The Hazard Analysis Verification (HAV) Task

Objectives

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

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 documents 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.

Reference

FSIS Directive 5000.6 Rev. 2, Performance of the Hazard Analysis Verification (HAV) Task, June 2018

Meat and Poultry Hazards and Controls Guide, March 2018

FSIS Compliance Guideline: Hazard Analysis and Critical Control Point (HACCP) Systems Validation, April 2015

The Hazard Analysis Verification (HAV) Task

IPP verify that the development and implementation of the establishment's food safety system meets the five regulatory requirements (i.e., monitoring, verification, corrective actions, recordkeeping and reassessment) addressed in 9 CFR Part 417. The "food safety system" can be defined as a systematic approach implemented to prevent food borne illness. It includes the development and implementation of a Hazard Analysis and Critical Control Point (HACCP) Plan in accordance with 9 CFR Part 417 and a Sanitation Standard Operating Procedure (SOP) in accordance with 9 CFR Part 416. It also includes any programs or procedures an establishment uses (e.g., prerequisite programs) to prevent food safety hazards from occurring and to support decisions in the hazard analysis.

The purpose of the HAV task is broader than simply to identify isolated noncompliance. IPP are also to consider what their findings show about the overall effectiveness of the establishment's food safety system. If IPP have concerns about the ability of the establishment's food safety system to produce safe products, they are to discuss those concerns with their supervisor. Guidance and instructions for performing the HAV task are in FSIS Directive 5000.6

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

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

We refer to these elements of a HACCP system as foundational because each element is critical to the sound development and maintenance of a HACCP plan. If an establishment fails to meet a regulatory requirement associated with any one of these elements, the HACCP plan, and ultimately the HACCP system may be fundamentally flawed. Even if the HACCP plan is well executed, a HACCP system that is inadequate with respect to these foundational elements may result in the production of adulterated product. IPP are to consider the implications of their findings with respect to the overall effectiveness of the establishment's food safety system.

The HAV methodology gives IPP an enhanced, step-by-step approach for reviewing these foundational elements of an establishment's HACCP system. Use the HAV methodology along with the inspection verification thought process: gather information from the establishment, assess the significance of the information, and determine compliance. IPP gather information about the food safety system by considering the answers to questions based on the establishment's HACCP process categories or product types. IPP assess that information as it compares to the regulatory requirements and as it affects food safety as a whole, and then they determine compliance. The questions that IPP consider are in FSIS Directive 5000.6 and in this handout.

Expectations of IPP Conducting the HAV Task

The safety of meat and poultry products depends on establishments developing and implementing effective food safety systems. IPP are in the best position to identify concerns about the effectiveness of an establishment's HACCP system because they are familiar with the daily operations and actual conditions in the establishment. By identifying concerns about the hazard analysis, supporting documentation, or prerequisite programs, IPP are acting to protect the public health by preventing products that present a risk from entering commerce.

Many establishments have developed unique and complicated HACCP systems. It is understandable and even expected that IPP involved in performing the HAV task will not always have the scientific, technical, or regulatory expertise necessary to determine the significance of their findings. When IPP have concerns about the establishment's hazard analysis but are unable to determine whether their findings constitute noncompliance, they should discuss their concerns with their supervisor.

IPP in slaughter establishments are to consult with their supervisor if they are uncertain about whether the available information supports a particular determination. Supervisors should be contacted immediately whenever IPP have reason to believe there are systematic problems with the establishment's food safety system or that adulterated product may have been produced and shipped.

Note that what is expected of IPP differs from what is expected of EIAOs. When conducting a comprehensive Food Safety Assessment, EIAOs determine the adequacy of an establishment's hazard analysis and supporting documentation. However, the EIAO's role involves more than the HAV methodology. EIAOs must comprehensively investigate every detail of an establishment's food safety system, and not only determine whether specific findings represent compliance or noncompliance, but analyze the various kinds of food safety noncompliance in that establishment to arrive at a sound, supportable conclusion about the adequacy of that establishment's overall food safety system. IPP will identify obvious cases of noncompliance and other issues of concern that may require further consideration or investigation by an EIAO.

Performing the HAV Task

Once per quarter, IPP are to review the hazard analyses of one HACCP plan in accordance with the instructions below, paying particular attention to any changes that may have been made since the previous review of that hazard analysis;

1. In establishments that have one HACCP plan that addresses a single process category, IPP are to conduct the HAV on that HACCP plan each quarter.

2. In establishments that have one or more HACCP plans IPP are to select one HACCP plan to review using the priority rankings in Table 1 below. IPP are to

select a different HACCP plan each quarter until they have ensured that all the HACCP plans are verified.

Table 1: HAV HACCP Category Priority Ranking
Slaughter
Raw/Non-Intact
Raw/Intact
Fully Cooked/Not Shelf Stable Post-lethality Exposed
Not Heat Treated/Shelf Stable
Heat Treated/Not Fully Cooked/Not Shelf Stable
Secondary Inhibitors
Heat Treated/Shelf Stable
Fully Cooked/Not Shelf Stable Not Post-lethality Exposed
Thermally Processed

In establishments that have more than one HACCP plans in a processing category, IPP are to select one of the HACCP plans in that processing category for that quarter, then select a different HACCP plan in that category during the next quarterly routine task.

For establishments with multiple IPP, the first level supervisor coordinates the work for only one HAV task to be performed per quarter, even if there are multiple shifts. The HAV task on the task list for the other shift(s) is marked as “not performed” using the justification “task assigned to another inspector.” All inspectors should have equal opportunity to perform the task.

In the following situations, IPP are to verify that the establishment meets the regulatory requirements using a **routine** task if the task is still available on the establishment task list. If the HAV Task is no longer available because it was recently performed, IPP are to schedule a **directed** HAV task:

1. Changes that could affect the hazard analysis or require altering the HACCP plan, such as an unforeseen hazard or a new or revised policy.

2. Addition or removal of a critical control point (CCP) or other control measure based on the establishment’s determination related to whether a food safety hazard is reasonably likely to occur (RLTO).

HAV Task Steps

When performing the HAV task, IPP use the **recordkeeping component** to review documentation, to verify that the establishment complies with the HACCP regulatory requirements. IPP may use the review and observation component when possible. For instance, IPP use the recordkeeping component to verify that the establishment has developed a flow chart and conducted a hazard analysis that addresses the relevant food safety hazards for the process, product, and intended use of the product in accordance with 9 CFR 417.2(a). IPP also use the recordkeeping component to verify that the establishment has developed a HACCP plan that has at least one CCP for each hazard that is reasonably likely to occur in the process and has support for the decisions made at that CCP in accordance with 9 CFR 417.2(c)(2) and 417.5(a)(2). When the establishment uses a prerequisite program (such as a Sanitation SOP, GMP, or purchase specifications) to support that an applicable hazard is not reasonably likely to occur, IPP use the recordkeeping component to verify that the establishment has the support for that decision in accordance with 9 CFR 417.5(a)(1). IPP use the review and observation component to verify the flow diagram represents the actual production process and verify that the establishment implements prerequisite programs effectively to support the decision that a hazard is not reasonably likely to occur in the process. These are just few examples demonstrating the use of both components. IPP are to contact their supervisor if the establishment does not make necessary records available for review as this may represent noncompliance with 9 CFR 417.5(f).

IPP use the thought process and methodology summarized in the **HAV Task Summary Table** on the following pages and discussed in subsequent sections of this handout to gather and assess information while performing the HAV task.

Note: If an establishment determines that no food safety hazards are reasonably likely to occur in the process, it is not required to develop CCPs or a HACCP plan. IPP will not perform HACCP verification tasks in this establishment. However, IPP will perform the HAV task on the hazard analysis specific to the product being produced without a HACCP plan, to verify that it has support for the decision that no hazards are reasonably likely to occur in the process.

HAV Task Summary Table

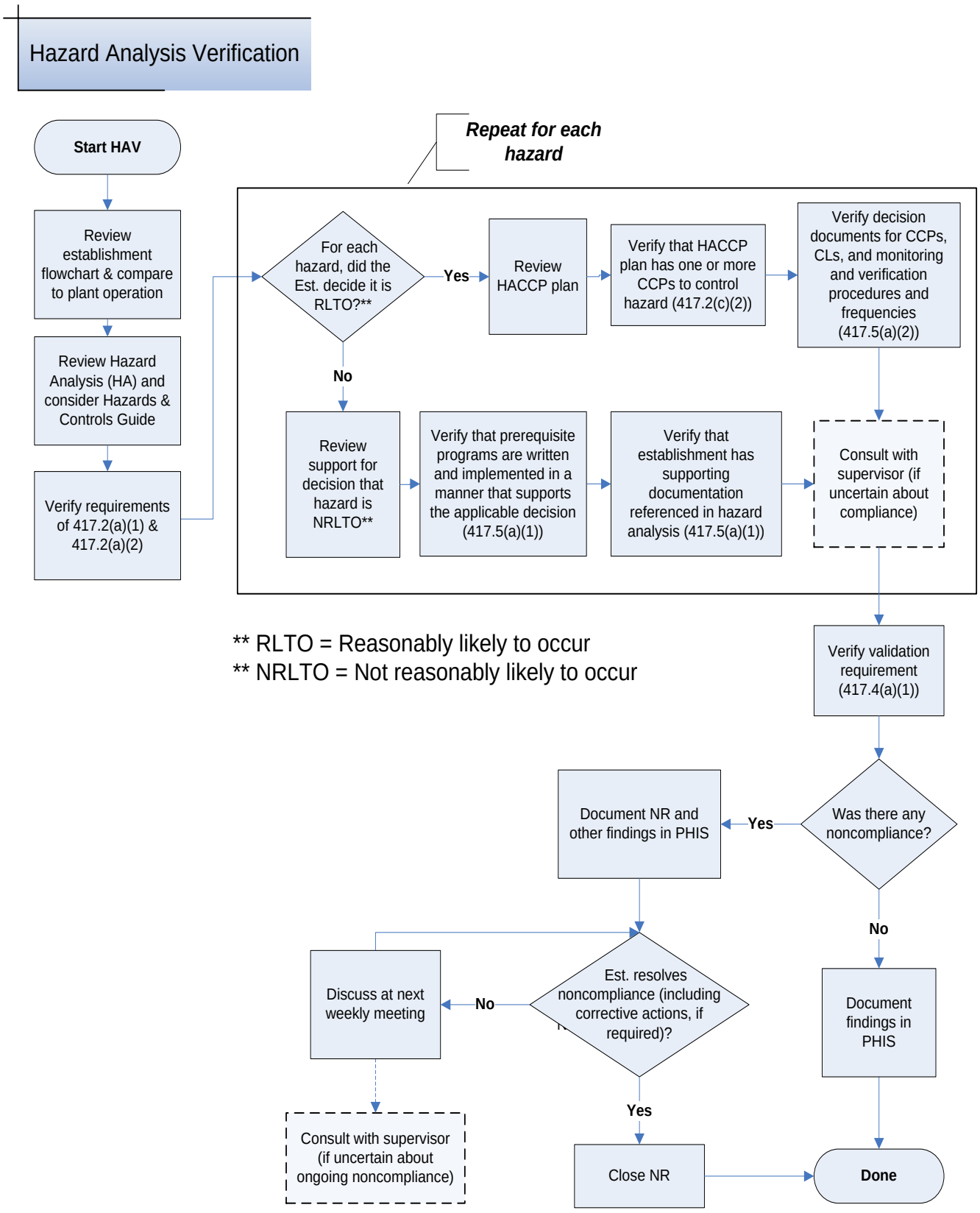
Refer to Directive 5000.6 for additional information about each step.

Step	Description	Verification Questions	Regs
1	Review flow chart and compare to production process.	• Does the flow chart represent the actual production process?	417.2(a)(2)
2	Review the hazard analysis and consider guidance in the FSIS Meat and Poultry Hazards and Controls Guide (HCG).	• Does the flow chart or hazard analysis identify the intended use or consumers of the product? • Does the hazard analysis appear to consider the relevant food safety hazards for the establishment's process, product, and intended use? • For each hazard, does the establishment consider it RLTO or NRLTO?	417.2(a)(2) 417.2(a)(1)
3	For each hazard the establishment considers RLTO, verify that the HACCP plan includes one or more CCPs to control it. *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)
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 continues to prevent the relevant hazard on an ongoing basis?	417.5(a)(1)

HAV Task Summary Table (cont'd)

Refer to Directive 5000.6 for additional information about each step.

Step	Description	Verification Questions	Regs
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)
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)
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)
8	Document your findings in PHIS	• No problems detected – document HAV task results in PHIS. • Clear case of noncompliance – document HAV task results and NR in PHIS and notify your supervisor. • Concerns about the establishment HACCP system – discuss situation with your supervisor for assistance in determining how to proceed. Document HAV task results in PHIS.	


Hazard Analysis Verification
Start HAV
Review establishment flowchart & compare to plant operation
Review Hazard Analysis (HA) and consider Hazards & Controls Guide
Verify requirements of 417.2(a)(1) & 417.2(a)(2)
Repeat for each hazard
For each hazard, did the Est. decide it is RLTO?**
Yes
Review HACCP plan
Verify that HACCP plan has one or more CCPs to control hazard (417.2(c)(2))
Verify decision documents for CCPs, CLs, and monitoring and verification procedures and frequencies (417.5(a)(2))
No
Review support for decision that hazard is NRLTO**
Verify that prerequisite programs are written and implemented in a manner that supports the applicable decision (417.5(a)(1))
Verify that establishment has supporting documentation referenced in hazard analysis (417.5(a)(1))
Consult with supervisor (if uncertain about compliance)
** RLTO = Reasonably likely to occur
** NRLTO = Not reasonably likely to occur
Verify validation requirement (417.4(a)(1))
Was there any noncompliance?
Yes
Document NR and other findings in PHIS
No
Document findings in PHIS
Est. resolves noncompliance (including corrective actions, if required)?
No
Discuss at next weekly meeting
Consult with supervisor (if uncertain about ongoing noncompliance)
Yes
Close NR
Done

Step 1: Reviewing the Establishment's Flow Chart

> ***9 CFR 417.2(a)(2):*** *A flow chart describing the steps of each process and product flow in the establishment shall be prepared, and the intended use or consumers of the finished product shall be identified.*

The flow chart and hazard analysis are essential for the development of an accurate and effective HACCP Plan. Each step in the establishment's process must be properly identified before the establishment can conduct an adequate hazard analysis. It is essential that IPP accurately assess and verify that flow charts accurately represent the steps in each process and the flow of product through each process. This requires IPP to become familiar with the production steps and product flow within the establishment by observing operations. If they have questions about the process steps and product flow, they are to ask establishment management for assistance in understanding the production process, including how the establishment handles rework or returned products.

FSIS developed the *Meat and Poultry Hazards and Controls Guide* (HCG) to help both FSIS and establishment personnel evaluate all aspects of an establishment's HACCP system for producing meat and poultry products. The HCG identifies common process steps that may be employed in each HACCP processing category. It lists the common biological, chemical and physical food safety hazards that have been traditionally associated with particular types of products or process steps, and cites some of the controls frequently used by processors to address these hazards.

This HCG provides IPP with suggested general and process-specific verification questions needed to determine whether the establishment considered all the possible hazards for each process step and verify that the hazard analysis and the HACCP plan appropriately take into account the relevant food safety information.

It is important to note that differences between the HCG and an establishment's hazard analysis are not, in themselves, sufficient to support a determination of noncompliance. However, IPP can use the HCG as a helpful reference when evaluating whether an establishment has considered the potential hazards associated with a particular production process.

When verifying compliance with 9 CFR 417.2(a)(2), IPP should consider questions such as:

1. Do the steps identified by the establishment reflect the actual production process? If not, it does not comply with 9 CFR 417.2(a)(2).

2. Does the flow chart, or hazard analysis, identify the intended use or consumers of each product, and is the identified use consistent with the actual production? If not, noncompliance with 9 CFR 417.2(a)(2) exists.

IPP are to refer to the HCG as they consider an establishment's flowchart. The HCG lists the process steps that are frequently associated with each HACCP processing category. IPP are to review the process steps in the Quick Reference Table for each processing category produced in the establishment. The establishment's process may not include all the steps listed in the HCG, but the steps in the table will help IPP identify steps in the establishment's process that are not in the flow chart.

An establishment may have a single flow chart that shows an entire production process or it may have multiple flow charts. In some establishments, the flowchart will be part of the HACCP plan, while in others it will be a separate document. All of these approaches to presenting the information are acceptable. IPP are not to focus on the format or structure of the flow chart. They are to verify that the flow chart contains the required information for the entire production process.

FSIS does not dictate the level of detail in the establishment flowchart. The establishment may incorporate several production steps into one step in a flow chart. However, the establishment must consider, and document, all the food safety hazards associated with all the activities embedded in that flow chart step to meet the requirements of 9 CFR 417.2(a).

Compliance Example 1

An establishment performs several different activities (cutting, needle tenderizing, injecting, and tumbling) when processing raw, non-intact products. The flow chart groups these activities in to the single step of "processing," but the flow chart lists each activity included in that step. Since the establishment listed the different activities associated with the step identified as "processing," this would not represent noncompliance with 9 CFR 417.2(a)(2).

Compliance Example 2

An establishment has a single flow chart that accurately reflects all steps and product flow for both its pork slaughter process and its raw, intact process (hot boning of carcasses). The single flow chart accurately represents the steps in both HACCP process categories; therefore, this would not represent noncompliance with 9 CFR 417.2(a)(2).

Compliance Example 3

An establishment does not have a statement of intended use on its raw, intact process flow chart, but has included it with the written product description with its hazard analysis. Since the establishment has accurately identified the intended use or consumer, this would not represent noncompliance with 9 CFR 417.2(a)(2).

Noncompliance with the Flow Chart:

IPP are to document noncompliance with 9 CFR 417.2(a)(2), whenever findings clearly indicate one or more of the following:

- The establishment's flow chart does not accurately represent all the steps in the establishment's production process.

- The establishment's flow chart does not accurately describe product flow.

- The establishment's flow chart (or hazard analysis) does not identify the intended use or consumers for all finished products.

Noncompliance Example:

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

Step 2: Reviewing the Hazard Analysis

> ***9 CFR 417.2(a)(1):*** *Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment. A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred or because there is a reasonable possibility that it will occur in the particular type of product being produced in the absence of those controls.*

IPP are to verify that the hazard analysis reflects all the steps in the flow chart and the establishment's actual production processes. When performing the HAV task, IPP are to review the HA for all products produced under that HA, and verify the HA reflects all steps in the flow chart and actual processes. The Hazards and Controls Guide can be used to help verify relevant hazards were considered.

There is no required format or specified structure of the hazard analysis. FSIS does not dictate the level of detail that must be in a hazard analysis, however IPP are to verify that the hazard analysis contains the required information for the entire production process.

When a hazard is considered by the establishment to be reasonably likely to occur (RLTO) in the hazard analysis, IPP are to verify that the establishment has included one or more CCPs to control that hazard.

When a hazard is considered by the establishment to be **not** reasonably likely to occur (NRLTO), IPP are to verify that the establishment has supporting documentation for that decision. This supporting information may be a program (prerequisite or other supporting program) that the establishment implements or some other documentation that shows that the hazard is not reasonably likely to occur.

An establishment may determine that certain hazards are not reasonably likely to occur because of the intended use of the product. In these cases, IPP are to verify that the establishment has documentation to support the intended use. This support might include labeling records, shipping invoices, letters of intent from receiving establishments or other records that demonstrate how the establishment ensures that products will be appropriate for their intended use.

Questions that IPP are to ask regarding the hazard analysis include, but are not limited to, the following:

1. Does the hazard analysis reflect all the steps in the flow chart and the actual production process? If not, it does not comply with 9 CFR 417.2(a)(1).

2. Has the establishment determined whether certain hazards are not reasonably likely (NRLTO) to occur because of the intended use of the product?

   a. If so, does the establishment have documentation (e.g., labeling records, shipping invoices, letter of intent from receiving establishments or other records) to support the intended use?
   b. If not, the establishment does not comply with 9 CFR 417.2(a)(2).

IPP are to consider general questions such as those provided below and those found in the HCG when evaluating the hazard analysis:

1. Has the establishment addressed this process step in the hazard analysis?

2. Does the establishment have a prerequisite program that addresses this step?

3. Has the establishment identified any hazards associated with this step?

4. Is this process step a CCP?

5. Is the establishment following all procedures identified in the hazard analysis?

6. Does the establishment maintain records associated with this step?

7. Do the establishment's records contain information that indicates that a reassessment of the hazard analysis or HACCP plan is necessary?

8. Are the records made available to FSIS?

For each food safety hazard identified in the hazard analysis, IPP are to ask the following questions:

1. Does the establishment consider the identified food safety hazard to be reasonably not likely to occur (NRLTO) in the production process? If so, does the establishment maintain support (such as a prerequisite program or other supporting documentation) for this decision? If not, noncompliance with 9 CFR 417.5(a)(1) exists.

2. Does the establishment consider the identified food safety hazard to be reasonably likely to occur (RLTO) in the production process? If so, does the establishment include one or more CCPs to control the hazard in the HACCP plan associated with that product? If not, noncompliance with 9 CFR 417.5(a)(1) exists.

Based on the establishment's hazard analysis, information in the HCG, and their knowledge of the actual establishment process, IPP are to assess whether the establishment's hazard analysis complies with 9 CFR 417.2(a).

Be aware that specific pathogens of concern are associated with the production of certain products (e.g., *E. coli* O157:H7 in a ground beef operation or *Listeria monocytogenes* in ready-to-eat products). If an establishment determines that biological hazards are RLTO in that specific process, the establishment may simply state "pathogens" in the hazard analysis and HACCP plan. However, the supporting documents and decision-making documents associated with the selection and development of the CCPs and CLs must be sufficient to demonstrate food safety hazards are controlled. The supporting documents must also demonstrate which pathogens were considered when the hazard analysis was conducted. The support should make evident that the HACCP system is sound and effective in controlling the pathogens of concern. If IPP have concerns about the supporting documentation, they are to seek input from their immediate supervisor or request the assistance of an EIAO.

Compliance Example

The IPP reviews a hazard analysis and determines that all the steps in the flow chart that appropriately reflect all steps in the production process are also included in the hazard analysis. She uses the HCG and the general and specific questions as an aid to verify whether the establishment has identified the logical food safety hazards at each step. She reviews the establishment's decisions for whether a hazard is reasonably likely to occur or not and the basis for the decision. For hazards deemed reasonably likely to occur, she verifies the establishment has identified critical control point(s).

A poultry establishment that produces ready-to-eat (RTE) cooked boneless skinless chicken fillets determined that a biological hazard (Salmonella) was reasonably likely to occur on raw poultry at the receiving step but stated that the receiving step was not a CCP because the biological hazard would be controlled at a step later in the process. The establishment identified that Salmonella would be controlled at the cooking step, and used the FSIS Salmonella Compliance Guidelines for Small and Very Small Meat and Poultry Establishments that Produce Ready-to-Eat (RTE) Products and Appendix A for the support of this CCP. Based on the HCG and her knowledge of pathogens, this appears logical.

For all other process steps, logical hazards and controls were considered. Based on the information gathered, she determined that the hazard analysis meets the requirements of 417.2(a)(1).

Noncompliance with the Hazard Analysis

IPP are to document noncompliance with 9 CFR 417.2(a), whenever findings clearly indicate one or more of the following:

- The hazard analysis does not reflect all the steps in the flow chart and the actual production processes. It does not comply with 9 CFR 417.2(a)(1).

- The hazard analysis does not consider the relevant food safety hazards at each step in the production process. It does not comply with 9 CFR 417.2(a)(1).

- The establishment determined that certain hazards are not reasonably likely to occur (NRLTO) because of the intended use of the product but does not have documentation (e.g., labeling records, shipping invoices, letter of intent from receiving establishments or other records) to support the intended use. It does not comply with 9 CFR 417.2(a)(2).

- The establishment failed to consider whether a hazard was reasonably likely to occur (RLTO) or not reasonably likely to occur (NRLTO). It does not comply with 9 CFR 417.2(a)(1).

- The hazard analysis identifies a hazard reasonably likely to occur (RLTO) but doesn't have an associated CCP.

If IPP are uncertain whether the establishment has considered the appropriate hazards at each process step, they are to contact their supervisors for assistance in order to determine if noncompliance with 9 CFR 417.2(a) exists.

Noncompliance Example

After verifying the flow chart matched the establishment's actual process flow, the IPP determines that the establishment is receiving returned products. However, the establishment failed to conduct the hazard analysis for the returned products step. The IPP determines that the establishment is not in compliance with 417.2(a)(1).

Step 3: Reviewing Support for the Critical Control Points and Critical Limits

9 CFR 417.5(a)(2): *The written HACCP plan, including decision making documents associated with the selection and development of CCPs and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.*

9 CFR 417.5(a)(2) requires the establishment to maintain the following types of supporting documentation for the HACCP plan:

1. Decision making documents associated with the selection and development of CCPs and critical limits;

2. Documents supporting the selection of monitoring procedures and their frequencies; and

3. Documents supporting the selection of verification procedures and their frequencies.

IPP are to review establishment records to verify that the establishment has evidence to support the development of all CCPs, critical limits, and monitoring and verification procedures as required by 9 CFR 417.5(a)(2). These supporting documents must be applicable to the establishment's actual process, and support the relevant establishment programs or interventions. IPP are to pay particular attention to verifying that the establishment has supporting documentation for any CCPs that have been added or modified since the last review.

Some examples of supporting documentation that an establishment might use to support decisions made in the HACCP plan include:

- Scientific journal articles
- Regulations
- Pathogen modeling program results
- Processing authority documents
- Challenge studies/Research
- In-plant (historical) data
- Agency guidance documents
- Decision-making documents

When performing the HAV task, CSIs are to verify that the establishment maintains these types of supporting documents for each CCP. These documents are also examples of supporting documentation the establishment may have on file to meet the validation requirements to be discussed in Step 6.

Scientific journal articles - Journal articles can be used to support a critical limit. IPP should consider what the critical parameters are in the journal article, and if the establishment is meeting all of the critical parameters. If they do not, IPP should look for additional support. Consider the date of the article and if the article has been peer reviewed. Look for whether the article relates to the process, product type and characteristics.

Regulations - There are specific regulations that outline prescribed regulatory procedures with applicable regulatory targets for chilling and storing product, such as 9 CFR 318.23—time and temperatures for heat processing uncured meat patties. Establishments may use regulations to support their critical limits.

Pathogen Modeling Program (PMP) - These are software programs that use several factors to *estimate* microbial growth, lethality, or survival of microbes in broths or foods. A PMP cannot stand alone as the only support for food safety unless the program has been validated for the specific type of product produced. Parameters used in the PMP should match the product characteristics.

Processing Authority (PA) - PA recommendations should be relevant to the process and product they are supporting. This documentation should reference scientific principles or peer-reviewed data in addition to the processing authority's opinion to ensure that the decision is science-based. IPP should ask their supervisor or utilize askFSIS to help evaluate such recommendations and data. PAs may evaluate heating or cooling deviations and make decisions about product disposition and safety.

Challenge Studies - These studies are typically conducted in a laboratory. A certain number of microorganisms are added to the product as part of such a study, and they are counted again after control measures have been applied. A challenge study may be used to support that a new process can produce a safe product. The challenge study should identify the hazard or target organism, indicate the log reduction/increase, specify the actual processing conditions, and list product characteristics.

In-plant data - If a process is not implemented exactly as the scientific paper outlines it, then in-plant generated data can be used to supplement the support. For example, if an establishment is introducing a new technology, applying standard technology in an unusual way, or lacking data generated from a new technology, in-plant data may be needed or used as additional support. This data should be considered on a case-by-case basis.

Agency compliance guidance documents - These are published by FSIS and are designed to assist establishments in complying with regulatory requirements. Guidance documents are not regulations. The establishment can use them as support and assistance in helping them achieve compliance.

Decision-making documents - These documents record the hazard analysis thought process the establishment used, or rationale for decisions made.

Job Aid for Considering Supporting Documentation

Important Note: These are ***just examples*** and ***should not*** be considered a comprehensive listing.

All Processes Systems	Examples of Supporting Documentation
Receive Raw Materials	LOG (Letter of Guarantee); COA (Certificate of Analysis); Product temperature controls; Microbial Testing +
Receive Packaging Materials and Non-Meat Ingredients	LOG to show free of hazards; Storage to prevent contamination; Temperature controls + Allergen controls
Store Raw Materials	Temperature controls; Sanitation; Maintain package integrity+; Store raw meat at 41˚F or below; Example: FDA Food Code states 'Red meat, which is a potentially hazardous food, must be stored at 41˚F or below.' ++
Thawing frozen meat	Temperature controls during thawing; Specifically surface temperatures + Example: In potable, flowing water at 70°F, chicken thawed to an internal temperature of 40°F in 5 hours showed no increase in *Salmonella*. ++
Formulation	Allergen Controls (clean up, progressive scheduling, & color-coding); Control of nitrate/nitrites; Temperature controls +
Mixing/Grinding	Temperature controls during processing Physical contamination: use most sensitive detection technique available +; Monitoring equipment should be sensitive enough to detect contamination as small as 1/32" (0.8mm); A visible inspection is prudent in addition to metal detection or x-ray machines; Hard or sharp objects 7-25mm represent a potential physical hazard, but objects < 7mm could also be a potential physical hazard for certain populations (children). ++
Rework	Cross-contamination of lots; Records to support distinction between lot/specific productions; Microbial testing +
Returned Product	Condition of product; Package Integrity +
Animal Receiving/Feed Control	Feed withdrawal and holding animals (beef/pork) 2 to 6 hours prior to slaughter has been shown to reduce the incidence of ruptured viscera and cross-contamination. ++
Residue controls	Slaughter establishments may request LOGs and copies of relevant animal treatment records. + Best Practices: animals identified for trace back, producers notified in writing when there's a positive/residue violation, require suppliers to participate in residue avoidance program, conduct live animal testing Residue Violators listing: www.fsis.usda.gov/Science/Chemistry/index.asp +++

Job Aid for Considering Supporting Documentation (cont'd)

All Processes Systems	Examples of Supporting Documentation
Hide removal/ evisceration	Steam vacuuming beef carcasses at 162°F, followed by a hot water spray of 203°F, at 24 psi, and/or an 11 second spray of 2% lactic acid at 131°F; Fecal contamination will be removed by steam vacuuming when accompanied by either or both of the hot water or lactic acid treatments. *E. coli*, Enterobacteriaceae, and total and thermotolerant coliforms were consistently reduced to less than 1.0 log. ++
Carcass Wash/ Antimicrobial Interventions	- Assure that time, temperature, pressure, dwell time, and other parameters are consistent with supporting documents. - Rinse beef carcasses with low pressure (10 psi) followed by high pressure (250 psi) 95°F water, then spray the area with a fine mist of 131˚F 2% acetic acid for 11 seconds; The addition of the 2% acetic acid treatment with the water wash, reduced *E. coli*, and *S. typhimurium* count 2.4 to 5.1 log units inside the contaminated area and to < 0.5 log units outside the initial contamination area to below detection level more effectively than just the water wash, or trimming. ++ - Spraying pork carcasses with 2% lactic acid solution reduced *S. typhimurium* by 2.25 log units. ++ - Lactic acid spray: concentration, time/temperature dwell time, pressure+; Lactic acid (livestock carcasses, offal, and variety meats prior to fabrication up to a 5% lactic acid solution; Beef heads and tongues 2.0-2.8% solution applied to brushes in a washer cabinet system used to clean beef heads and tongues. - Organic Acids (lactic, acetic, citric acid) As part of a carcass wash applied pre-chill up to 2.5% solution FSIS Notice 49-94
Scalding Pork Carcasses	Scalding in water to 145°F; *E. coli*, *Salmonella* and *Campylobacter* are killed at 145°F instantaneous. ++
Poultry Scalding	Counter-current scalders; multistage tanks; maintain water pH at either above or below 6.5-7.5 to preclude the growth of *Salmonella*
Poultry Dip/Rinse	- Chlorine, chlorine dioxide, acidifed sodium chlorite (500-1200ppm to achieve pH of 2.3-2.9; 21 CFR 173.325), TSP, Inspexx 100 (peroxyacetic acid), lactic acid - Sodium hypochlorite Reprocessing contaminated poultry carcasses 20 ppm calculated as free available chlorine Note: Agency guidance has allowed the use of up to 50 ppm calculated as free available chlorine (9 CFR 381.91)++++
SRM controls	9 CFR 310.22 - recordkeeping requirements - www.fsis.usda.gov/PDF/9CFR_310.22.pdf
E. coli Prerequisites	Validated interventions; Certificates of Analysis; Microbial testing of product by supplier and processor; 3rd party audits

References: +Meat and Poultry Hazards and Controls Guide; FSIS
++Supporting Document Materials for HACCP Decisions, Folk and Knipe, The Ohio State University
+++FSIS training ++++FSIS Directive 7120.1

Compliance Example 1

An establishment has an antimicrobial intervention CCP in the beef slaughter process at the carcass wash location that identifies minimum concentration as the critical limit. The establishment maintains the following supporting documents to meet the requirement of 9 CFR 417.5(a)(2):

- *A decision-making document that describes how establishment management selected the CCP based on a particular scientific article that addresses the establishment's particular hazard and product.*
- *A copy of the referenced scientific article.*
- *A document from the test kit manufacturer that describes a method for monitoring the concentration of the antimicrobial solution to support the establishment's monitoring procedure.*
- *A written decision document to monitor the critical limit once per day because the establishment mixes the antimicrobial solution daily.*
- *A written decision memo stating that the establishment will verify that it maintains the necessary minimum concentration of antimicrobial weekly because historical records show consistent control of this CCP.*

Compliance Example 2

The IPP reviews the hazard analysis and HACCP plan for a beef slaughter operation. The IPP finds that at the receiving step the establishment has identified that there is a biological food safety hazard, "presence of Salmonella spp. and E. coli O157:H7 microorganisms on the live animal and in the intestinal tract" that is reasonably likely to occur. Later steps in the process, evisceration and final wash, are identified as the points (CCPs) to reduce the prevalence of these pathogens in the finished product. The HACCP plan indicates that a steam-vacuum sanitizer is utilized to remove visible fecal contamination after the carcass is eviscerated. The steam vacuum delivers a continuous stream of 7 to 10 PSI water at a temperature between 179.6° F and 185° F at the inside of the nozzle. The static vacuum for the system is a minimum of 7 inches of mercury. The IPP decides to request the supporting documentation for these critical parameters. The establishment provides a copy of a scientific article. The article addresses the effectiveness of steam-vacuum sanitizing for reducing E. coli O157:H7 on beef carcass surface tissue that has been inoculated with *E. coli O157:H7*. *The same operating parameters for the steam vacuum that the establishment is using in the HACCP plan are identified in the materials and methods section of the paper. The abstract and results and discussion sections of the article state that the steam-vacuum sanitizer reduced aerobic plate counts associated with bovine fecal contamination 2.5* log_{10} *cfu/cm*^{2} *on beef carcass short plates and on the same beef carcass short plates inoculated with* E. coli *O157:H7 in feces there was a 5.5* log_{10} *cfu/cm*^{2} *reduction after*

steam-vacuum treatment. The IPP concludes that the article is relevant to the process, identifies the hazard, level of pathogen reduction achieved, and supports the establishment's critical limits in the HACCP plan. Based upon the review, the IPP determines that the establishment is in compliance with 417.5(a)(2).

Compliance Example 3

The IPP reviews the hazard analysis and HACCP plan for a young chicken slaughter operation. The IPP finds that at the carcass chilling step the establishment has identified that there is a biological food safety hazard, "growth of Salmonella spp and Campylobacter can result in higher prevalence of these pathogens in the final product." A time and temperature combination is listed at the chilling step in the HACCP plan. Carcasses and major portions of carcasses are chilled immediately after processing to an internal temperature of 40°F or less within 4 hours. The IPP decides to request the supporting documentation for these critical limits. The establishment provides a copy of FSIS Compliance Guide - Modernization of Poultry Slaughter Inspection: Chilling Requirements. It has the same temperature values listed for chilling poultry carcasses. Based upon the review, the IPP determines that the establishment is in compliance with 9 CFR 417.5(a)(2).

Compliance Example 4

An IPP reviews the HACCP plan, hazard analysis, and supporting documentation for the steam pasteurization CCP in a beef slaughter operation to verify that it meets the requirement in 417.5(a)(2). They find that the supporting documents describe the rationale for the location and critical limits of the CCP. The supporting documentation includes scientific articles by researchers at various institutions supporting the location and the critical limits for the steam pasteurization CCP. The establishment also has documents supporting the monitoring and verification procedures and frequencies. Based upon the review, the IPP determines that the establishment is in compliance with 417.5(a)(2).

After the IPP has gathered and assessed all available information pertaining to the supporting documentation requirement, he or she must determine regulatory compliance. If he or she finds that the establishment has met all regulatory requirements for §417.5(a)(2), then there is no regulatory noncompliance. If he or she finds that the establishment has not met all regulatory requirements for §417.5(a) (2), there is noncompliance.

Noncompliance with the HACCP Plan and Its Supporting Documentation

IPP are to document noncompliance with 9 CFR 417.5(a)(2), whenever findings clearly indicate the establishment does not have documentation to support the development of CCPs, critical limits, or monitoring and verification procedures. IPP are not tasked with determining the adequacy of the supporting documentation, however, if they have

concerns about the documentation, they are to discuss the issue with their supervisor prior to making a compliance determination.

Noncompliance Example 1

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

Noncompliance Example 2

The HACCP plan has a monitoring procedure for checking the finished product chilling medium by hand thermometer at the beginning of each shift. The establishment is not able to provide any supporting documentation for this procedure or frequency. The establishment has no documentation supporting the monitoring procedures and frequencies; therefore, it is not in compliance with 417.5(a)(2).

Noncompliance Example 3

The hazard analysis has identified that Salmonella *is reasonably likely to occur, and a CCP was established to control this hazard. The establishment provides as supporting documentation for its critical limit some charts from a microbial pathogen computer modeling program. Upon examination, the IPP observes that the parameters used in the predictive model do not match the ones used by the establishment in its process. The establishment has documentation, but the documentation does not support what the establishment is trying to support. The IPP discusses the finding with his supervisor and they determine the establishment is not in compliance with 417.5(a)(2).*

Workshop: HAV Task—Supporting Documentation

Case Study. While performing the HAV Task, an IPP is reviewing the HACCP plan for a large beef slaughter establishment. They find that the establishment has a CCP for control of *E. coli* O157:H7 at the hot water carcass rinse prior to chilling. The critical limit for the hot water wash is 140º F. The IPP asks the establishment for scientific support for this temperature. The establishment provides him with a scientific study paper from researchers at a major university that supports the use of hot water washes with a minimum of 165º F as a method to effectively reduce the numbers of *E. coli* O157:H7. The IPP then asks the establishment for supporting documents for the 140º F critical limit at the CCP. The establishment tells him that the critical limit was put at 140º F because that was the maximum output temperature for the establishment boiler.

Is this a noncompliance? Explain your answer and cite the relevant regulation.

Step 4: Reviewing NRLTO Decisions Including Prerequisite Programs

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

Prerequisite Programs

As establishments make decisions in their hazard analysis, they must decide if potential hazards are or are not reasonably likely to occur. For not reasonably likely to occur (NRLTO) hazards, they must have documentation that supports that decision. The implementation of a prerequisite program may be used to prevent a hazard from occurring, therefore making it the supporting documentation for the NRLTO decision.

In other words, prerequisite program's purpose is not to control a food safety hazard that was identified in the hazard analysis as being RLTO, but instead, its purpose is to prevent the hazard from becoming RLTO. An establishment can determine, through its hazard analysis, that a food safety hazard is NRLTO because data collected from the implementation of a prerequisite program supports that that program is preventing the hazard from occurring.

When a prerequisite program is used to support decisions in the hazard analysis, it is supporting documentation in accordance with 9 CFR 417.5(a)(1), and any records associated with the prerequisite program must be available for FSIS review.

When reviewing records associated with NRLTO decisions, IPP should consider these criteria:

1. Is the program written, and if so, does it describe procedures implemented by the establishment to support that a hazard is not reasonably likely to occur?

2. Does the program describes records that the establishment keeps to show the program is implemented as written?

3. Does the establishment maintain records showing that the implementation of the prerequisite continually supports that a hazard is prevented from becoming RLTO?

4. Does the program describe activities the establishment conducts if it fails to implement the program, or if it finds that implementation of the program failed to prevent a hazard from becoming RLTO?

If an establishment's prerequisite program is not designed in the manner defined by these criteria, it is likely that the establishment has not met the requirements of 9 CFR 417.5(a)(1). IPP are to contact their supervisor for assistance if they have concerns about whether the prerequisite program is designed to prevent the relevant hazard.

NOTE: Establishments are not required to maintain records for prerequisite programs. In situations where the prerequisite program does not generate records, IPP are to determine compliance by observing whether the establishment implements the prerequisite program sufficient to prevent the hazard from being RLTO.

Verifying NRLTO Decisions and Implementation of Prerequisite Programs

The regulations in 9 CFR 417 do not include specific requirements (e.g., monitoring, recordkeeping, corrective actions) for prerequisite programs. However, without maintaining some level of documentation that demonstrates that the prerequisite program has been implemented effectively and serves its intended purpose, it may be difficult for establishments to support a decision that a food safety hazard is NRLTO or to comply with the requirements of 9 CFR 417.5(a)(1).

Based on the information they gather from the records review and observations, IPP are to consider whether the establishment is implementing the prerequisite program or other control measures in a manner that supports the relevant hazard analysis decisions.

In general, the failure to comply with one aspect of the prerequisite program may not result in direct product contamination or adulteration; however, the safety of the product or the adequacy of the food safety system may need further evaluation by a supervisor or EIAO.

Compliance Example 1

An establishment implements a prerequisite program to maintain raw product coolers below 35°F to prevent the hazard of pathogen growth from being reasonably likely to occur. On 3 separate days last week, the employee recording the cooler temperature records did not record his initials as specified in the written program. This minor failure to follow the program would not represent a failure to support the hazard analysis, as long as there is no reason to believe that the 35°F temperature was not maintained. Therefore, the establishment is in compliance with 9 CFR 417.5(a)(1).

Noncompliance

Repeated failure to implement procedures in a prerequisite program, or evidence that the program is not effectively preventing the hazard, is an indication that the establishment does not have adequate support for the relevant decisions in its hazard analysis. Failure to support hazard analysis decisions is cause for IPP to document noncompliance with 9 CFR 417.5(a)(1) and may be grounds for an enforcement action.

Noncompliance Example 1

An establishment implements a prerequisite program to support that the hazard of E. coli O157:H7 is not reasonably likely to occur in received beef trimmings. The

prerequisite program states that a production supervisor will verify receipt of a certificate of analysis (COA) for each lot of trimmings before grinding. It also states that the establishment will sample and test a lot of its finished ground product for E. coli O157:H7 quarterly. While performing the HAV task, the IPP notes that the establishment has not received a COA for the lot of trimmings they are presently grinding. The IPP asks the establishment for evidence to support product safety for the lot in question, and the establishment cannot provide any other evidence to support product safety of the lot. This finding calls into question the establishment's decision that E. coli O157:H7 is not reasonably likely to occur. Therefore, 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 E. coli O157:H7 was not reasonably likely to occur.

Noncompliance Example 2

At the product receiving step, an establishment that further processed raw poultry determined the potential hazard of contamination with pathogens was not reasonably likely to occur based on its Product Receiving SOP. The written SOP specified the shipping manager or a designee would visually inspect and check temperatures on incoming product. Product was to be returned to suppliers if there was any evidence of contamination or temperature abuse. When performing the HAV task, the IPP reviewed the prerequisite program records and discovered that establishment employees had failed to document results of visual inspection and temperature checks on 10 loads of incoming product over the previous 4 weeks. The IPP determined that the establishment had failed to maintain adequate supporting documentation for these decisions in its hazard analysis because this was not an isolated incident; the establishment was regularly failing to implement the procedures specified in its prerequisite program.

If IPP are uncertain whether the implementation and records of a prerequisite program support the hazard analysis decisions, they are to discuss the issue with their supervisor.

Workshop: HAV Task—
Reviewing NRLTO Decisions Including Prerequisite Programs

While conducting an HAV task, an IPP noted that in its hazard analysis, a poultry slaughter establishment referenced a chlorination system to prevent pathogens (Salmonella & Campylobacter) from occurring in its poultry chiller water reuse (a.k.a. "red water"). This system depended on control of both the free available (residual) chlorine and pH levels through the addition of chlorine and carbon dioxide to the red water. The inspector reviewed the prerequisite program, which specified the following:

Chlorine Residual	***pH***	***Procedure***	***Frequency***	***Actions***
1-5 ppm	*5.5 – 6.0*	• *Sample red water at inflow to chiller* • *Determine chlorine and pH levels with handheld colorimeter*	*QA will test chlorine and pH every hour of production*	• *Record results on Red Water Check form* • *Contact maintenance if chlorine or pH are out of range so adjustments can be made*

1. Is the program written and does it describe procedures that the establishment will implement to show the hazard is not reasonably likely to occur?

2. Does the program describe records that the establishment will keep to demonstrate that the program is being implemented as written?

3. What will the establishment do if there is a failure to implement the program or meet the critical operating parameters?

4. Who could the IPP talk to about the program and these parameters to ensure they are adequate?

5. What documents might the IPP ask for to determine compliance?

The IPP noted the establishment had failed to document a chlorine test result on three scattered production days over the past month. All other results recorded for those production days indicated that the establishment had been maintaining the chlorine and pH levels within the specified operating parameters.

6. Does it appear that the establishment is continuing to support the decision in the hazard analysis that the hazards, Salmonella and Campylobacter, are not reasonably likely to occur?

7. Is the establishment in compliance? What regulation has been verified?

Step 5: Reviewing Other Supporting Documentation

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

IPP are to verify that the establishment maintains copies of all the documents referenced in the hazard analysis that are designated as support for the decisions regarding the prevention or elimination of food safety hazards or their reduction to an acceptable level. In many cases, this supporting documentation will take the form of scientific documents, establishment historical records, or other establishment-generated data. IPP are to verify that the establishment maintains the documents referenced in the hazard analysis to support the relevant decision regarding a hazard being not reasonably likely to occur.

When verifying compliance with 9 CFR 417.5(a)(1), IPP should consider questions such as:

1. If establishment records or data are being used, does the establishment include a decision document that explains why the data or records support its decision?

2. If a scientific document is being used, is the establishment following the criteria addressed in the document?

3. If multiple records are being used to support a single outcome (e.g., multiple slaughter interventions used to support a specific log reduction), does the establishment provide a decision document that explains how the documents support the outcome?

Compliance Example

Recall from a previous example (in Step 4) that an IPP was reviewing an establishment's support for its NRLTO decision at the product packaging material receiving step. The support was based in part on letters of guaranty from its packaging material suppliers. Next, the IPP requested the letters of guaranty from the QA manager. While reviewing the letters of guaranty, the inspector took notes on suppliers, types of packaging material, and the shipments of packaging material covered by a particular letter of guaranty based on information in the receiving logs. The inspector then went to the area where packaging materials were stored and verified that all packaging materials could be associated with a particular letter of guaranty. She concluded that the establishment was in compliance with 381.144(b), and with respect to this particular decision in its hazard analysis, also in compliance with 417.5(a)(1).

Noncompliance with Other Supporting Documentation

IPP are to document noncompliance with 9 CFR 417.5(a)(1) when the establishment does not maintain copies of the documents referenced in the hazard analysis. If IPP have concerns that the documents referenced in the hazard analysis do not support the relevant decisions, they are to discuss the issue with their supervisors.

Noncompliance Example

An IPP is performing a HAV task and notes in the hazard analysis that SRMs are deemed not reasonably likely to occur at the receiving step of a raw intact process because the establishment obtains supplier certificates with each shipment that state carcasses and primal parts are derived from cattle that are less than 30 months of age. He asks the establishment for the certificates from the previous 2 weeks of production so he can review them. Establishment management informs you that their supplier neglected to send them. The establishment had received 12 shipments of carcasses and primal parts during this period.

Step 6: Verify Establishment HACCP System Validation Documents

> ***9 CFR 417.4(a):*** *Every establishment shall validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis, and shall verify that the plan is being effectively implemented.*
>
> ***9 CFR 417.4(a)(1):*** *Initial validation. Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCP, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities.*

Establishments are required to validate the adequacy of their HACCP systems in controlling the food safety hazards identified in its hazard analysis.

Establishments are required to assemble the two elements of supporting documentation to demonstrate a HACCP system is validated:

1. The scientific or technical support for the HACCP system design (design), and
2. The in-plant implementation (validation) data (execution).

When verifying that establishments meet validation requirements, IPP are to review the scientific and technical support and the documents associated with the effectiveness of the HACCP plan in operation in-plant (i.e., in-plant validation data). IPP are to verify that the establishment maintains both types of validation documents.

Verifying Scientific and Technical Support

The following are examples of scientific or technical support for a HACCP system:

- Scientific journal articles
- Regulations
- Pathogen modeling program results
- Processing authority documents
- Challenge studies/Research
- In-plant (historical) data
- Agency guidance documents
- Decision-making documents

The scientific and technical support establishes a documented basis for the HACCP system. This consists of having scientific and technical documentation demonstrating that the designed process can control the identified hazards. The documentation should

identify the hazard, the level of hazard prevention or control to be achieved, all critical parameters or conditions, the processing steps that will achieve the specified prevention, reduction or control, and the way these processing steps will be monitored. In other words, these documents support how the HACCP system works in theory.

The supporting documentation must be complete, available for review and related to the process, product and hazard identified in the hazard analysis. Critical operational parameters are those parameters of an intervention that must be met in order for the intervention to operate effectively and as intended. Examples of critical operational parameters include: time, temperature, pressure, water activity, humidity, etc.

IPP review the establishment's scientific or technical support and verify the establishment maintains references and copies of relevant portions of text from the scientific or technical support to address the effectiveness of the CCPs and prerequisite programs that support decisions in the hazard analysis.

Examples which may warrant IPP to have a discussion with their supervisor might include:

1. The scientific or technical support documentation is for a product that is different from the product that the establishment produces. In general, the establishment should be using scientific or technical support that is related to the product produced or provide support for why research with a different product applies to the product in question. For example, a documentation that shows a process achieves a 5-log reduction of *E. coli* O157:H7 in apple cider would not be sufficient scientific support for the reduction of *E. coli* O157:H7 in a beef product without additional justification. In addition, documentation that shows a process achieves a 1-log reduction in *Salmonella* in poultry would not be sufficient scientific support for the reduction of *Salmonella* in beef without additional justification.

2. The scientific or technical support documentation contains expert opinion from a processing authority without any reference to scientific principles or peer-reviewed data. The documentation should contain reference to scientific principles or peer-reviewed data in addition to the processing authority's opinion to ensure that the decision is science-based.

3. The scientific or technical support documentation specifies the log reduction or prevention achieved by the process but does not include information on the critical operational parameters, such as pH, pressure, contact time, temperature, or relative humidity, critical to achieving that reduction. That information should be included in order for the process to be considered validated, and so that the establishment can implement the process consistent with the support.

4. The establishment's CCPs, prerequisite programs, or other programs do not incorporate the critical operational parameters described in the supporting

documentation, and the establishment does not maintain additional data to support the adequacy of the measures that incorporate different parameters. Establishments should be using the same critical operational parameters as those in the scientific or technical support. However, some minor differences may be acceptable, and establishments may be able to provide additional data to support different parameters.

Verifying Initial In-Plant Demonstration

The initial in-plant demonstration takes place during the initial 90 days of operation under that HACCP system according to 9 CFR 304.3(b) and 381.22(b). It involves collecting data that proves the system can perform as expected in the establishment's process with its own equipment, employees, environment, etc.

Establishments must collect in-plant data to demonstrate that they are able to routinely implement and meet the critical operational parameters and/or CCPs for the controls, interventions, or other procedures in their HACCP systems. This data would include observations, measurements, or other information that demonstrates the establishment can successfully implement these parameters in its process. The establishment is to maintain the initial in-plant demonstration records for the life of the HACCP system to meet the requirements of 9 CFR 417.5(a)(1) and 9 CFR 417.5(a)(2).
The initial in-plant validation data includes the in-plant observations, measurements, microbiological test results, or other information demonstrating that the control measures, as written into a HACCP system, can be implemented within a particular establishment, and that when they are, they achieve the intended food safety objectives.

IPP review the records that document initial in-plant validation and verify that the establishment maintains its in-plant validation data for the life of the HACCP system. Establishments must maintain the original in-plant validation data for the life of the HACCP system. In addition, if establishments make changes to the HACCP system and determine as part of reassessment, that in-plant validation data should be gathered to demonstrate the modified system is being implemented effectively, that new data is to be kept for the life of the HACCP system.

Validation Example 1

An establishment utilizes an antimicrobial carcass spray intervention. Supporting scientific documentation for this intervention provides critical parameters of water pressure at the nozzle, water temperature at the carcass surface, whole carcass coverage, and a water/carcass contact time. The establishment would be expected to have data showing that those parameters are actually being achieved in the process. It is crucial that measurements for collecting the data be designed to actually measure the correct parameter. For instance, the water temperature measured at a holding tank or at the nozzle may not be the actual water temperature at point of contact with a carcass so

the measurements for this parameter must be indicative of carcass surface temperature.

Validation Example 2

A small cattle slaughter establishment has a CCP for antimicrobial carcass treatment with lactic acid. The establishment's supporting document for this CCP and critical limit is a journal article. The IPP verifies that the journal article supports the critical parameters of the intervention and that the establishment is able to consistently meet those parameters. Records reflecting the first 90 days implementation of this CCP are available and show that the critical parameters are consistently met.

Validation Example 3

An establishment uses the following supporting documentation and conducts the in-plant demonstration as validation for their beef carcass, lactic acid spray process:

Product: Beef Carcass Process: Lactic Acid Spray

Hazard: E. coli O157:H7, *Salmonella Typhimurium*

Scientific Supporting Documentation:
Antimicrobial Spray Treatments for Red Meat Carcasses Processed in Very Small Meat Establishments. Pennsylvania State University. 2005. http://extension.psu.edu/food-safety/resources-contacts/small-*and-very-small-meat-processors/resources/antimicrobial-spray/intervention-booklet-2005.pdf/view.*

Critical Operational Parameters:
2% lactic acid applied within 12 inches of carcass surface and entire carcass covered using a stainless steel spray tank fitted with a pressure gauge and air compressor. Each side of beef should be sprayed for at least 1 minute and sprayed from top to bottom and sufficient lactic acid is applied such that some of it drips off.
Note: The entire carcass is sprayed with lactic acid following washing each side of beef from top to bottom for at least 2 minutes with hot water and allowing a 5 minute drip time after the hot water wash.

Initial In-Plant Documentation:
In plant monitoring records for 90 day period recorded on Hot Water and Drip Time Monitoring Check Sheet (including parameters for the time the carcass is sprayed with hot water, carcass coverage, method application (from top to bottom and spray nozzle within 12 inches of carcass), and drip time.
Records of lactic acid concentration. Trial Reports run under specified lactic acid critical parameters demonstrating complete carcass coverage, sufficient amount (lactic acid drips off carcass), contact time, method of application (spray nozzle within 12 inches of carcass and from top to bottom).

If, while reviewing the in-plant validation data, IPP have a concern about a technical aspect of the documentation, they are to contact their supervisor. The following are examples of issues IPP may identify regarding in-plant validation data that could warrant a discussion with their supervisor:

1. The in-plant validation data was collected from HACCP records or other data collected or maintained by the establishment as part of its HACCP system, and the records do not include all critical operational parameters. IPP are to be aware that establishments that did not keep their in-plant validation data from when their HACCP systems were first implemented were given time by FSIS (until January 4, 2016 at large establishments and April 4, 2016 at small and very small establishments) to collect in-plant validation data from HACCP records, provided the data included all critical operational parameters, or the establishment provided additional support that all critical operational parameters are being implemented. An establishment may use data from records generated as part of the HACCP system in place of their original in-plant validation data provided it has support for its monitoring procedures and frequencies per 9 CFR 417.5(a)(2) and there is no evidence that the monitoring procedures and frequencies are insufficient to monitor the CLs and identify deviations. IPP are also to be aware that although FSIS recommends establishments gather in-plant validation data at an increased frequency compared to the frequency listed in the HACCP plan or prerequisite program, there is no requirement that an establishment do so.

2. The documentation does not contain in-plant validation data for at least one product per HACCP category and the establishment does not have support for why less data is sufficient. 9 CFR 417.2(b)(1) contains a list of HACCP processing categories. Depending on the HACCP category, products, and the frequency with which they are produced, establishments may be able to support collecting in-plant validation data for at least one product in some but not all the HACCP categories used.

3. The documentation contains in-plant validation data from fewer than the total number of production days the establishment operated within its 90-calendar day validation period. For large establishments, 90 calendar days equates to approximately 60 production days. For small and very small establishments, 90-calendar days may equate to a minimum level of records from 13 production days. IPP are to be aware that establishments may be able to provide support for why gathering records from less days than the total number of production days it operated, within a 90calendar day period, is sufficient (e.g., by providing a written justification that explains how the records it did gather demonstrate the system is validated).

IPP are to contact their supervisor for assistance if they have any concerns regarding the establishment’s scientific or technical support or in-plant validation data not covered in this notice.

Noncompliance

If the establishment does not make documents or data available to IPP to demonstrate both parts of validation, there is noncompliance with 9 CFR 417.5(a)(1).

If the establishment does not maintain documents to support the scientific or technical basis for the CCPs and prerequisite programs used to support decisions in the hazard analysis there is noncompliance with 9 CFR 417.5(a)(1). When determining noncompliance, IPP are to be aware:

1. The establishment must have scientific or technical support for CCPs and prerequisite programs that support decisions in the hazard analysis because these programs are considered part of the HACCP system and, therefore, must be validated.

2. Establishments may use more than one scientific or technical support document to support the effectiveness of an intervention in its HACCP system.

If the establishment does not maintain validation data, there is noncompliance with 9 CFR 417.4(a)(1). When determining noncompliance, IPP are to be aware that FSIS does not require establishments to collect in-plant microbiological data provided that the establishment has adequate scientific or technical support, is following the parameters in the scientific or technical support, and has in-plant validation data demonstrating that it can meet the critical parameters during operation.

If IPP have concerns about the adequacy of the establishment’s validation records, they are to discuss the issue with their supervisor.

Step 7: Verifying the Reassessment Requirements

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

***(ii)** Each establishment must make a record of each reassessment required by paragraph (a)(3)(i) of this section and must document the reasons for any changes to the HACCP plan based on the reassessment, or the reasons for not changing the HACCP plan based on the reassessment. For annual reassessments, if the establishment determines that no changes are needed to its HACCP plan, it is not required to document the basis for this determination.*

***9 CFR 417.7(a)** Only an individual who has met the requirements of paragraph (b) of this section, but who need not be an employee of the establishment shall be permitted to perform the following functions:*
(1) Development of the HACCP plan, in accordance with section 417.2(b) of this part, which could include adapting a generic model that is appropriate for the specific product, and
(2) Reassessment and modification of the HACCP plan, in accordance with section 417.3 of this part.
***(b)** The individual performing the functions listed in paragraph (a) of this section shall have successfully completed course of instruction in the application of the seven HACCP principles to meat and poultry product processing including a segment on the development of a HACCP plan for a specific product and on record review.*

A reassessment of the HACCP system and/or HACCP plan must be conducted under the following conditions:

1. At least annually
2. Whenever changes occur that could affect the hazard analysis or require modification of the HACCP plan
3. As part of the corrective actions when an unforeseen hazard has occurred, or
4. When otherwise directed by the Agency based on the regulations, such as a Federal Register notice

IPP are to review establishment records and ask establishment management about reassessments conducted since the previous HAV task. IPP are also to consider

whether there have been any changes within the establishment that could affect the hazard analysis (including prerequisite programs) or present the need to modify the HACCP plan, including violative sample results for residues or pathogens. IPP are also to consider whether any unforeseen hazards have occurred since the last HAV task that would have required reassessment.

In an establishment that has a HACCP plan, reassessment of the food safety system, including the hazard analysis and any prerequisite programs is required at least annually, and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan (9 CFR 417.4(a)(3)).

The establishment can reassess its HACCP plan, or plans, any time during the calendar year to meet the annual reassessment requirement. This requirement does not expect the establishment to reassess every 12 months.

The establishment must reassess the adequacy of the HACCP plan whenever a change occurs that could affect the hazard analysis or alter the HACCP plan. The establishment is required to 1) document this reassessment and 2) document the rationale for the decision to change or not to change the plan.

The occurrence of unforeseen hazards may also reflect changes that could affect the hazard analysis or alter the HACCP plan (9 CFR 417.4(a)(3)), therefore establishments must reassess the hazard analysis and any applicable prerequisite programs when an unforeseen hazard occurs as part of complying with the corrective action requirement specified by 9 CFR 417.3(b)(4).

The individual who performs a reassessment or makes modifications to the HACCP plan **must have successfully completed a training course** in the application of the seven HACCP principles to meat or poultry product processing. However, there is no requirement for the establishment to provide documentation of training. IPP are to accept oral statements that establishment employees have been trained in accordance with 9 CFR 417.7.

While performing the HAV task, IPP verify compliance with §417.4(a)(3), §417.7, and §417.3(b) by:

- Reviewing reassessment records
- Reviewing the HACCP plan,
- Asking establishment management about reassessments conducted since the previous HAV task, and
- Asking establishment management whether the individual performing any reassessments or making modifications to the HACCP plan have been trained.

Compliance Example

On 1-28-2018, an IPP is performing the HAV task in a turkey slaughter operation. She reviews the HACCP plan and verifies that the annual reassessment was last performed and signed off on 4-1-2017. She learned in her HACCP training that the establishment reassessment requirement is based upon the calendar year and not upon a 12-month period. The person who signed the plan has been identified as someone who completed a HACCP training course meeting the requirements in §417.7. She determines that the establishment is in compliance with the annual reassessment and training requirements since reassessment was performed in 2017 and the person that reassessed the plan was HACCP trained.

Noncompliance with Reassessment of the HACCP Plan and Establishment Training

One or more of the following findings are evidence of noncompliance:

1. Changes that could affect the hazard analysis or HACCP plan or unforeseen hazards have occurred, but the establishment has not performed a reassessment; or if the reassessment was performed but not documented. Document noncompliance with 9 CFR 417.4(a)(3)(ii).

2. The establishment did not perform a reassessment at least once in the previous calendar year (i.e. the 12-month period ending on the previous December 31st); or if the reassessment was performed but not documented. Document noncompliance with 9CFR 417.4(a)(3)(ii).

3. The reassessment was not performed by an individual trained in accordance with the regulations. Document noncompliance with 9 CFR 417.7.

Noncompliance Example 1

On 2-2-2016, the IPP is performing the HAV task and is reviewing the HACCP plan to verify it meets the annual reassessment and training requirements. The HACCP plan is signed and dated 11-11-2014. She questions the HACCP coordinator and determines that the last reassessment was in November of 2014. The annual reassessment requirement was not met.

Noncompliance Example 2

A large beef slaughter establishment received a positive E. coli *O157:H7 test result from their own sampling. The hazard analysis stated that STEC were not reasonably likely to occur, and the establishment made no changes to its hazard analysis or its HACCP plan. The establishment failed to perform the reassessment as a result of this change.*

Reassessment of the Hazard Analysis

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

Some establishments do not have a HACCP plan because they have determined that no hazards were reasonably likely to occur. They must reassess their HACCP system whenever any changes occur that could reasonably affect whether a food safety hazard is reasonably likely to occur.

Unlike the requirement for a HACCP plan, there is no annual reassessment requirement for the hazard analysis in these establishments.

Noncompliance with Reassessment of the Hazard Analysis and Establishment Training

If an establishment does not have a HACCP plan because the hazard analysis shows that no food safety hazards are reasonably likely to occur, the following is evidence that the establishment does not comply with 9 CFR 417.4(b):

Changes that could affect the hazard analysis have occurred but the establishment has not performed a reassessment.

Workshop: HAV Task—Reassessment

1. On 1-15-2018, an IPP is performing a scheduled HAV task in a turkey slaughter operation and elects to include verification of the annual reassessment as part of the task. He reviews the HACCP plan and finds that the annual reassessment was last performed and signed on 1-1-2017.

   What would be the last date this plan would be in compliance with the regulatory requirement for reassessment?

2. An IPP is performing the HAV task at a raw ground beef patty operation. She observes employees adding dry seasoning ingredients at the mixer. She is familiar with this establishment, and this is the first time that she has observed any non-meat ingredients being used. She goes to the HACCP office and reviews the HACCP plan. She finds no documentation that this change to the product formula has triggered a reassessment.

   a. What should she do next?

   b. Why would she do that?

   c. Is there a HACCP noncompliance? If so, what regulations should be cited on the noncompliance (NR)?

Step 8: Documenting HAV Task Results in PHIS

IPP are to use PHIS to document the results of HAV tasks. PHIS is designed to capture information about the regulatory requirements verified and whether there was compliance or noncompliance with each regulatory requirement. Therefore, IPP will document findings of regulatory compliance and findings of noncompliance when conducting the HAV task. When documenting the performance of the HAV, the Questionnaire tab will be available in PHIS. IPP are to complete the questionnaire each time they perform the HAV.

Compliance Determination

If IPP do not identify any issues of noncompliance, and find no evidence of potential problems in the food safety system, they are to document the results of the HAV task in PHIS, including specifying compliance with each of the regulatory requirements verified. If IPP are unable to determine whether their findings represent regulatory compliance, they are to discuss the issue with their supervisor before making a determination.

Noncompliance Determination

Anytime IPP find noncompliance, they are to document the noncompliance in PHIS in accordance with FSIS Directive 5000.1, Verifying an Establishment's Food Safety System. IPP are to discuss noncompliance found while performing the HAV task with their supervisor, as needed, to determine if additional action may be necessary.

When documenting noncompliance identified with the HAV task, IPP are to describe why the findings led them to a determination of noncompliance. For example, a single failure to make a temperature entry on prerequisite program record for received product is not, in itself, sufficient to support noncompliance. However, failure to complete the temperature log multiple times over the course of a production week, or inspection findings that received product exceeded the specified temperature in even one instance, may be sufficient to determine that this prerequisite program does not support the establishment's decision that a hazard will be prevented by the prerequisite program. Therefore, IPP need to precisely describe the facts of a case in such a way as to show how they arrived at a decision of noncompliance.

If IPP have questions regarding whether or not the establishment is implementing the prerequisite program as described, or does not maintain sufficient records to support their decision, IPP may wish to discuss their concerns with their supervisor. The supervisor may determine that it is necessary to request the assistance of an EIAO, who may conclude that the prerequisite program is not capable of supporting the decisions made in the hazard analysis.

If it is determined that the implementation of the prerequisite program no longer supports the decisions made in the hazard analysis, IPP are to do the following:

1. Document the noncompliance on an Noncompliance Record (NR) citing 9 CFR 417.5(a)(1)

2. Verify that the establishment conducts the following activities:

    a. Reassesses its hazard analysis as required in 9 CFR 417.4(b) because the decisions made in the hazard analysis may no longer be supported as per 9 CFR 417.5(a)(1); and

    b. Provides data supporting the decisions made during this reassessment as required in 9 CFR 417.5(a)(1)

If IPP determine that the failure to implement a prerequisite program results in a hazard being RLTO or that an unforeseen hazard has occurred, they are to:

1. Describe those findings in a noncompliance citing 9 CFR 417.5(a)(1);

2. Verify that the establishment performs and documents corrective actions in accordance with 9 CFR 417.3(b), including controlling the affected product;

3. Retain affected product if the establishment does not have other information to demonstrate that the product is not adulterated; and

4. Seek guidance through supervisory channels regarding what additional actions may be necessary.

Before the HAV task can be completed, IPP must (1) verify that the establishment takes necessary actions to return to compliance with the applicable regulatory requirement(s) and (2) record in PHIS that the establishment has brought itself back into compliance. The HAV inspection task cannot be marked as completed in PHIS until the IPP has documented the establishment's return to compliance.

If IPP are unable to determine whether their findings represent regulatory noncompliance, they are to discuss those findings with their supervisor before making a determination. In some cases, it may be necessary to request **policy and technical guidance** through askFSIS. IPP may have findings that do not rise to the level of noncompliance but warrant discussion with establishment management. These issues should be discussed as they arise or in weekly meetings with establishment management. IPP are to document these discussions in an MOI in PHIS, and provide establishment management with a copy of the MOI.

Supervisory Responsibilities

If IPP have a question or concern they should seek assistance from their supervisor. The supervisor plays a key role in ensuring that decisions made by IPP are consistent with FSIS statutory authority and Agency policy, and that IPP duties are performed according to the directive. If IPP have obtained additional information from askFSIS or other resources, supervisors should be actively engaged with reviewing the information and assisting in the process of making compliance determinations. If IPP have concerns with prerequisite programs or scientific support for the hazard analysis or the in-plant validation data, supervisors need to address these questions and concerns. If needed, the supervisor is to ask the DO to assign an EIAO to review the prerequisite program or scientific support. Supervisors are to keep track of when HAV tasks are scheduled by their IPP to ensure that these tasks are performed in a timely and complete manner and ensure IPP understand and apply the Gather, Assess, and Determine (GAD) thought process.

Workshop: HAV Task

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

1. When should IPP perform the HAV task?

2. Review the flow diagram, product description, hazard analysis, and HACCP plan on the following pages, and answer the following questions:

   a. How did the establishment address biological hazards at receiving? (circle the answer on the form and mark “a”)

   b. How did the establishment address physical hazards at receiving? (circle the answer on the form and mark “b”)

   c. How did the establishment address biological hazards at storage? (circle the answer on the form and mark “c”)

3. What decisions in the hazard analysis would the IPP request supporting documentation for, if any? Please explain your answer?

4. Are all steps in the flow diagram addressed in the hazard analysis? If not, please explain.

5. Are all hazards identified as reasonably likely to occur addressed by a CCP somewhere in the process? If not please explain.

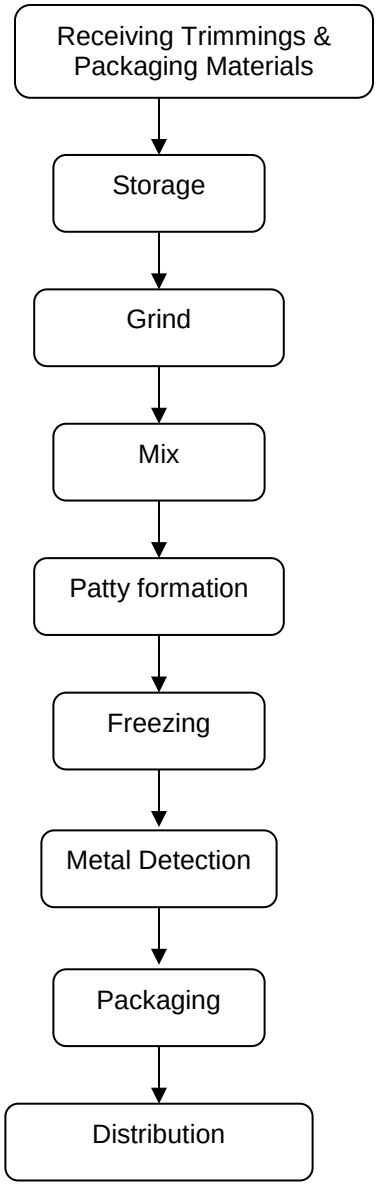
6. How does the establishment monitor temperature at storage?

7. Is the use of terms like “microbial growth” or “growth of pathogens” sufficient to identify microbiological hazards?

8. What decision in the HACCP Plan would the IPP request supporting documentation for, if any?

Raw ground beef patties

Process flow diagram



Product Description:

Process category: Raw ground

Product: Frozen ground beef patties

Name: Ground beef patties 6 per pound

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

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

Intended use: Fast food restaurant

Labeling instructions: Keep frozen, safe food handling label

Note: No rework used in this process

Example: for training use only

Hazard Analysis: Raw ground beef patties

Process Step	Food Safety Hazards	Is hazard likely to occur?	Justification for decision	What control measures can be applied to prevent the significant hazards?	Is step a critical control point?
Receiving trimmings & Packing materials	Biological: Pathogens *E. coli* O157:H7 and *Salmonella*	No	*E. coli* O157:H7 or *Salmonella* may be present on trimmings received	Purchase specifications for certification from all suppliers that trimmings are from carcasses that received validated interventions effective to eliminate or reduce *E. coli* O157:H7 to an undetectable level & negative microbiological test results for *E. coli* O157:H7 required from suppliers	No
	Chemical: non-food grade	No	Letters of guarantee		
	Physical: foreign material	No	Establishment records show that there has been no incidence of foreign material in products in past several years		No

Hazard Analysis: Raw ground beef patties (**Continued)**

Process Step	Food Safety Hazards	Is hazard likely to occur?	Justification for decision	What control measures can be applied to prevent the significant hazards?	Is step a critical control point?
Storage	Biological: Growth of pathogens Chemical: none Physical: none	Yes	*E. coli* O157:H7 or *Salmonella* may grow if not maintained at proper refrigeration temperatures	Maintain product temperature at or below a level sufficient to prevent growth	Yes
Grind	Biological: none Chemical: none Physical: metal Contamination	Yes	Past history indicates that metal contamination has occurred during grinding	Proper maintenance of equipment, routine examination during cleaning, metal detector later in process	No

Example: for training use only

Hazard Analysis: Raw ground beef patties (**Continued)**					
Process Step	**Food Safety Hazards**	**Is hazard likely to occur?**	**Justification for decision**	**What control measures can be applied to prevent the significant hazards?**	**Is step a critical control point?**
Mix	Biological: none Chemical: none Physical: none				
Patty formation	Biological: none Chemical: none Physical: metal contamination	Yes	Past history indicates that metal contamination has occurred during patty formation	Proper maintenance of equipment, routine examination during cleaning, metal detector later in process	No
Freezing	Biological: none Chemical: none Physical: none				
Metal Detection	Biological: none Chemical: none Physical: none		Past history indicates that metal contamination has occurred in previous process steps	Functioning metal detection equipment to identify and reject contaminated product	Yes
Packaging	Biological: none Chemical: none Physical: none				

HACCP Plan: Raw ground beef patties

CCP	Critical Limits	Monitoring Procedures and Frequencies	HACCP Records	Verification Procedures & Frequencies	Corrective Actions
# 1 Temp control at storage	Product temperature ≤44 ° F	QC personnel will record temperature of product exiting grinder every hour	Product Temperature Log Corrective Action Log Thermometer Calibration Log	HACCP Coordinator will verify accuracy of the Product Temperature Log once per shift and observe QC personnel performing monitoring. HACCP Coordinator will verify temperature of raw materials cooler and freezer daily. QC check all thermometers used for monitoring devices for accuracy by immersion in slush ice, and will verify to within 2 degrees F daily. All thermometers found to be inaccurate will be calibrated using immersion in slush ice and re-evaluated	Corrective actions shall meet all requirements of Part 417.3 (a)

Example: for training use only

HACCP Plan: Raw ground beef patties (Continued)					
CCP	**Critical Limits**	**Monitoring Procedures and Frequencies**	**HACCP Records**	**Verification Procedures & Frequencies**	**Corrective Actions**
# 2 Metal Detector	Functional Metal Detector	Packaging line supervisor will check the metal detector using a seeded sample every two hours to determine limits are not exceeded	Metal Detection Log Corrective Action Log	QC personnel will verify that the metal detector is functioning as intended by running the seeded sample (2 mm) through the metal detector twice per shift. Functioning metal detector must identify and remove the seeded sample. HACCP Coordinator will verify accuracy of the Metal Detection Log and observe packaging line supervisor performing monitoring once per shift. Maintenance personnel will perform calibration procedure once per shift.	Corrective actions shall meet all requirements of Part 417.3 (a)

Example: for training use only