

# HACCP REGULATORY PROCESS

## Objectives

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

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.

## Overview of the Regulatory Process

An establishment’s food safety system consists of the HACCP plans, a Sanitation SOP and other programs, measures, and procedures that it implements to prevent, eliminate, or otherwise control identified food safety hazards in the products it produces. Inspection Program Personnel (IPP) allow the application marks of inspection to products when they are able to find that the products are not adulterated. A fundamental step in producing products that are not adulterated is to produce the product in accordance with the elements of a valid HACCP system. 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.

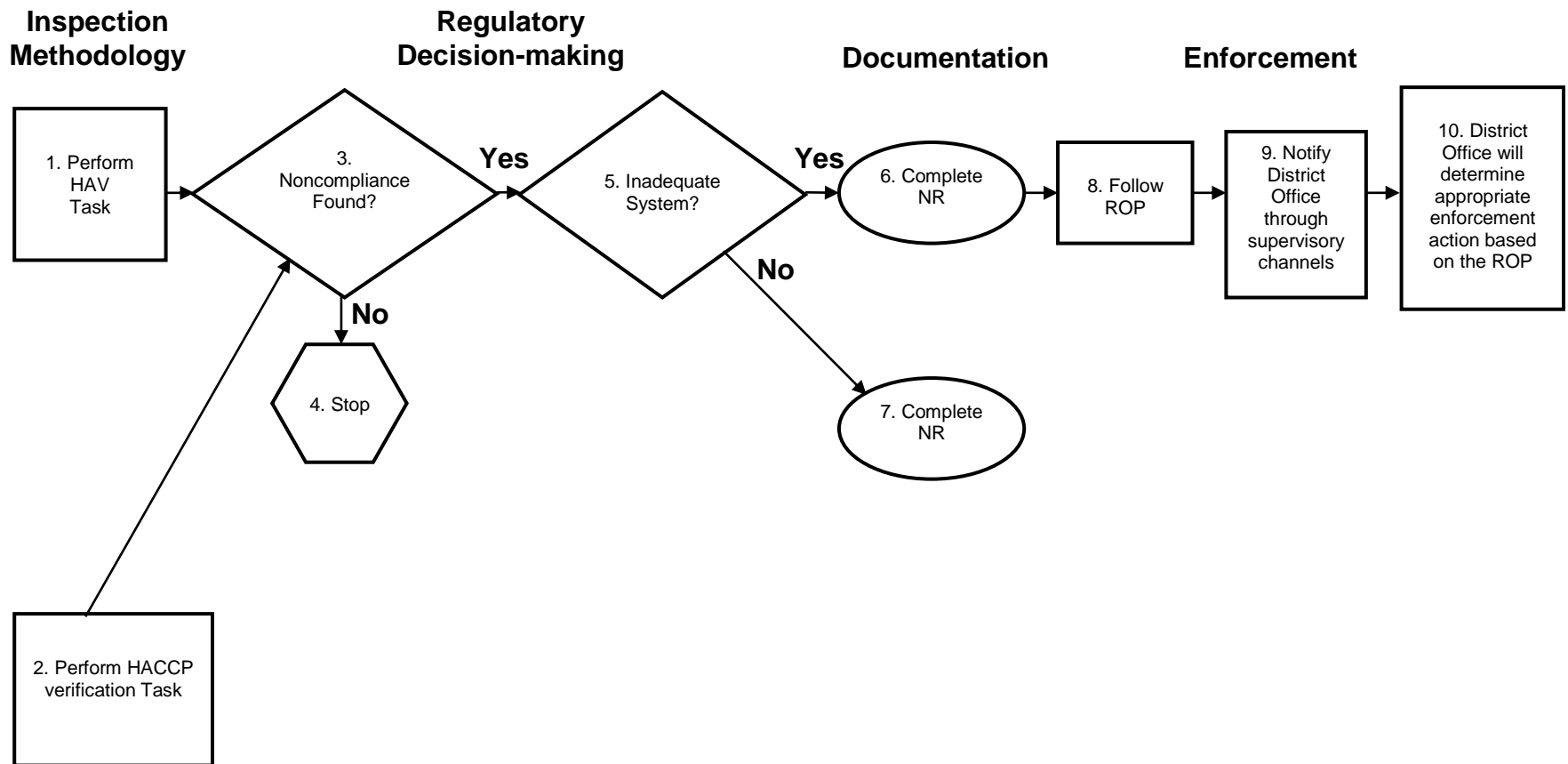
IPP must focus on the overall effectiveness of the establishment’s HACCP system. Hands-on sensory inspection to determine whether individual product units are wholesome is important but is not the best method of assessing the ongoing effectiveness of the establishment’s HACCP system. Sensory inspection may not identify all products that may be unsafe or unwholesome. By verifying that an establishment is implementing an effective HACCP system,

FSIS can best ensure that the establishment is producing wholesome, unadulterated products.

The diagram on the next page shows the **HACCP Regulatory Process**. It 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 from the same cause
  
- **Enforcement**
  - Following the Rules of Practice (ROP)
  - Providing the establishment with due process

### HACCP Regulatory Process



## FSIS Responsibilities

FSIS responsibilities for verifying an establishment 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. The information in the Directives follows the regulatory process. These Directives are the foundation for this training course.

IPP verify HACCP regulatory requirements by performing the HACCP inspection tasks that appear on the establishment's task list. 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.

***Example:** If an establishment slaughters, fabricates and grinds meat, there will be HACCP verification tasks for the raw HACCP category of Slaughter, Raw Intact, and Raw Non-Intact on the task list. Each task in PHIS directs IPP to the applicable policy documents and provides instructions to help them understand how to verify HACCP requirements for the particular HACCP process or product type.*

## HACCP Inspection Tasks (Blocks 1 and 2 on the Regulatory Process Diagram)

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 of the HACCP verification tasks can be performed as a routine or directed task. Each HACCP task has two verification components:

Perform HAV or HACCP verification task
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- **A recordkeeping component, and**
- **A review and observation component**

IPP use either component or a combination of the components to verify regulatory compliance. For example, an IPP may decide to review monitoring records at one CCP and take a measurement, or observe the establishment taking a measurement at another CCP to verify that the monitoring requirement is met. Similarly, an IPP may observe something while reviewing monitoring records for a CCP that prompts him or her to perform a review or observation at that CCP.

## **How to Perform the Two Components**

### **Recordkeeping Component**

To perform the **recordkeeping** (Rk) component, the IPP will gather information by looking at establishment records associated with the HACCP system. Depending on the HACCP verification task, these records might include the hazard analysis, records of any prerequisite or supporting programs, the HACCP plans, or HACCP records that document monitoring, verification, corrective actions, and reassessment activities. For example, the IPP may review HACCP records to determine if the establishment recorded its test results or measurements at the required frequency, if all required data was recorded, if the data is accurate, if critical limits have been met, and if corrective action was taken when necessary. When the IPP performs the recordkeeping component, he or she is only reviewing records. Typically, this review would take place where the records are maintained and may not be at the physical location of the CCP.

Regulation 9 CFR 417.5(f) requires the establishment to make all such records available for official review. Some establishments, however, control access to their food safety records. In such situations, the IPP needs to work with the establishment to develop a mechanism to allow him or her access to food safety records within a reasonable time of a request. If the establishment does not provide access to the records needed to perform the verification tasks, the IPP is to document noncompliance with 417.5(f) and bring the matter to the attention of his or her immediate supervisor.

***Example 1:** The IPP is performing a HACCP verification task and is verifying the monitoring regulatory requirement. He decides to perform the recordkeeping component and reviews the monitoring records generated for the chilling CCP listed in the HACCP plan. He looks at the frequency of the temperature entries and the actual recorded temperature values and then compares the recorded temperatures to the critical limit for this step.*

### **Review and Observation Component**

To perform the **review and observation** (R&O) component, IPP gather information by directly observing the establishment employees performing procedures or activities as stated in the HACCP plan or prerequisite program

(observation), taking measurements to see if the values they obtained match those recorded by the establishment (review), or observing the product or conditions within the establishment.

**Note:** When taking a measurement, IPP are to use the calibrated instrument that the establishment uses for the monitoring or verification activities and use the procedures as described in the HACCP plan.

**Example 2:** *The IPP is performing a HACCP verification task and verifying the monitoring requirement, which in this case, is a product temperature check. She decides to perform both parts of the review and observation component. She directly observes the establishment employee carry out the product temperature check. Then, she takes a product temperature measurement, and compares the result that she obtained to the one just recorded by the establishment employee.*

## 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** all available information to help them determine regulatory compliance by:

- 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, and
- Observe product and occasionally take measurements as specified in the establishment HACCP plans, prerequisite programs, or other supporting programs or procedures.

**Note:** 9 CFR 417.5(f) requires that all records required under Part 417 be available for official review by FSIS inspection personnel. IPP are to contact their supervisor if an establishment refuses to make necessary records available for review.

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.

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, and no other action is necessary. 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.

### **Examples of Determining if HACCP Noncompliance should be Documented**

The following are examples of situations that require IPP to determine if they should document HACCP noncompliance. For purposes of consistency, all the examples below use the HACCP monitoring regulatory requirement. The methodology applies to problems with the HACCP verification, recordkeeping, and corrective actions requirements as well.

**Example 1:** *While performing a Raw Intact HACCP verification task, using recordkeeping component, the IPP finds that an establishment employee missed a 9:00 a.m. monitoring check. She then finds that the establishment found the error during its records verification, demonstrated product safety with other records, and took immediate measures for the noncompliance by re-training the employee. Also, the IPP looked at previous NR and determined that the establishment had not missed a monitoring check in over three months. In this situation no NR is necessary even though there was a missed monitoring check. However, if the IPP found that adequate preventive measures were not in place, and that the missed monitoring check and correction had occurred several times, she may determine that a trend for monitoring noncompliance has developed. In this case, she would issue an NR, verify the establishment brings itself back into regulatory compliance and discuss this trend with establishment management during the weekly meeting.*

**Example 2:** *While performing a Raw Non-Intact HACCP verification task using the recordkeeping component, the IPP finds that an establishment employee*



*missed a 9:00 a.m. monitoring check and finds no indication that the establishment identified the missed monitoring check. He writes a noncompliance. He continues to verify and finds that the product was shipped without a pre-shipment review. In this situation, on the same NR the IPP would write another noncompliance that explains his findings. Next, the IPP would determine whether the establishment can provide other documentation that establishes product safety. If the establishment cannot demonstrate product safety, he would take action in accordance with the Rules of Practice, 9 CFR Part 500.*

**Example 3:** *While performing a HACCP verification task using the recordkeeping component, the IPP observes that an establishment employee recorded a deviation from a critical limit on the monitoring record. She verifies that the corrective actions taken by the establishment meet the requirements of 417.3(a). There is no regulatory noncompliance, and an NR is not necessary.*

**Example 4:** *While performing a Raw Non-Intact HACCP verification task records review for a single lot of product, the IPP sees in the records that an establishment employee missed a monitoring check at 10:00 a.m. and had a deviation from a critical limit at 11:00 a.m. He continues to review the records and finds that at pre-shipment review the establishment identified the deviation and took the proper 417.3 corrective and preventive measures but failed to address the monitoring error. In this situation, the IPP would write a noncompliance for the monitoring error and determine whether the establishment can demonstrate product safety relevant to the missed monitoring check. If so, no other action is necessary. If the establishment cannot support product safety, he should take action in accordance with the Rules of Practice, 9 CFR Part 500.*

**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 issue of noncompliance is important and must be properly documented, the purpose of the HACCP verification tasks 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.

In the upcoming training modules, we will focus on verifying that establishment's food safety system is in compliance with the HACCP regulatory requirements in 9 CFR Part 417. We will demonstrate the IPP's responsibilities within the HACCP regulatory process. For instance, you will learn how the IPP verifies regulatory compliance and makes supportable decisions when performing the HAV task and HACCP verification task. Several workshops will reinforce the PHIS documentation concepts you learned earlier in the course. A more detailed discussion on enforcement will occur near the end of the course to reinforce the overview of enforcement actions that was provided during the Rules of Practice module.

## **HACCP Regulatory Process Workshop**

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

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