency progresses with further enforcement actions and under what circumstances.

When a noncompliance determination is made, it may be necessary to take an **enforcement action** to prevent adulterated product from being produced and shipped. In accordance with the rules of practice, this enforcement action could be one of three types.

1. A "**regulatory control action**," is the retention of product, rejection of equipment or facilities, slowing or stopping of lines, or refusal to allow the processing of specifically identified product.

2. A "**withholding action**," is the refusal to allow the marks of inspection to be applied to products. A withholding action may affect all product in the establishment or product produced by a particular process.

3. A "**suspension**," is an interruption in the assignment of program employees to all or part of an establishment.

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 if there are: *(1) insanitary conditions or practices; (2) product adulteration or misbranding; (3) conditions that preclude FSIS from determining that product is not adulterated or not misbranded; or (4). inhumane handling or slaughtering of livestock.*

A regulatory control action permits IPP to identify regulatory noncompliance and prevent the movement of the product involved 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 regulatory control action.

If there is SPS noncompliance without direct product contamination or adulteration, but there is an imminent probability that the noncompliance will result in product contamination or adulteration if not addressed immediately, you will take a regulatory control action such as retaining product or rejecting the equipment or room with a tag, and then complete an NR. Regulatory control actions should remain in effect until the establishment has brought itself back into compliance with regulations.

If there is SPS or SSOP noncompliance with direct product contamination or adulteration, you will verify that the establishment addresses the noncompliance by meeting the requirements of either Part 416 or Part 417. You will write an NR using the appropriate SSOP regulations or the appropriate HACCP regulations. You will verify that the establishment implements corrective actions, including product control actions that meet the requirements of 9 CFR 416.15. The establishment may need to re-evaluate the effectiveness of its procedures in its SSOP and modify them if they are no longer effective in preventing direct contamination or adulteration of product.

If the direct product contamination poses a food safety hazard, you will verify that the establishment implements corrective actions, including product control actions, that meet the requirements of 9 CFR 417.3(b). These corrective actions include a reassessment to determine whether the unforeseen hazard should be incorporated into the 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 would be stopping a line or retaining a carcass as a result of a slaughter food safety standard finding.

Withholding Action Without Prior Notice
There may be instances when it is necessary for you to take immediate enforcement actions to prevent imminent threat to public health, without giving the establishment prior notice. For example, if the establishment produced and shipped adulterated product, you would need to take an immediate withholding action. In these situations, first take the immediate withholding action, and then as soon as possible notify the District Office and your supervisor. For further information, refer to the Rules of Practice module.

Withholding and Suspension Actions With Prior Notification
Keep in mind that some withholding and suspension actions require prior notification according to the rules of practice. The most common withholding or suspension actions related to HACCP noncompliance are those in which the HACCP system is found inadequate due to multiple or

recurring noncompliance. Withholding or suspending inspection for this cause does require prior notification to the establishment. The prior notice is in the form of a written Notice of Intended Enforcement Action (NOIE). Remember that a suspension may only be issued by a District Manager or higher FSIS official.

Notify the District Office

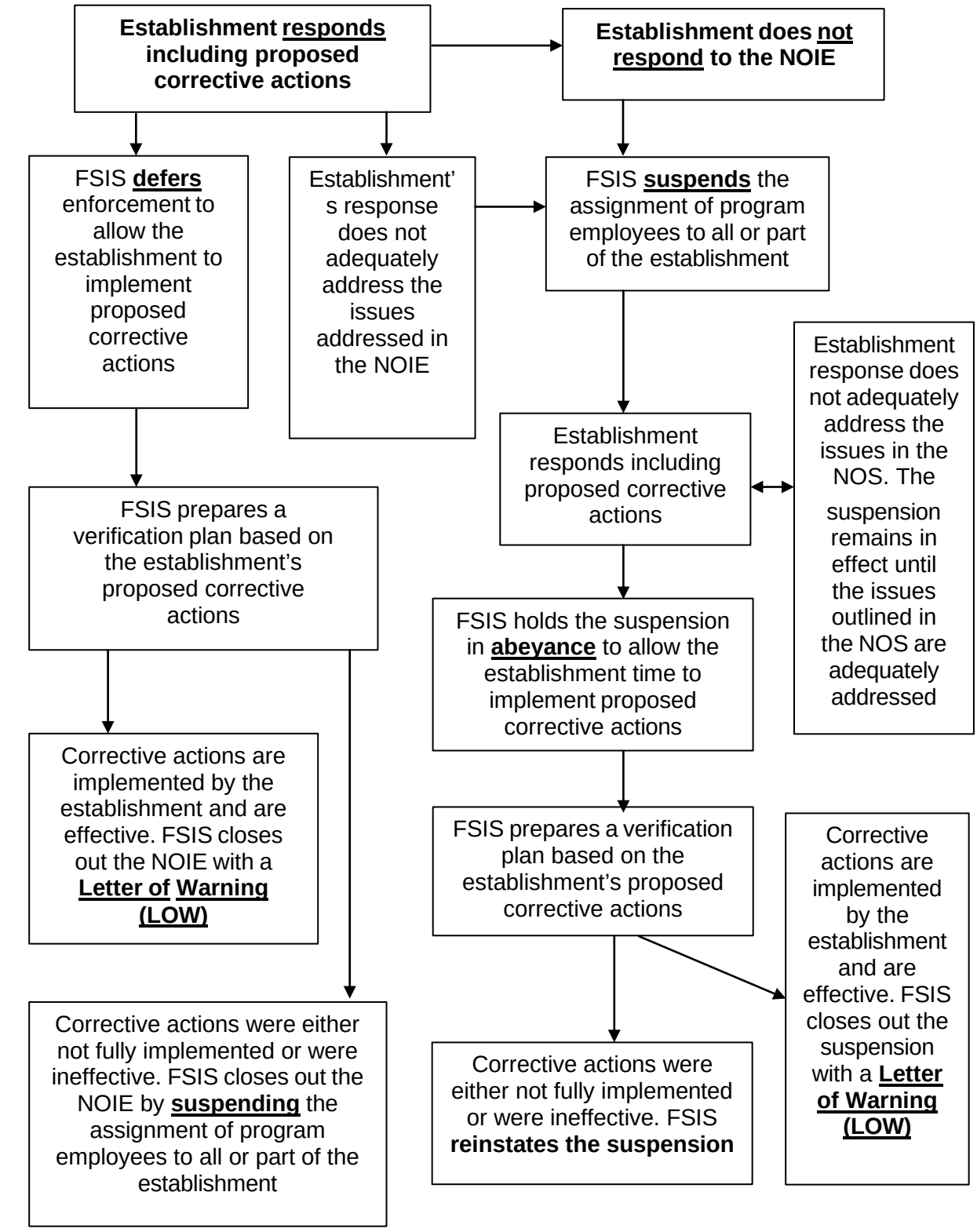
If you determine that an inadequate system may exist, you should notify the District Office. Provide the DO with all of the information about the situation. You should request that a Notice of Intended Enforcement be issued to the establishment. The DO will provide direction about further actions you need to take. The DO may assign an EIAO to evaluate the establishment's HACCP system.

District Office Determines Enforcement Action

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

Notice of Intended Enforcement Action

Establishment has 3 business days to respond



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

A **VP**:

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

IPP schedule and perform directed verification activities identified in the VP. On a weekly basis, the in-plant team reports, via e-mail to the District Office, the results of the activities conducted under the VP. 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, for example, when a positive pathogen sample result is obtained for product that the establishment has shipped. FSIS Directive 8080.1, Recall of Meat and Poultry Products, details all verification requirements for recalls.

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 District Office 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);
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); and
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))

Establishments must notify the District Office that an adulterated or misbranded meat or poultry product received by or originating from the official establishment has entered commerce. Official establishments are to provide the DO with the type, amount, origin, and destination of the adulterated or misbranded product.

1. 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).

2. The 24-hour period begins when an establishment has reason to believe that a product in commerce is adulterated or misbranded under the Federal Meat Inspection Act (FMIA) or the Poultry Products Inspection Act (PPIA). For example, product would be adulterated if the final results of a laboratory analysis show that raw ground beef contains *E. coli* O157:H7, or if product contains an allergen that is not declared on the product label.

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

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). The RMTAD is notified immediately if product has left the establishment's control, and they coordinate any recall activities.

More or less product may be determined to be "affected product" based on all considered factors (e.g., whether some or all products produced under the same or a substantially similar HACCP plan have been affected, what pathogens 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 noncompliances in the establishment). The RMTAD is notified so a press release can be issued, and effectiveness checks can be performed.

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

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.

See E11 HACCP Systems and Recall Workshop

Reference:

FSIS Directives and Notices

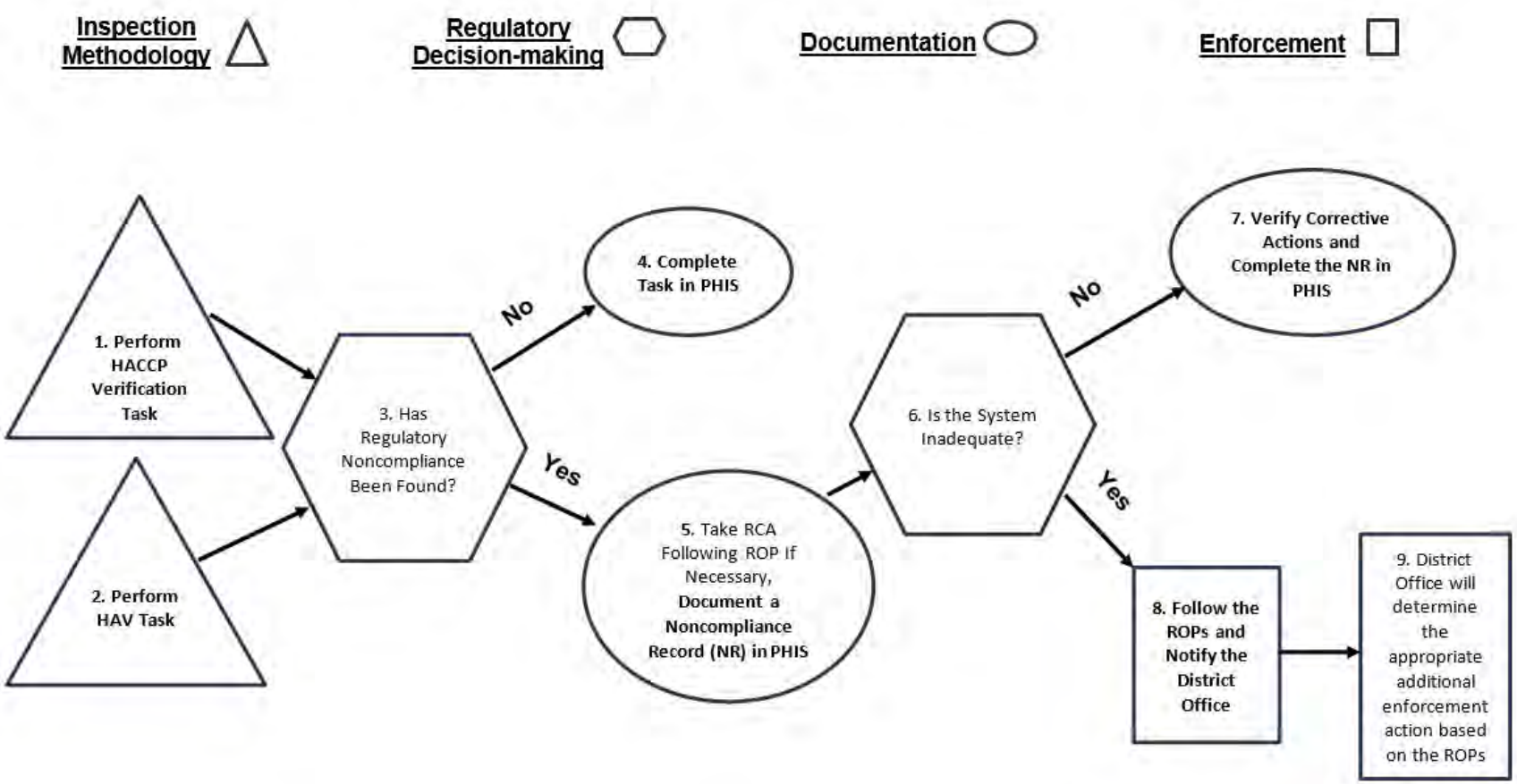
FSIS Directive 5000.1, Verifying an Establishment's Food Safety System

FSIS Directive 5000.6, Performance of the Hazard Analysis Verification (HAV) Task

FSIS Directive 5000.8 Verifying Compliance with Requirements for Written Recall Procedures

FSIS Directive 8080.1, Recall of Meat and Poultry Products

HACCP Regulatory Process



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